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TRICARE  
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The TRICARE Management Activity has authorized the following addition(s)/revision(s).

**CHANGE TITLE:** CONSOLIDATED CHANGE 12-001

**CONREQ:** 16099

**PAGE CHANGE(S):** See pages 2 and 3.

**SUMMARY OF CHANGE(S):** See pages 4 and 5.

**EFFECTIVE DATE:** See the Summary of Changes.

**IMPLEMENTATION DATE:** Upon direction of the Contracting Officer.

**This change is made in conjunction with Feb 2008 TPM, Change No. 97 and Feb 2008 TRM, Change No. 86.**

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**ATTACHMENT(S): 173 PAGES  
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WHEN PRESCRIBED ACTION HAS BEEN TAKEN, FILE THIS TRANSMITTAL WITH BASIC DOCUMENT.

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## **SUMMARY OF CHANGES**

### **CHAPTER 1**

1. Section 3. Updates Electronic Claims Submittal for the West Region.

### **CHAPTER 6**

2. Section 1. Clarifies TRICARE Prime eligibility for dual eligibles.

### **CHAPTER 8**

3. Section 5. Adds language to ensure appropriate care coordination between the MCSCs and TOP Contractor when an overseas Prime/Prime Remote enrollee is authorized care by one of the MCSCs to receive health care in the United States.
4. Section 6. Clarifies language on the preparation of TED records with multiple line items where begin date of care crosses contract option periods.

### **CHAPTER 10**

5. Section 4. Adds language regarding funds overpaid to VA Facilities.

### **CHAPTER 17**

6. Section 3. Removes obsolete language.

### **CHAPTER 18**

7. Table of Contents. Adds notation to indicate demonstrations have expired.
8. Section 2. Adds notation to indicate the demonstration has expired.
9. Section 3. Adds notation to indicate the demonstration has expired.
10. Section 4. Adds notation to indicate the demonstration has expired.
11. Section 5. Adds notation to indicate the demonstration has expired.
12. Section 6. Adds notation to indicate the demonstration has expired.
13. Section 7. Adds notation to indicate the demonstration has expired.

**SUMMARY OF CHANGES (Continued)**

**CHAPTER 8 (Continued)**

- 14. Section 9. Adds notation to indicate the demonstration has expired.
- 15. Section 10. Adds notation to indicate the demonstration has expired.

**CHAPTER 20**

- 16. Section 1. Updates language related to claims processing procedures for TRICARE beneficiaries under the age of 65 who become entitled to Medicare due to a retroactive disability. EFFECTIVE October 28, 2009.
- 17. Section 3. Adds new paragraph regarding TRICARE referral requirements.

**CHAPTER 22**

- 18. Section 1. Revises language regarding Dual Eligibles.
- 19. Section 2. Revises language regarding Dual Eligibles.

**CHAPTER 25**

- 20. Section 1. Revises language regarding Dual Eligibles.

**CHAPTER 26**

- 21. Section 1. Adds effective coverage date and procedures for CHCBP coverage.

**INDEX**

- 22. Adds notation to indicate demonstrations have expired.



## TRICARE Processing Standards

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### 1.0 TIMELINESS AND QUALITY STANDARDS OF PERFORMANCE

Contractors are charged with providing or arranging for delivery of quality, timely health care services and have the responsibility for providing the timely and accurate processing of all claims received into their custody, whether for network or non-network care. In addition, the contractor must provide courteous, accurate, and timely response to all inquiries from beneficiaries, providers, TRICARE Management Activity (TMA), and other legitimately interested parties. TMA has established standards of performance which will be monitored by TMA and other government agencies to measure contractor performance. Minimum performance standards are listed below.

#### 1.1 Preauthorizations/Authorizations

The contractor shall issue determinations on at least:

- Ninety percent (90%) of all requests for preauthorization/authorization within two working days following receipt of the request and all required information.
- One hundred percent (100%) of such requests within five working days following receipt of the request and all required information.

#### 1.2 Referrals/Network Adequacy

**1.2.1** Following the date of receipt of a request for a referral, the contractor shall issue a referral authorization or denial on at least:

- Ninety percent (90%) of all requests within two workdays
- One hundred percent (100%) of all requests within three workdays

**1.2.2** A minimum of 96% of referrals for Prime enrollees who reside in TRICARE Prime Service Areas (PSAs) and Prime enrollees who reside outside PSAs and have waived the travel-time access standards shall be to the Military Treatment Facility (MTF) or a civilian network provider. All referrals, except the following, will be included to determine compliance with the standard: (1) referrals that are unknown to the contractor before the visit (specifically Emergency Room (ER) visits, retroactively authorized referrals), (2) self referrals and referrals of beneficiaries who use Other Health Insurance (OHI) as first payor, (3) MTF directed referrals to non-network providers when network providers are available, and (4) the eight mental health self-referrals. All other referrals are included without exception.

**1.3 Network Adequacy**

In Option Period One, the following percent of claims for Prime enrollees region-wide (excluding TPR enrollees) will be for care rendered by a network provider. This includes all claims for Prime enrollees except emergency room claims, Point of Service (POS) claims, or claims with OHI.

- North Region: 86%
- South Region: 86%
- West Region: 72%

This percent for the number of claims from network providers will increase 1% each option period.

**1.4 Electronic Claims Submittal**

The following percentage of all claims shall be submitted electronically after the specified percentage of claims has been excluded. For the North Region, 30% of paper claims will be excluded each option year from the total number of paper claims processed. For the South Region, 25% of paper claims will be excluded each option year from the total number of paper claims processed. For the West Region, 28% of paper claims will be excluded each option year from the total number of paper claims processed.

OPTION YEAR	NORTH	SOUTH	WEST
1	74%	78%	83%
2	77%	81%	84%
3	79%	83%	85%
4	80%	84%	86%
5	81%	85%	87%

**1.5 Claims Processing Timeliness**

Unless otherwise specified, the standards below apply to all claims.

**1.5.1 Retained Claims**

- Ninety-eight (98%) of retained claims and adjustment claims shall be processed to completion within 30 calendar days from the date of receipt.

A "Retained Claim" is defined as any claim retained (held in the contractor's possession) for any reason. Contractors shall retain all claims that contain sufficient information to allow processing to completion and all claims for which missing information may be developed from in-house sources, including DEERS and contractor operated or maintained electronic, paper, or film files.

**Note:** Nothing in this definition prohibits a contractor from retaining a claim for external development.

## Enrollment Processing

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The contractor shall record all enrollments on Defense Enrollment Eligibility Reporting System (DEERS), as specified in the TRICARE Systems Manual (TSM), [Chapter 3](#).

The contractor shall develop and implement an enrollment plan to support contractor enrollment of beneficiaries. The contractor shall consult with the Regional Director (RD) and all Military Treatment Facility (MTF) Commanders where Prime is offered in developing the enrollment plan.

### 1.0 ENROLLMENT PROCESSING

**1.1** The contractor shall use the TRICARE Prime Enrollment Application and Primary Care Manager (PCM) Change Form (one combined form) Department of Defense (DD) Form 2876, and the TRICARE Prime Disenrollment Form DD Form 2877. The contractor shall ensure aforementioned forms are readily available to potential enrollees. The contractor shall implement enrollment processes (which do not duplicate Government systems) that ensure success and assistance to all beneficiaries.

**1.1.1** The contractor shall collect TRICARE Prime enrollment applications at the TRICARE Service Centers (TSCs) or other sites mutually agreed to by the contractor, RD, and the MTF Commander, by mail, or by other methods proposed by the contractor and accepted by the Government.

**1.1.2** Enrollment applications must be signed by the sponsor, spouse or other legal guardian of the beneficiary. A signed enrollment application includes those with (1) an original signature, (2) an electronic signature offered by and collected by the contractor, or (3) the self attestation by the beneficiary when using the Beneficiary Web Enrollment (BWE) system. An Active Duty Service Member (ADSM) or Active Duty Family Member (ADFM) signature is not required to make enrollment changes using the Enrollment Portability process outlined in [Chapter 6, Section 2, paragraph 1.4](#). A signature from an ADSM, although desired, is not required to complete Prime enrollment as enrollment in Prime is mandatory per the TRICARE Policy Manual (TPM), [Chapter 10, Section 2.1, paragraph 1.1](#).

**1.1.3** The contractor shall also accept and process TRICARE Prime enrollment applications via the BWE process.

**1.2** The contractor shall provide beneficiaries who enroll full and fair disclosure of any restrictions on freedom of choice that apply to enrollees, including the Point of Service (POS) option and the consequences of failing to make enrollment fee payments on time.

**1.3** Enrollment shall be on an individual or family basis. For newborns and adoptees, see the TPM, [Chapter 10, Section 3.1](#).

## TRICARE Operations Manual 6010.56-M, February 1, 2008

### Chapter 6, Section 1

#### Enrollment Processing

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**1.4** The contractor shall follow the specifications of the Memorandum of Understanding (MOU) with the appropriate MTF Commander and RD and any other instructions from the RD in performing and coordinating enrollment processing with the MTF, the appropriate RD, and DEERS.

**1.5** The contractor shall record all Prime enrollments from a centralized contractor data entry point on the DEERS using a Government-furnished systems application, the DEERS Online Enrollment System (DOES). The equipment needed to run the DEERS desktop enrollment application shall be furnished by the Managed Care Support Contractor (MCSC) and shall meet technical specifications in the TSM, [Chapter 3](#).

**1.5.1** MCSCs shall resend PCM Information Transfers (PITs) to MTFs when requested.

**1.5.2** The MCSC shall submit required changes to the DEERS Support Office (DSO) as required.

**1.6** At the time of enrollment processing, the contractor shall access DEERS to verify beneficiary eligibility and shall update the residential and mailing addresses and any other fields that they can update on DEERS.

**1.6.1** If the enrollment form contains neither a residence address nor a mailing address, the contractor shall attempt to develop the enrollment form for a residence address. If it is determined the beneficiary does not have an established residence address or that the beneficiary's mailing address differs from the residence address, the contractor shall also develop the enrollment form for a mailing address.

**1.6.2** Enrollees may submit a temporary address (i.e., Post Office Box, Unit address, etc.), until a permanent address is established. Temporary addresses must be updated with the permanent address when provided to the contractor by the enrollee in accordance with the TSM, [Chapter 3, Section 1.4](#). Contractors shall not input temporary addresses not provided by the enrollee.

**1.6.3** If the DEERS record does not contain an address, or if the application contains information different from that contained on DEERS in fields for which the contractor does not have update capability, the contractor shall contact the beneficiary by telephone within five calendar days, outlining the discrepant information and requesting that the beneficiary contact the military personnel information office.

**1.7** Defense Manpower Data Center (DMDC)/DEERS shall print and mail the Universal TRICARE Beneficiary Cards directly to the enrollee at the residential mailing address specified on the enrollment application after receipt of the enrollment record. DMDC will also provide notification of PCM assignments for new enrollments, enrollment transfers, PCM changes, and the replacement of TRICARE Universal Beneficiary Cards. (See TSM, [Chapter 3, Section 1.4](#).) The return address on the envelope mailed by DMDC will be that of the appropriate MCSC. In the case of receiving returned mail, the MCSC shall develop a process to fulfill the delivery to the enrollee.

**1.8** An enrollee must present both a TRICARE Prime identification card and a military identification card to a provider to demonstrate eligibility for TRICARE Prime program benefits.

## **2.0 DUAL ELIGIBLES (ENTITLEMENT UNDER BOTH MEDICARE AND TRICARE)**

**2.1** Dual eligibles, retired, and under age 65 are eligible to enroll in TRICARE Prime provided they maintain Medicare Part A and Part B. Dual eligible ADFMs, regardless of age, are eligible to enroll in Prime. Dual eligible retirees and family members age 65 and over are not eligible to enroll in Prime (unless they are not eligible for premium-free Medicare Part A on their own record or the record of their current, former, or deceased spouse). Medicare is primary payor for all dual eligibles regardless of their sponsor's status. (See the TPM, Chapter 10, Section 6.1 for additional dual eligible information.)

**2.2** Prime-enrolled dual eligibles, to the extent practicable, should follow all TRICARE Prime requirements for PCM assignment, referrals and authorizations. However, they are not subject to POS cost-sharing. Enrollment fees are waived for dual eligibles as described below.

## **3.0 ASSIGNMENT OF PCM**

The contractor shall assign all enrollees a PCM by name (PCMBN) on DOES at the time of enrollment. This applies to beneficiaries assigned to Direct Care (DC) and civilian network PCMs.

**3.1** All DC TRICARE Prime enrollees shall be enrolled to a Department of Defense (DoD) MTF Primary Care Location by the MCSCs. The contractor shall comply with the MTF Commander's specifications in the MTF MOU for which enrollees or categories of enrollees shall be assigned a DC PCM or offered a choice of civilian network PCMs.

**3.1.1** The contractor shall enroll TRICARE Prime beneficiaries to the MTF until the capacity is optimized in accordance with the MTF Commander's determinations; TRICARE Prime beneficiaries who cannot be enrolled to the MTF will be enrolled to the contractor's network.

**3.1.2** All active duty personnel not meeting the requirements for TRICARE Prime Remote (TPR) shall be enrolled to an MTF, not the contractor's network, regardless of capacities.

**3.1.3** When a family member of a sponsor E-1 through E-4 requests a PCM in an MTF that offers TRICARE Prime for any beneficiary category other than active duty, that beneficiary must be assigned an MTF PCM unless capacity has been reached. If overall MTF capacity has not been reached, the MCSC shall request the MTF to shift capacity in DOES to the ADFM beneficiary category from another category if necessary to accommodate an E-1 - E-4 ADFM beneficiary's PCM assignment request.

**3.2** MTFs will provide the MCSC a current listing of all Primary Care Locations with associated groups or a current listings of DC PCMs. The list(s) will be made available for the beneficiary's use for the initial selection or change of a PCM. The MCSC will provide guidance to the enrollee in selecting a Primary Care Location or PCM, as appropriate given MTF guidance in the MOU. Upon receipt of an inquiry from a DC enrollee in regards to the person's assigned PCM, the MCSC shall refer the beneficiary to the MTF to which the beneficiary is enrolled.

**3.3** At the time of enrollment, the contractor is responsible for determining the appropriate enrollment Defense Medical Information System Identification (DMIS-ID) based on the regional and MTF MOUs, access standards and/or other specific Government guidance. The contractor shall

assign each enrollee a PCMBN at the time of enrollment based on those PCMs available within DOES.

**3.3.1** The contractor will attempt to assign the beneficiary to the PCM requested on the enrollment form if capacity is available. If the preferred PCM is not available, the contractor will use the default PCM for that DMIS.

**3.3.2** If the enrollment form contains a gender or specialty preference, the MCSC will try to assign an appropriate PCM. If the gender or specialty is not available, the beneficiary will be enrolled to the default PCM for that DMIS.

**3.3.3** If there is no PCM preference stated on the enrollment form, the contractor will use the default PCM for that DMIS.

**3.3.4** If there is no DC PCM available in the appropriate DMIS/MTF, nonactive duty beneficiaries may be enrolled to a civilian PCM, by following the procedures specified for such situations in the local MTF MOU.

**3.3.5** If there is no PCM capacity in the MTF for an ADSM, then the MCSC will contact the MTF for instructions.

**3.4** DOES reflects only those DC PCMs that the MTF has loaded onto the DEERS PCM Repository. Further, DOES will only display PCMs with available capacity for the specific beneficiary's category and age. The contractors cannot add, delete, or modify DC PCMs on the repository.

**3.5** The contractor shall complete all panel PCM reassignments (batch) using a Government-provided systems application, PCM Reassignment System (PCMRS). Panel reassignments may be specified by the appropriate MTF Commander for a variety of reasons, including the rotation or deployment of DC PCMs. MCSCs should expect at least one-half of DC PCM assignments to change each year. These moves may be based on various factors of either the enrollment or the individual beneficiary, including:

- DMIS ID to DMIS ID
- PCM ID to PCM ID
- Health Care Delivery Program (HCDP)
- Sex of beneficiary
- Unit Identification Code (UIC) (active duty only)
- Age of beneficiary
- Sponsor Social Security Number (SSN) (for family moves)
- Name of beneficiary

**3.6** MTFs may request PCM reassignment, including panel reassignments, in several ways, including telephone, e-mail or other electronic submissions. The most common method to request individual PCM reassignments is the telephone. The preferred method for panel reassignments is the batch staging application within PCMRS. Regardless of the submission method, the MTF must provide sufficient information identifying both the PCMs and beneficiaries involved in a move to allow the contractor to reasonably accomplish the move. Thereafter, the contractor shall complete each DC PCM reassignment, both individual and panel reassignment, within three working days of receiving all necessary information from the MTF.

**3.7** PCM change requests submitted via any means other than BWE application by beneficiaries enrolled to the civilian network must be processed by the MCSC within three working days of receipt, with an effective date no later than (NLT) the third working day.

**3.8** PCM change requests submitted to the MCSC via the BWE application by beneficiaries will be processed within six calendar days of receiving the requests, and the effective date will be the sixth calendar day after the request was submitted or the date requested by the beneficiary if over six days but less than 91 days.

## **4.0 ENROLLMENT PERIOD**

### **4.1 Effective Date of Enrollment**

The contractor shall support continuous open enrollment for all beneficiaries. Enrollment may occur any time during the contract period; however, all new enrollment periods shall coincide with the fiscal year. The contractor shall align any enrollment established based on an enrollment year period to the fiscal year upon the first renewal of the enrollment period.

**4.1.1** The effective date of enrollment for ADSMs shall be the date the contractor receives the signed enrollment application. A signed enrollment application includes those with (1) an original signature, (2) an electronic signature offered by and collected by the contractor, or (3) the self attestation by the beneficiary when using the BWE system.

**4.1.2** All other enrollment periods shall begin on the first day of the month following the month in which the enrollment application and any required enrollment fee payment are received by the contractor. If an application and fee are received after the 20th day of the month, enrollment will be on the first day of the second month after the month in which the contractor received the application. (This recurring principle is referred to as the 20th of the month rule.)

**4.1.3** Enrollees who transfer enrollment continue with the same enrollment period. The enrollment transfer, however, is effective the date the gaining contractor receives a signed enrollment application or transfer application. See TPM, [Chapter 10, Sections 2.1 and 5.1](#) for information on Transitional Assistance Management Program (TAMP) and other changes in status. An ADSM or ADFM signature is not required to make enrollment changes when using the Enrollment Portability process outlined in [Chapter 6, Section 2, paragraph 1.4](#).

### **4.2 Enrollment Expiration**

**4.2.1** NLT 30 calendar days before the expiration date of an enrollment, the contractor shall send the appropriate individual (sponsor, custodial parent, retiree, retiree family member, survivor or eligible former spouse, etc.) a written notification of the pending expiration and renewal of the TRICARE Prime enrollment and a bill for the enrollment fee, if applicable (since ADSMs must be enrolled but their family members need not be, there is no action required if an ADSM does not have enrolled family members). The bill shall offer all available payment options and methods. The contractor shall issue a delinquency notice to the appropriate individual 15 calendar days after the expiration date of the enrollment.

**4.2.2** The contractor shall automatically renew enrollments, including those for ADSMs, upon expiration unless the enrollee declines renewal, is no longer eligible for Prime enrollment, or fails to

pay any required enrollment fee on a timely basis, including a 30 calendar day grace period beginning the first day following the last day of the enrollment period.

**4.2.3** If the enrollee requests disenrollment during this grace period, the contractor shall disenroll the beneficiary effective retroactive to the enrollment period expiration date.

**4.2.4** If an enrollee does not respond to the re-enrollment notification and fails to make an enrollment fee payment by the end of the grace period, the contractor is to assume that the enrollee has declined re-enrollment. The contractor shall disenroll the beneficiary retroactive to the enrollment expiration date.

**4.2.5** ADSMs may not decline reenrollment nor may they request disenrollment.

**4.2.6** DMDC sends written notification to the beneficiary of the disenrollment and the reason for the disenrollment within five business days of the disenrollment transaction.

### **4.3 Disenrollment**

**4.3.1** The contractor shall automatically disenroll beneficiaries when the appropriate enrollment fee payment is not received by the 30th calendar day following the enrollment period expiration date or the due date for the installment payment. The contractor shall set the disenrollment effective date retroactive to the annual renewal date or the payment due date, whichever applies. An appropriate enrollment fee payment includes the appropriate form of payment for the period the fee is intended to cover (i.e., monthly, quarterly, or annually).

**4.3.2** Prior to processing a disenrollment for “non-payment of fees,” the MCSC or Uniformed Services Family Health Plan (USFHP) provider must reconcile their fee payment system against the fee totals in DEERS. Once the contractor confirms that the payment amounts match, the disenrollment may be entered in DOES.

**4.3.3** The disenrolled beneficiary will be responsible for the deductible and cost-shares applicable under TRICARE Extra or Standard for any health care received during the 30 day grace period. In addition, the beneficiary shall be responsible for the cost of any services received during the 30 day grace period that may have been covered under TRICARE Prime but are not a benefit under TRICARE Extra or Standard, e.g., preventive care.

**4.3.4** The contractor may suspend claims processing during the grace period to avoid the need to recoup overpayments.

**4.3.5** See the TPM, [Chapter 10, Sections 2.1 and 3.1](#) for additional information on disenrollment.

### **4.4 Enrollment Lockout**

**4.4.1** The contractor shall “lockout” or deny re-enrollment for a period of 12 months from the effective date of disenrollment for the following beneficiaries:

- Retirees and/or their family members who voluntarily disenroll prior to their annual enrollment renewal date;

- ADFMs (E-5 and above) who change their enrollment status (i.e., from enrolled to disenrolled twice in a given year) for any reason during the enrollment year (October 1 to September 30) (refer to this chapter and TPM, [Chapter 10, Sections 2.1 and 3.1](#); and
- Any beneficiary disenrolled for failure to pay required enrollment fees during a period of enrollment.

**Note:** The 12 month lockout provision does not apply to ADFMs whose sponsor's pay grade is E-1 through E-4.

**4.4.2** Beneficiaries who decline re-enrollment during their annual renewal period are not subject to the 12 month enrollment lockout. At the end of an annual enrollment period, if the beneficiary declines to continue their enrollment and subsequently requests re-enrollment, a new enrollment form is required and the contractor shall process the request as a "new" enrollment. (If an enrollee did not respond to a re-enrollment notification and failed to make an enrollment fee payment by the end of the grace period, the contractor is to assume that the enrollee declined re-enrollment.)

**4.4.3** The contractor shall not grant waivers to the 12 month lockout provision. TRICARE Regional Office (TRO) Directors may grant waivers to the lockout provisions in extraordinary circumstances.

## **5.0 ENROLLMENT FEES**

### **5.1 General**

The contractor shall collect enrollment fee payments from TRICARE Prime enrollees as appropriate and shall report those fees, including any overpayments that are not refunded to the enrollee, to DEERS. (See the TSM, [Chapter 3](#).) The Prime enrollee may select one of the following three payment fee options (i.e., annual, quarterly, or monthly). In the event that there are insufficient funds to process a premium payment, the contractor may assess the account holder a fee of up to 20 U.S. dollars (\$20.00). The contractor shall provide commercial payment methods for Prime enrollment fees that best meet the needs of beneficiaries while conforming to the following ([paragraphs 5.1.1 through 5.1.3.7](#)):

#### **5.1.1 Annual Payment Fee Option**

An annual installment is collected in one lump sum. For initial enrollments, the contractor shall prorate the fee from the enrollment date to September 30. The contractor shall accept payment of the annual enrollment fee only by credit card (e.g., Visa/MasterCard). See [paragraph 4.3.1](#) for disenrollment information if the appropriate enrollment fee payment is not received.

#### **5.1.2 Quarterly Payment Fee Option**

Quarterly installments are equal to one-fourth (1/4) of the total annual fee amount. For initial enrollments, the contractor shall prorate the quarterly fee to cover the period until the next fiscal year quarter. (Fiscal quarters begin on January 1, April 1, July 1, and October 1.) The contractor shall collect quarterly fees thereafter. The contractor shall accept payment of the quarterly

enrollment fee only by credit card (e.g., Visa/MasterCard). See [paragraph 4.3.1](#) for disenrollment information if the appropriate enrollment fee payment is not received.

### **5.1.3 Monthly Payment Fee Option**

Monthly installments are equal to one-twelfth (1/12) of the total annual fee amount. Monthly enrollment fees must be paid-through an automated, recurring electronic payment either in the form of an allotment from retirement pay or through Electronic Funds Transfer (EFTs) from the enrollee's designated financial institution (which may include a recurring credit or debit card charge). These are the only acceptable payment methods for the monthly payment option.

**5.1.3.1** Enrollees who elect the monthly fee payment option must pay the first quarterly installment (i.e., the first three months) at the time the enrollment application is submitted to allow time for the allotment or EFT to be established. The contractor shall accept payment of the first quarterly installment by personal check, cashier's check, traveler's check, money order, or credit card (e.g., Visa/MasterCard).

**5.1.3.2** The contractor shall initiate monthly allotments and EFTs and is responsible for obtaining and verifying the information necessary to do so.

**5.1.3.3** The contractor shall direct bill the beneficiary only when a problem occurs in initially setting up the allotment or EFT.

**5.1.3.4** When an administrative issue arises that stops or prevents an automated monthly payment from being received by the contractor (e.g., incorrect or transposed number provided by the beneficiary, credit card expired, bank account closed, etc.), the contractor shall grant the enrollee 30 days to provide information for a new automated monthly payment method or the option to pay quarterly or annually. The contractor may accept payment by check during this 30 day period in order to preserve the beneficiary's Prime enrollment status.

**5.1.3.5** Allotments from retired pay will be coordinated through the contractor with the Defense Finance and Accounting Service (DFAS), U.S. Coast Guard (USCG), or Public Health Service (PHS), as appropriate (see the TSM, [Chapter 1, Section 1.1, paragraph 11.10](#) for Payroll Allotment Interface Requirements). The contractor shall process all allotment requests submitted by beneficiaries.

**5.1.3.6** The contractor shall also research all requests that have been rejected or not processed by DFAS, USCG, or PHS. If the contractor's research results in the positive application of the allotment action, the contractor shall resubmit the allotment request.

**5.1.3.7** Within five business days, the contractor will notify the beneficiary of rejected allotment requests and issue an invoice to the beneficiary for any outstanding enrollment fees due. The contractor will respond to all beneficiary inquiries regarding allotments.

## **5.2 Member Category**

The sponsor's member category on the effective date of the initial enrollment, as displayed in DOES, shall determine the requirement for an enrollment fee.

### **5.3 Unremarried Former Spouses (URFSs) and Children Residing with Them**

**5.3.1** URFSs became sponsors in their own right as of October 1, 2003. As such, they are enrolled under their own SSNs and pay an individual enrollment fee. URFS may not “sponsor” other family members and their fees may not be factored into any family fees associated with the former spouse/sponsor.

**5.3.2** Children residing with the URFS and whose eligibility for benefits is based on the ex-spouse/former sponsor are identified under the ex-spouse/former sponsor’s SSN on DEERS. Likewise, they are enrolled under the ex-spouse/former sponsor and fees for these children shall be combined with other fees paid under the ex-spouse/former sponsor.

**Example:** A contractor would collect the individual enrollment fee for an URFS’s enrollment under the URFS’s own SSN. The contractor would also collect a family enrollment fee for any two or more eligible family members enrolled under the SSN of the ex-spouse/former sponsor. These enrollees might include the sponsor, any current spouse, and all eligible children, including those living with the URFS.

### **5.4 Medicare Part B Fee Waiver**

Each Prime enrolled beneficiary under age 65, who maintains enrollment in Medicare Part B, is entitled to a waiver of an amount equivalent to the individual TRICARE Prime enrollment fee. Hence, individual enrollments for such beneficiaries will have the enrollment fee waived. A family enrollment in TRICARE Prime, where one family member is under age 65 and maintains enrollment in Medicare Part B, shall have one-half of the family enrollment fee waived; the remaining half must be paid. For a family enrollment where two or more family members are under age 65 and maintain enrollment in Medicare Part B, the family enrollment fee is waived regardless of the number of family members who are enrolled in addition to those entitled to Medicare Part B.

### **5.5 Survivors of Active Duty Deceased Sponsors and Medically Retired Uniformed Services Members and their Dependents**

Effective Fiscal Year (FY) 2012, beneficiaries who are (1) survivors of active duty deceased sponsors, or (2) medically retired Uniformed Services members and their dependents, shall have their Prime enrollment fees frozen at the rate in effect when classified and enrolled in a fee paying Prime plan. (This does not include TRICARE Young Adult (TYA) plans). Beneficiaries in these two categories who were enrolled in FY 2011 will continue paying the FY 2011 rate. The beneficiaries who become eligible in either category and enroll during FY 2012, or in any future fiscal year, shall have their fee frozen at the rate in effect at the time of enrollment in Prime. The fee for these beneficiaries shall remain frozen as long as at least one family member remains enrolled in Prime. The fee for the dependent(s) of a medically retired Uniformed Services member shall not change if the dependent(s) is later re-classified a survivor.

### **5.6 Mid-Month Enrollees**

The contractor shall collect any applicable enrollment fee from mid-month enrollees at the time of enrollment. However, there will be no enrollment fee collected for the days between the effective enrollment date and the determined enrollment date.

**5.6.1** The effective enrollment date shall be the actual start date of the enrollment.

**5.6.2** The determined enrollment date shall be established using the 20th of the month rule, as it is for initial enrollments.

**Example:** If the retirement date is May 27, the effective enrollment date will be May 27 and the determined enrollment date will be July 1. Fees will be charged for the period from July 1 forward; no fees will be assessed for the period from May 27 through June 30. Effective with enrollment fees that are to be applied to periods on or after October 1, 2012, DEERS will calculate the paid-through dates based on DEERS data and the enrollment fee amount collected and entered into DEERS by the contractor. Reference the TPM, [Chapter 10, Section 3.1](#).

## **5.7 Overpayment Of Enrollment Fees**

### **5.7.1 Prior To October 1, 2012**

If enrollment fees are overpaid at any point during an enrollment year, the contractor may credit the overpayment to any outstanding payments due. Such credits shall be reported on DEERS. If the overpayment of enrollment fees is not applied to outstanding payments due, the contractor shall refund any overpayments of \$1 or more to the enrollee. When TRICARE Prime enrollment changes from a family to an individual prior to annual renewal, the unused portion of the enrollment fee shall be prorated on a monthly basis and shall be applied toward a new enrollment period.

### **5.7.2 On Or After October 1, 2012**

Effective with enrollment fees that are to be applied for coverage on or after October 1, 2012, the contractor shall update DEERS with the fee amount collected and DEERS will calculate the paid-through date and notify the contractor. DEERS will only extend the paid-through date to cover the current enrollment year, plus two future fiscal years. DEERS will store amounts that cannot cover one month's fees or amounts that extend the paid-through date beyond two fiscal years in the future as a credit. Additionally, funds applied that would move the paid-through date beyond the policy end date will be stored as a credit. (The exception is when Prime policies end mid-month; DEERS will set a paid-through date to the end of that month.) Also, if there is a 100% fee waiver with an end date that exceeds more than two fiscal years beyond the current enrollment year, the paid period can extend beyond the two fiscal years and any fee amounts sent to DEERS will be applied as a credit. The contractor shall refund any credit of \$1 or more on a current enrollment that extends beyond two fiscal years. The contractor shall update DEERS with any fee amount refunded within 30 calendar days. The contractor shall include an explanation for the premium refund.

**5.8** The following reports will be provided to the contractor by DEERS to assist with identifying and correcting enrollment fee discrepancies. The contractor shall correct all accounts identified as discrepant. The contractor who is responsible for a beneficiary's current enrollment is responsible for resolving any over/under payments. For split enrollments, the reports will use the billing hierarchy to determine the responsible contractor.

**5.8.1 Monthly Under Report (Prior To October 1, 2012)**

Enrollment fees are considered delinquent and will show up on the Monthly Under Report when the paid-through date associated with a policy is greater than 60 days in the past. The Under Report will be provided on the first of each month. The contractor is required to analyze and correct all reported delinquencies within 30 days of the report's availability. The corrections may include synchronizing the fee data between the contractor's system and DEERS, correcting data discrepancies, and potentially terminating enrollments for failure to pay fees.

**5.8.2 Monthly Over Report (Prior To October 1, 2012)**

The Monthly Over Report will identify those policies where the paid amount is over the amount owed. Amount owed is based on the enrollment begin date, the paid-through date, any existing fee waivers, and DEERS data used to determine payment tiers (if applicable) and/or freezes of enrollment fees (premium override periods). The Over Report will be provided before the 10th business day of each month. The contractor is required to analyze and correct all reported accounts within 30 days of the report's availability. The contractor is responsible for correcting any data inaccuracies within the enrollment fee reporting system to include the refunding of any enrollment fees in excess of what is due if necessary.

**5.8.3 Quarterly Under Report (Prior To October 1, 2012)**

The Quarterly Under Report will identify all terminated policies since the inception of the contract that have an associated paid-through date prior to the termination date. The Quarterly Report will be provided on the first day of the first month of the fiscal quarter (i.e., October 1, January 1, April 1, and July 1). The contractor shall correct all data discrepancies within 60 days of the report's availability.

**5.8.4 Monthly Reports (On or After October 1, 2012)**

**5.8.4.1** DEERS will provide the following reports on a monthly basis:

- Current policies that are two months past due (paid period end date more than two months in the past)
- Any policies where the paid period end date exceeds the policy end date
- Policies where the paid period end date meets the policy end date but a credit exists
- Terminated policies where the paid period end date does not meet the policy end date

**5.8.4.2** These reports will be provided before the 10th business day of each month. The contractor is required to analyze and correct all report accounts within 30 days of the report's availability. The contractor is responsible for correcting any data inaccuracies within the enrollment fee reporting system to include the refunding of any enrollment fees in excess of what is due if necessary. For enrollment fee payments effective on or after October 1, 2012, the contractor shall update DEERS with any fee amount refunded within 30 calendar days.

## **6.0 ENROLLMENT OF FAMILY MEMBERS OF E-1 THROUGH E-4**

**6.1** When family members of E-1 through E-4 reside in a Prime Service Area (PSA) of an MTF offering TRICARE Prime, the family members will be encouraged to enroll in TRICARE Prime. Upon enrollment, they will choose or be assigned a PCM located in the MTF. Such family members may, however, specifically decline such enrollment without adverse consequences. The choice of whether to enroll in TRICARE Prime, or to decline enrollment is completely voluntary. Family members of E-1 through E-4 who decline enrollment or who enroll in Prime and subsequently disenroll may re-enroll at any time. The completion of an enrollment application is a prerequisite for enrollment of such family members.

**6.2** Enrollment processing and allowance of civilian PCM assignments will be in accordance with the Memorandum of Understanding between the contractor and the MTF.

**6.3** The primary means of identification and subsequent referral for enrollment will occur during in-processing. These non-enrolled families may also be referred to the local TSC by the MTF, Commanders, First Sergeants/Sergeants Major, supervisors, Family Support Centers, and others.

**6.4** The local TSC will provide enrollment information and support the family member in making an enrollment decision (i.e., to enroll in TRICARE Prime or to decline enrollment). The education of such potential enrollees shall specifically address the advantages of TRICARE Prime enrollment, including guaranteed access, the support of a PCM, etc. The contractor shall reinforce that enrollment is at no cost for family members of E-1 through E-4 and will give them the opportunity to select or be assigned an MTF PCM, to select a civilian PCM if permitted by applicable MOU, or to decline enrollment in TRICARE Prime.

**6.5** The contractor shall also discuss the potential effective date of the enrollment, explaining that the actual effective date will depend upon the date the enrollment application is received, consistent with current TRICARE rules (i.e., the "20th of the month" rule). The effective date of enrollment shall be determined by the date the enrollment application is received by the MCSC. These enrollments and enrollment refusals should not be tracked, nor the enrollees identified differently than enrollments initiated through any other process, such as the MCSC's own marketing efforts.

**6.6** Enrollment may be terminated at any time upon request of the enrollee, sponsor or other party as appropriate under existing enrollment/disenrollment procedures. Beneficiaries in this group may re-enroll at any time without restriction or penalty. However, such re-enrollments are subject to the 20th of the month rule.

**6.7** Contractors are not required to screen TRICARE claims to determine whether it may be for treatment of a non-enrolled ADFM of E-1 through E-4 living in a PSA. Rather, they are to support the prompt and informed enrollment of such individuals when they have been identified by DoD in the course of such a person's interaction with the military health care system or personnel community and have been referred to the contractor for enrollment.

## **7.0 TRICARE ELIGIBILITY CHANGES/REFUNDS OF FEES**

**7.1** Refer to the TPM, [Chapter 10, Section 3.1](#), for information on changes in eligibility.

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**7.2** The contractor shall allow a TRICARE-eligible beneficiary who has less than 12 months of eligibility remaining to enroll in TRICARE Prime until such time as the enrollee loses his/her TRICARE eligibility. The beneficiary shall have the choice of paying the entire enrollment fee or paying the fees on a more frequent basis (e.g., monthly or quarterly). If the enrollee chooses to pay by installments, the contractor shall collect only those installments required to cover the period of eligibility. For enrollment fee payments effective on or after October 1, 2012, DEERS will calculate the paid-through date based on the enrollment fee amount collected and entered into DEERS by the contractor, which in this circumstance, should cover the period of the beneficiary's eligibility. The contractor shall refund any overpayment of \$1 or more that DEERS does not use to extend the paid-through date to the policy end date (or the last day of the month in which a Prime policy ends). The contractor shall include an explanation to the beneficiary for the fee refund. The contractor shall update DEERS with any fee amount refunded within 30 calendar days.

**7.3** Contractors shall refund the unused portion of the TRICARE Prime enrollment fee to retired TRICARE Prime enrollees and their families who have been recalled to active duty. The contractor shall include an explanation to the beneficiary for the fee refund. Contractors shall calculate the refund using monthly prorating, and shall report such refunds to DEERS within 30 calendar days. If the reactivated member's family chooses continued enrollment in TRICARE Prime, the family shall begin a new enrollment period and shall be offered the opportunity to keep its PCM, if possible. Any enrollment/fiscal year catastrophic cap accumulations shall be applied to the new enrollment period.

**7.4** The contractor shall refund enrollment fees for deceased enrollees upon receiving a written request from the remaining enrollee or the executor of the decedent's estate. The contractor shall include an explanation to the beneficiary for the fee refund. The enrollee's request must include a copy of the death certificate. Refunds shall be prorated on a monthly basis and apply both to individual plans where the sole enrollee is deceased and to the conversion of a family enrollment to an individual plan upon the death of one or more family members. For individual enrollments, the contractor shall refund remaining enrollment fees to the executor of the estate. For family enrollments that convert to individual plans, the contractor shall either credit the excess fees to the individual plan or refund them either to the remaining enrollee or to the executor of the decedent's estate, as appropriate. Enrollment fees for family enrollments of three or more members are not affected by the death of only one enrollee and no refunds shall be issued. The contractor shall update DEERS with any amount refunded within 30 calendar days.

**7.5** The contractors shall refund the unused portion of the TRICARE Prime enrollment fee to TRICARE Prime enrollees who become eligible for Medicare Part A based upon disability, End Stage Renal Disease (ESRD) or upon attaining age 65, provided the beneficiary has Medicare Part B coverage.

**7.5.1** The contractor shall issue refunds to these beneficiaries upon receiving (1) a written request from the beneficiary (that includes a copy of their Medicare card) and either confirming their Part B enrollment in DEERS or in a previous Policy Notification Transaction (PNT), or (2) upon receipt of an unsolicited PNT noting a beneficiary's fee waiver update based on the Part B enrollment. DEERS generates a PNT when the Centers for Medicare and Medicaid Services (CMS) sends DEERS data indicating a Part B enrollment or disenrollment. Refunds are required for all payments that extend beyond the date the enrollee has Medicare Part B coverage, as calculated by DEERS. The contractor shall update DEERS with any amount refunded within 30 calendar days. The contractor shall include an explanation to the beneficiary for the fee refund. Effective October 1,

2012, if the fee waiver is a 100% waiver of the Prime enrollment fee, the contractor shall send a refund to the beneficiary. If the fee waiver is a 50% waiver of the Prime enrollment fee, DEERS will automatically calculate the overpayment and extend the paid through date for the policy, as appropriate; therefore, a refund may not be required unless a credit remains when the policy is paid in full.

**7.5.2** For Prime enrollees who become Medicare eligible and who maintain Medicare Part B coverage, refunds are required for overpayments occurring on and after the start of health care delivery of all MCS contracts. The contractor shall utilize the PNTs received indicating a fee waiver based on Medicare to substantiate any claim of overpayment.

**7.5.3** Medicare eligible ADFMs age 65 and over are not required to have Medicare Part B to remain enrolled in TRICARE Prime. To maintain TRICARE coverage upon the sponsor's retirement, they must enroll in Medicare Part B during Medicare's Special Enrollment Period prior to their sponsor's retirement date. (The Special Enrollment Period is available anytime the sponsor is on active duty or within the first eight months of the sponsor's retirement. If they enroll in Part B after their sponsor's retirement date, they will have a break in TRICARE coverage.)

**7.5.4** Medicare eligibles age 65 and over who are not entitled to premium-free Medicare Part A are not required to have Medicare Part B to remain enrolled in TRICARE Prime. Because they may become eligible for premium-free Medicare Part A at a later date, under their or their spouse's SSN, they should enroll in Medicare Part B when first eligible at age 65 to avoid the Medicare surcharge for late enrollment.

**7.6** The contractor shall include full and complete information about the effects of changes in eligibility and rank in beneficiary education materials and briefings.

## **8.0 WOUNDED, ILL, AND INJURED (WII) ENROLLMENT CLASSIFICATION**

The WII program provides a continuum of integrated care from the point of injury to the return to duty or transition to active citizenship for the Active Component (AC) or the Reserve Component (RC) service members who have been activated for more than 30 days. These AC/RC service members, referred to as ADSMs, have been injured or become ill while on active duty and will remain in an active duty status while receiving medical care or undergoing physical disability processing. WII programs vary in name according to Service. The Service shall determine member eligibility for enrollment into a WII program, as well as whether or not to utilize these enrollments.

To better manage this population, a secondary enrollment classification of HCDP Plan Coverage Codes, WII 415 and WII 416 were developed. The primary rules apply to the WII HCDP codes:

- ADSMs must be enrolled to a TRICARE Prime program prior to, or at the same time, as being enrolled into a WII 415 or WII 416 program.
- A member cannot be enrolled in WII 415 and WII 416 programs at the same time.
- WII 415 and WII 416 enrollments will terminate at the end of the member's active duty eligibility, when members transfer enrollment to another MTF, change of a plan code, or at the direction of the Service-specific WII entity.

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- Any claims processed for WII 415/416 enrollees shall follow the rules associated with the primary HCDP Plan Coverage Code, such as TRICARE Prime, TRICARE Prime Remote (TPR), TRICARE Overseas Program (TOP) Prime, or TOP Prime Remote. All claims will process and pay under Supplemental Health Care Program (SHCP) rules. DEERS will not produce specific enrollment cards or letters for WII 415/416 enrollment.

WII 415/416 TRICARE Encounter Data (TED) records shall be coded with the WII 415/416 HCDP Plan Coverage Code; however, the Enrollment/Health Plan Code data element on the TED record shall reflect the appropriate value for the primary HCDP Plan Coverage Code. For example, a TED record for a WII 416 enrollee with primary enrollment to TPR would reflect the HCDP Plan Coverage Code of "416" but the Enrollment/Health Plan Code would be coded "W TPR Active Duty Service Member".

#### **8.1 WII 415 - Wounded, Ill, And Injured (e.g., Warrior Transition/MEDHOLD Unit (WTU))**

**8.1.1** Service defined eligible ADSMs assigned to a WII 415 Program such as a MEDHOLD or WTU shall be enrolled to TRICARE Prime or TOP Prime prior to, or at the same time, as being enrolled into the WII 415. Members cannot be enrolled to the WII 415 without a concurrent TRICARE Prime or TOP Prime enrollment. Service appointed WII case managers as determined by the Services, will coordinate with the MTF to facilitate TRICARE Prime PCM assignments for WII 415 members. The contractor shall then assign a PCM in accordance with the MTF MOU and in coordination with the WII case manager. WII 415 enrollment will not run in conjunction with TAMP and members enrolled in TPR, or TOP Prime Remote are not eligible to enroll in the WII 415.

**8.1.2** The Service-specific WII entity will stamp the front page of the DD Form 2876, enrollment application form, with WII 415 for new enrollments that begin after the DEERS implementation date. The enrollment form will then be sent to the appropriate contractor who shall perform the enrollment in the DOES and include the following information:

- WII 415 HCDP Plan Coverage Code
- WII 415 Enrollment Start Date (Contractors may change the DOES defaulted start date, which may or may not coincide with the Prime Enrollment Start Date. The start date can be changed up to 289 days in the past or 90 days into the future.)

**8.1.3** WII 415 enrollments will be in conjunction with an MTF enrollment only, not to civilian network PCMs under TPR enrollment rules. DEERS will end WII 415 enrollments upon loss of member's active duty eligibility. WII 415 program enrollments will not be portable across programs or regions. The TOP contractor will enter WII 415 enrollments through DOES for outside the 50 United States and the District of Columbia.

**8.1.4** The contractors shall accomplish the following functions based on receipt of notification from the Service-specific WII program entities:

- Enrollment
- Disenrollment
- Cancel enrollment
- Cancel disenrollment
- Address update

- Contractors can request unsolicited PNTs resend
- Modify begin date
- Modify end date

**8.1.5** Service WII entities will provide contractors with a list by name and SSN of those ADSMs currently assigned to their WII program at the time the program is implemented by DEERS. The contractors shall enter these ADSMs into DOES as enrolled in WII 415 with a start date of the date of implementation, unless another date, up to 289 days in the past, is provided by the WII entity.

## **8.2 WII 416 - Wounded, Ill, And Injured - Community-Based (e.g., Community-Based Health Care Organization (CBHCO))**

**8.2.1** Service defined eligible ADSMs may be assigned to a WII 416 Program such as the Army's CBHCO and receive required medical care near the member's home. The service member shall be enrolled to TRICARE Prime, TPR, TOP Prime, or TOP Prime Remote prior to or at the same time as being enrolled into WII 416. Members cannot be enrolled to the WII 416 program without a concurrent Prime, TPR, TOP Prime, or TOP Prime Remote enrollment. Service appointed case managers will coordinate with the contractor or MTF to facilitate TRICARE Prime or TPR PCM assignments for eligible beneficiaries. The contractor shall then assign a PCM based on the MTF MOU and in coordination with the WII entity (e.g., CBHCO). WII 416 enrollments will not run in conjunction with TAMP.

**8.2.2** The Service-specific WII Program will stamp the front page of the DD Form 2876, enrollment application form, with WII 416 for all new enrollments. The begin date will be the date the contractors receive the signed enrollment form. A signed enrollment application includes those with (1) an original signature, (2) an electronic signature offered by and collected by the contractor, or (3) the self attestation by the beneficiary when using the BWE system. The enrollment form will then be sent to the appropriate contractor who shall perform the enrollment in the DOES and include the following information:

- WII 416 HCDP Plan Coverage Code
- WII 416 Enrollment Start Date (Date received by the contractor or the date indicated by the Service-specific WII Program which can be up to 289 days in the past, or 90 days in the future.)

An ADSM or ADFM signature is not required to make enrollment changes when using the Enrollment Portability process outlined in [Chapter 6, Section 2, paragraph 1.4](#).

**8.2.3** WII 416 enrollments can be in conjunction with an MTF, TPR, TOP Prime, or TOP Prime Remote enrollment. DEERS will end WII 416 enrollments upon loss of member's active duty eligibility. WII 416 program enrollments will not be portable across programs or regions.

**8.2.4** The contractors shall accomplish the following functions based on receipt of notification from Service-specific WII program entities:

- Enrollment
- Disenrollment
- Cancel enrollment

- Cancel disenrollment
- Address update
- Contractors can request PNT resend
- Modify begin date
- Modify end date

**8.2.5** Service-specific WII entities will provide contractors with a list by name and SSN of those ADSMs currently participating in their WII program at the time the program is implemented by DMDC. The contractors shall enter these ADSMs into DOES as enrolled to WII 416 with a start date as the date of implementation, unless another date up to 289 days in the past is provided by the Service-specific WII program entities.

## **9.0 TRICARE POLICY FOR ACCESS TO CARE (ATC) AND PRIME SERVICE AREA (PSA) STANDARDS**

**9.1** Non-active duty beneficiaries in the Continental United States (CONUS) and Hawaii who reside more than 30 minutes travel time from their desired PCM must waive primary and specialty drive-time ATC standards. (Due to the unique health care delivery challenges in Alaska, the requirement to request a waiver for the drive-time access standard does not apply to beneficiaries in Alaska.) Before effecting an enrollment or portability transfer request, contractors shall ensure that the applicant has waived travel time ATC standards either by signing Sections V and VI of the DD Form 2876 enrollment application (this includes an electronic signature offered by and collected by the contractor) or by requesting enrollment through the BWE service (for both civilian and MTF PCMs). An approved waiver for a beneficiary residing less than 100 miles from their PCM will remain in effect until the beneficiary changes residence.

**9.2** Contractors must estimate the travel time or distance between a beneficiary's residence to a PCM (either a civilian PCM or an MTF) using at least one web-based mapping program. The choice of the mapping program(s) is at the discretion of the contractor, but the contractor must use a consistent process to determine the driving distance for each enrollee applicant who may reside more than 30 minutes travel time from their PCM. The time or distance shall be computed between the enrollee's residence and the physical location of the PCM (including MTFs). It is not acceptable to use a geographic substitute, such as a geographic centroid.

**9.3** Contractors (in conjunction with MTFs for MTF enrollees) are responsible for beneficiary drive-time waiver education and must ensure that beneficiaries who choose to waive these standards have a complete understanding of the rules associated with their enrollment and the travel time standards they are forfeiting. This includes educating beneficiaries who waive their ATC travel standards of the following:

- They should expect to travel more than 30 minutes for access to primary care (including urgent care) and possibly more than one hour for access to specialty care services.
- They will be held responsible for POS charges for care they seek that has not been referred by their PCM (or for MTF enrollees, by another MTF provider).
- They should consider whether any delay in accessing their enrollment site might aggravate their health status or delay receiving timely medical treatment.

**9.4** Enrollment shall only be effected for beneficiaries who reside in the Region. If at any point during the enrollment period the contractor determines or is advised that a beneficiary's residential address is outside the Region, the contractor shall inform the beneficiary of the discrepant address situation. This notification shall occur when the discrepant information is known to the contractor (i.e., not wait until the end of the enrollment period). When there is a discrepant address situation, the contractor shall confirm with the beneficiary the correct address. If the beneficiary confirms that a DEERS-recorded address is incorrect, the contractor shall request the beneficiary update DEERS with correct information (and assist as appropriate). If the contractor determines that the beneficiary resides outside the Region in which they are enrolled, the contractor shall inform the beneficiary no later than two months prior to expiration of the current enrollment period that enrollment will not be renewed to a Region in which they do not reside. The contractor shall provide information necessary for the beneficiary to contact the contractor for the region in which they do reside to request enrollment in that region.

## **9.5 MTF Enrollees**

**9.5.1** Non-active duty beneficiaries must reside within 30 minutes travel time from an MTF to which they desire to enroll. If a beneficiary desiring enrollment resides more than 30 minutes (but less than 100 miles) from the MTF, they may be enrolled so long as they waive primary and specialty ATC standards and the MTF Commander (or designee) approves the enrollment. (If the MOU includes zip codes or drive-time distances for which the MTF is willing to accept enrollments that are beyond a 30 minute drive, this constitutes approval. If not addressed in the MOU, the contractor shall submit each request to the MTF Commander (or designee) in a method that is outlined in the MOU.) The TRICARE Regional Office (TRO) Director may approve waiver requests from beneficiaries who desire to enroll to an MTF and who reside 100 miles or more from the MTF. In these cases, the MTF Commander must also be agreeable to the enrollment and have sufficient capacity and capability.

**9.5.2** The contractor shall process all requests for enrollment to an MTF in accordance with the MOU between the MTF and the contractor. Enrollment guidelines in MOUs may include:

**9.5.2.1** Zip codes and/or distances for which the MTF Commander is mandating enrollment to the MTF. These mandatory MTF enrollment areas must be within access standards (i.e., a 30 minute drive-time of the MTF) and can apply to all eligible beneficiaries or can be based on beneficiary category priorities for MTF access.

**Note:** Non-active duty TRICARE Prime applicants who reside more than 30 minutes travel time from an MTF must be afforded the opportunity to enroll with a civilian PCM if they live in a PSA.

**9.5.2.2** Zip codes and/or distances for which the MTF Commander is willing to accept enrollment. This can include both areas within a 30 minute or less drive-time and over a 30 minute drive but within 100 miles. Any enrollment for a beneficiary with a drive of more than 30 minutes requires a signed waiver of access standards. If an enrollee applicant resides within a zip code previously determined to lie entirely within 30 minutes travel time from the MTF, the contractor need not compute the travel time for that applicant.

**9.5.2.3** Whether or not the MTF Commander will consider a request for enrollment for 100 miles or greater. In determining whether or not the MTF Commander will consider a request for

enrollment beyond 100 miles, the MTF Commander may use zip codes to designate those areas the MTF Commander will consider requests or will not consider requests.

**9.5.3** The contractor shall notify the MTF Commander (or designee) when a beneficiary residing 100 miles or more from the MTF, but in the same Region, requests a new enrollment or portability transfer to the MTF. Such notification is not necessary if the MOU has already established that the MTF Commander will not accept enrollment of beneficiaries who reside 100 miles or more from the MTF. The contractor shall make this notification by any mutually agreeable method specified in the MOU. The contractor shall not make the MTF enrollment effective unless notified by the MTF to do so.

**9.5.3.1** The MTF Commander will notify the TRO Director of their desire to enroll a beneficiary who resides 100 miles or greater from the MTF and request approval for the enrollment. The TRO Director will make a determination on whether or not to approve or deny the request and notify the MTF Commander of their decision by a mutually agreeable method. The MTF Commander is responsible for notifying the contractor of all approved enrollment requests for beneficiaries who reside 100 miles or greater from the MTF. The contractor shall notify the beneficiary of the final decision.

**9.5.3.2** Approved waivers for beneficiaries residing 100 miles or more from the MTF shall remain in effect until the beneficiary changes residence or unless the MTF Commander determines that they will no longer allow these enrollments. Even if a beneficiary has previously waived travel time standards, any MTF Commander may revise the MOU (following the MOU revision process) to state that enrollment of some or all current enrollees who reside 100 or more miles from the MTF are not to be renewed at the end of the enrollment period. The contractor shall inform such beneficiaries no later than two months prior to expiration of the current enrollment period that they are no longer qualified for renewal of enrollment to the MTF. Prior to notification, the contractor shall obtain the rationale for the change from the MTF to include in the notice to the beneficiary. The proposed notice shall be reviewed and concurred on by the TRO prior to being sent to the impacted beneficiaries. (The TRO will coordinate notices with the TRICARE Management Activity (TMA) Beneficiary Education and Support Division (BE&SD) prior to approval.)

**9.5.4** At any time during the enrollment period, if the contractor determines there is no signed travel time waiver on file for a current MTF enrollee who resides more than 30 minutes from the MTF, the contractor shall, at the next annual TRICARE Prime renewal point, require the beneficiary to waive the primary and specialty care ATC standards before the enrollment will be renewed. (This includes monitoring address changes received by the contractor from all sources.) The contractor shall notify the beneficiary of this waiver requirement no later than two months before expiration of the annual enrollment period. The language for all beneficiary notices shall be reviewed and concurred on by the TRO prior to being sent to beneficiaries. (The TRO will coordinate notices with TMA BE&SD prior to approval.)

- Any notice to a beneficiary that is requesting they sign a waiver of access standards, denying their enrollment, or advising them they are not eligible for re-enrollment to an MTF, shall include information on any alternative options for enrollment. The notice must also advise the beneficiary of the option to participate in TRICARE Standard, Extra, or the USFHP where available.

**9.5.5** For each approved enrollment to an MTF where the beneficiary has waived access standards (whether by DD Form 2876 or BWE), the contractor shall retain the enrollment request in a searchable electronic file until 24 months after the beneficiary is no longer enrolled to the MTF. The contractor shall provide the retained file to a successor contractor at the end of the final option period.

**9.5.6** When an enrollment request requires MTF Commander or TRO Director approval, any contractual requirements relating to processing timeliness for enrollment requests will begin when the contractor has obtained direction from the MTF Commander or TRO Director regarding waiver approval or disapproval.

**9.5.7** The contractor shall apprise the MTF Commander (or designee) of all enrollees to the MTF who have waived their ATC travel standards. The contractor shall separate the information into two categories, those who reside within 100 miles of the MTF and those who reside 100 miles or more from the MTF. This notification shall be by any mutually agreement means specified in the MOU between the contractor and the MTF Commander.

## **9.6 Civilian Enrollees**

**9.6.1** Within a PSA, the civilian network must have the capability and capacity to allow beneficiaries who reside in the PSA to enroll to a PCM within access standards. If a beneficiary who resides in the PSA requests enrollment to a specific PCM who is located more than a 30 minute drive from the beneficiary's residence, the contractor may allow the enrollment so long as the beneficiary waives travel time access standards. (Also, see [Chapter 5, Section 1.](#))

**9.6.2** For new enrollments (including portability transfers), the contractor is not required to establish a network with the capability and capacity to grant enrollment to beneficiaries who reside outside a PSA. Requests for new enrollments to the civilian network from beneficiaries residing outside a PSA will be granted provided there is sufficient unused network capacity and capability to accommodate the enrollment and that the PSA civilian network PCM to be assigned is located less than 100 miles from the beneficiary's residence. Beneficiaries who reside outside the PSA and enroll in TRICARE Prime must waive their primary and specialty care travel time access standards. (The network shall have the capability and capacity to allow beneficiaries enrolled in TRICARE Prime, residing outside of PSAs, with a civilian network PCM prior to the beginning of Option Period One of the applicable regional Managed Care Support (MCS) contract to enroll to a PSA PCM provided the beneficiary resides less than 100 miles from an available network PCM in the PSA and waives both primary and specialty care travel time standards.)

**9.6.3** Beneficiaries who reside outside the PSA and are 100 miles or greater from an available civilian network PCM in the PSA shall not be allowed to enroll in TRICARE Prime.

- END -

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REQUIRED DATA ELEMENT*	DESCRIPTION/PURPOSE/USE
Request Date/Time	DD MMM YY hhmm
Request Priority	STAT/24-hour/ASAP/Today/72-hour/Routine
Requester	
Referring Provider Name	Name of PCM/MTF individual provider making request
Referring Provider National Provider Identifier (NPI)	Health Insurance Portability and Accountability Act (HIPAA) NPI - Type 1 (Individual)
Referring MTF	Name of MTF
Referring MTF NPI	HIPAA NPI - Type 2 (Organizational)
PATIENT INFORMATION	
Sponsor Social Security Number (SSN)	
Patient ID	Electronic Data Interchange Patient Number (EDI_PN) (from DEERS) if available
Patient Name	Full Name of Patient (if no EDI_PN available)
Patient Date of Birth (DOB)	Date of Birth (required if patient not on DEERS)
Patient Gender	
Patient Address	Full Address of Beneficiary (including zip)
Patient Telephone Number	If available - Telephone Number (including area code)
CLINICAL INFORMATION	
Patient Primary Provisional Diagnosis	Description
Reason for Request	Sufficient Clinical Info to Perform Medical Necessity Report (MNR)
SERVICE	
Service 1 - Provider	Specialty of Service Provider
Service 1 - Provider Sub-Specialty	Additional Sub-Specialist Info if Needed (Free Text Clarifying Info Entered with Reason for Request) e.g., Pediatric Nephrologist
Service 1 - By Name Provider Request if Applicable - First and Last Name	Optional Info Regarding Preferred Specialist Provider (Free Text)
Service 1 - Service Type	Inpatient, Specialty Referral, Durable Medical Equipment (DME) Purchase/Rental, Other Health Service, et al DME Provider to do Certificates of Medical Necessity (CMN)
Service 1 - Service Quantity (optional)	Number of Visits, Units, etc.
Composite Health Care System (CHCS) Generated Order Number (Defense Medical Information System (DMIS)-YYMMDD-XXXXX)	Unique Identifier Number (UIN). The UIN is the DMIS (of the referring facility identified in the "Referring MTF" field on this request) --Date in format indicated-- Consult Order Number from CHCS.
Special Instructions:	
<b>Note 1:</b> *Above data elements are required unless otherwise noted as "Optional."	
<b>Note 2:</b> Use of the NPI is required in accordance with Health and Human Services (HHS) NPI Final Rule by May 23, 2007 or upon service direction and/or direction of the Contracting Officer (CO). Implementation requirements may be found at <a href="#">Chapter 19, Section 4</a> .	
<b>Note 3:</b> When issuing a preauthorization for an ADSM while in terminal leave status to obtain medical care from the Department of Veterans Affairs (DVA), as required by <a href="#">Chapter 17, Section 1, paragraph 4.5</a> , the MTF shall make special entries for data elements as follows:	
Patient Primary Provisional Diagnosis	Condition of a routine or urgent nature as specified by the patient at a future date.

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REQUIRED DATA ELEMENT*	DESCRIPTION/PURPOSE/USE
<b>SERVICE (CONTINUED)</b>	
Reason for Request	Provide preauthorization for outpatient treatment by the DVA for routine or urgent conditions while the active duty patient is in a terminal leave status.
Service 1 - Provider	Any DVA provider.
Service 1 - By Name Provider Request if Applicable - First and Last Name	DVA provider only.
<b>Note 4:</b> When issuing an authorization for the DVA to provide a Compensation and Pension (C&P) examination for a service member as required by <a href="#">Chapter 17, Section 2, paragraph 3.2.2</a> , the MTF shall make special entries for data elements as follows:	
Patient Primary Provisional Diagnosis	V68.01 - Disability Examination
Reason for Request	DVA only: Integrated Disability Evaluation System (IDES) C&P Examinations for Fitness for Duty Determination
Service 1 - Provider	Any DVA Provider
Service 1 - By Name Provider Request if Applicable - First and Last Name	DVA Provider Only
Service 1 - Service Quantity	Number of C&P Examinations Authorized
<b>Special Instructions:</b>	
This blanket preauthorization is only for routine and urgent outpatient primary medical care provided by the DVA while the patient is in a terminal leave status. Terminal leave for this patient concludes at midnight on DD MMM YY.	

**6.1.1** The contractor shall use the CHCS generated order number (DMIS-YYMMDD-XXXXX) as a unique identifier. The first four digits of the UIN is the DMIS of the referring facility only. Using the unique identifier, the contractor will locate related referrals, authorizations, and claims. Contractor generated MTF reports shall be modified to accommodate the unique identifier and NPI as needed. The unique identifier shall also be used for all related customer service inquiries. UINs and NPIs will be attached to all MTF referrals and will be portable across all regions of care. The contractor shall capture the NPIs from the referral transmission report and forward the NPI to the referred-to provider on all referrals.

**6.1.2** The MCSC where care is rendered will apply their best business practices when authorizing care for referrals to their network and will retain responsibility for managing requests for additional services or inpatient concurrent stay reviews associated with the original referral as well as changes to the speciality provider identified to deliver the care. The MCSC authorizing the care shall forward the referral/authorization information, including the range of codes authorized (i.e., Episode Of Care (EOC)) and the name, the NPI, and demographic information of the speciality provider to the MCSC for the region to which the patient is enrolled. **If the patient is enrolled overseas, the MCSC will provide the same service and information required above to the TRICARE Overseas Program (TOP) contractor. If a CONUS Prime retiree/retiree family member receives authorization to obtain care overseas from an MCSC, the MCSC shall forward the authorization information to the TOP contractor to ensure appropriate adjudication of the claim.** Claims submitted by the provider will be processed by the MCSC **or the TOP contractor according to [Chapter 8, Section 2](#).**

**6.1.3** The contractor shall screen the information provided and return, by fax or other electronic means acceptable to the MTF and the MCSC, incomplete requests within one business day. The return of a referral to the MTF is considered processed to completion. One business day is

defined as the work day following the day of transmission at the close of business at the location of the receiving entity. A business day is Monday through Friday, excluding federal holidays.

**6.1.4** The contractor shall verify that the services are a TRICARE benefit through appropriate medical review and screening to ensure that the service requested is reimbursable through TRICARE. The contractor's medical review shall be in accordance with the contractor's best business practices. This process does not alter the TRICARE Operations Manual (TOM), TRICARE Policy Manual (TPM), or TRICARE Systems Manual (TSM) provisions covering active duty personnel or TRICARE For Life (TFL) beneficiaries.

**6.1.5** The MCSC shall advise the patient, referring MTF, and receiving provider of all approved referrals. The MTF single Point Of Contact (POC) shall be advised via fax or other electronic means acceptable to the MTF and the MCSC. (The MTF single POC may be an individual or a single office with more than one telephone number.) The notice to the beneficiary shall contain the unique identifier and information necessary to support obtaining ordered services or an appointment with the referred to provider within the access standards. The notice shall also provide the beneficiary with instructions on how to change their provider, if desired. If the MCSC is made aware the beneficiary changed the provider listed on the referral, the MCSC will make appropriate modifications to MTF issued referral (to revise the provider the beneficiary was referred to by the MTF). The revised referral shall contain the same level of data as the initial MTF referral. The revised referral will be issued to the current provider, with a copy to the MTF. For same day, 24-hour, and 72-hour referrals no beneficiary notification shall be issued. The MCSC shall notify the provider to whom the beneficiary is being referred of the approved services, to include clinical information furnished by the referring provider.

**6.1.6** If services are denied, the MCSC shall notify the patient and shall advise the patient of their right to appeal consistent with the TOM. The MCSC shall also notify the referring single MTF POC by fax of the initial denial.

**6.1.7** For services beyond the initial authorization, the MCSC shall use its best practices in determining the extent of additional services to authorize. The MCSC shall not request a referral from the MTF but shall provide the MTF, through the MTF's single POC, a copy of the authorization and clinical information that served as the basis for the new authorization.

## **6.2 Referrals From The Contractor To The MTF**

Referrals subject to the ROFR provision from the civilian sector shall be processed in accordance with the following procedures.

**6.2.1** The contractor shall fax, or send via other electronic means acceptable to the MTF and the MCSC, the referral to the single MTF POC. The request shall contain the minimum data set described in [paragraph 6.1](#) (with the exception of the UIN) plus the civilian provider's fax number, telephone number, and mailing address. This data set shall be provided to the MTF in plain text with or without diagnosis or procedure codes. This transmission will generally take place within one business day. A business day is Monday through Friday, excluding Federal holidays.

**6.2.2** The MTF will respond via fax or other electronic means acceptable to the MTF and the MCSC, generally within one business day, as defined in [paragraph 6.2.1](#), from receipt of the request to the single POC provided in the MOU by the contractor. When no response is received from the

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MTF in response to the ROFR request in one business day as defined above, the contractor shall process the referral request as if the MTF declined to see the patient. The contractor shall provide each MTF with a report of the number of referrals forwarded based on the ROFR provision.

**6.2.3** The contractor shall contact the MTF POC for the coordination of same day and 72-hour referrals in accordance with the MTF MOU. In general, the MTF will respond within 30 minutes of notification. When no response is received from the MTF within 30 minutes, the contractor shall process the referral request as if the MTF declined to see the patient.

**6.2.4** The ROFR will be forwarded for only those beneficiaries residing within the PSA access standards and for whom the MTF has indicated the desire to receive referral request based on specialty or selective diagnosis code or procedure codes, and/or enrollment category. ROFR requests shall be provided prior to the MCSCs medical necessity and covered benefit review to afford the MTF the opportunity to see the patient prior to any decision.

**6.2.5** In instances where the MTF elects to accept the patient, the MTF will advise the MCSC within one business day, as defined in [paragraph 6.2.1](#). The MCSC will notify the beneficiary of the MTF's acceptance and provide instructions for contacting the MTF to obtain an appointment.

- END -

monthly installment will exclude any approved accumulation of past installments (to be reimbursed as one claim) due on the initial claim. Must be split under TEDs.

**9.3** A claim that contains services, supplies or equipment covering more than one contractor's jurisdiction shall be split. See [Section 2](#), for information on transferring partially out-of-jurisdiction claims.

**9.4** An inpatient maternity claim which is subject to the TRICARE Diagnosis Related Group (DRG)-based payment system and which contains charges for the mother and the newborn shall be split, only when there are no nursery/room charges for the newborn. See the TRM, [Chapter 1, Section 31](#).

**9.5** Hospice claims that contain both institutional and physician services shall be split for reporting purposes. Institutional services (i.e., routine home care - 651, continuous home care - 652, inpatient respite care - 655, and general inpatient care - 656) shall be reported on an institutional claim format while hospice physician services (revenue code 657 and accompanying Current Procedural Terminology (CPT) codes) shall be reported on a non-institutional format. See the TRM, [Chapter 11, Section 4](#).

**9.6** A claim for ambulatory surgery services submitted by an ambulatory surgery facility (either freestanding or hospital-based) may be split into separate claims for:

**9.6.1** Charges for services which are included in the prospective group payment rate;

**9.6.2** Charges for services which are not included in the prospective group payment rate and are separately allowable; and

**9.6.3** Physician's fees which are allowable in addition to the facility charges. See the TRM, [Chapter 9, Section 1](#).

**9.7** A claim submitted with both non-financially underwritten and financially underwritten charges shall be split.

**9.8** A non-institutional financially underwritten claim where Begin Date of Care (TRICARE Systems Manual (TSM) Data Element 2-150) crosses contract option periods shall be split. See the TSM [Chapter 2, Section 1.1, paragraph 6.0](#).

**9.9** A claim that contains both institutional and professional services may be split into separate claims for:

**9.9.1** Charges for services included in the Outpatient Prospective Payment System (OPPS); and

**9.9.2** Charges for professional services which are not included in the OPPS and are separately allowable.

**9.10** Claims which include services covered by NDAA for FY 2008, Section 1637, Transitional Care for Service-Related Conditions (TCSRC) shall be processed in accordance with [Chapter 17, Section 3, paragraph 2.5.5](#).

**9.11** Outpatient claims with dates of service that cross October 1, 2014, the date for ICD-10-CM coding implementation, must be split to accommodate the new coding regulations. A separate claim shall be submitted for services provided on or before September 30, 2014, and be coded in accordance with the ICD-9-CM, as appropriate. Claims for services provided on or after October 1, 2014, shall be submitted and coded with the ICD-10-CM as appropriate.

## **10.0 PROVIDER NUMBERS**

**10.1** Claims received from covered entities with the provider's National Provider Identifier (NPI) (individual and organizational) shall be processed using the NPI. Electronic claim transactions received from covered entities without the requisite NPIs in accordance with Implementation Guide for the ASC X12N 837 transaction shall be denied. See [Chapter 20](#) for further information.

**10.2** Claims received (electronic, paper, or other acceptable medium) with provider's Medicare Provider Number (institutional and non-institutional) shall not be returned to the provider to obtain the TRICARE Provider Number. The contractor shall accept the claim for processing, develop the provider number internally, and report the TRICARE Provider Number as required by the TSM, [Chapter 2](#), on the TED records.

## **11.0 TRANSGENDERED BENEFICIARIES**

If a beneficiary or provider notifies the contractor of the beneficiary's transgendered status (either prospectively or through an appeal), the contractor shall flag that patient's file and defer claims for medical review when there is a discrepancy between the patient's gender and the procedure, diagnosis\*, ICD-9-CM surgical procedure code (for procedures on or before September 30, 2014), or ICD-10-PCS surgical procedure code (for procedures on or after October 1, 2014). For care that the review determines to be medically necessary and appropriate, the contractor shall override any edit identifying a discrepancy between the procedure and the patient's gender. TED record data for transgendered claims must reflect the Person Sex as downloaded from DEERS (TSM, [Chapter 2, Section 2.7](#)) and the appropriate override code.

**Note:** \*The edition of the International Classification of Diseases, Clinical Modification reference to be used is determined by the date of service for outpatient services or date of discharge for inpatient services. Diagnoses coding for dates of service or dates of discharge prior to ICD-10 implementation should be consistent with the ICD-9-CM. Diagnoses coding for dates of service or dates of discharge on or after October 1, 2014, should be consistent with ICD-10-CM.

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## Overpayments Recovery - Non-Financially Underwritten Funds

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This section applies to funds for which the contractor is non-financially underwritten, with the exception of funds overpaid to Veterans Administration (VA) facilities (see paragraph 33.0). For recovery of overpayments involving funds for which the contractor is financially underwritten, see Section 3.

### 1.0 CAUSES OF OVERPAYMENTS

The occurrence of any of the following circumstances may result in an erroneous payment and a requirement for recoupment action. (This list is not intended to be all-inclusive).

- Erroneous calculation of the allowable charge
- Erroneous coding of a procedure
- Erroneous calculation of the cost-share or deductible
- Duplicate payment
- Incorrect payee
- Payment by other insurance
- Erroneous billing
- Patient not eligible
- Unauthorized provider
- Noncovered service or supply
- Service not actually received
- Services not medically necessary

### 2.0 DETERMINATION OF LIABILITY FOR OVERPAYMENT

The general rule for determining liability for overpayments is that the person or provider who received the erroneous payment is responsible for the refund.

### 3.0 PROVIDER LIABLE

Overpayment refunds shall be sought from the provider who received the incorrect payment in the following situations:

- 3.1** The provider furnished erroneous information or failed to disclose facts that the provider knew or should have known were relevant to payment of the benefit. (Refer to [Chapter 13](#).)
- 3.2** The payment was based on an amount in excess of that allowable.
- 3.3** The provider received and retained duplicate TRICARE payments.

- 3.4** The provider turned a duplicate TRICARE payment over to the beneficiary.
  
- 3.5** The overpayment was due to a mathematical or clerical error; e.g., an error in calculation of overlapping or duplicate bills. Mathematical error does not include a failure to properly assess the deductible. Where a provider has been incorrectly paid a deductible, the provider shall be deemed to be without fault and any required recovery shall be sought from the beneficiary.
  
- 3.6** The overpayment was for noncovered services, supplies, or pharmaceutical agents.
  
- 3.7** The services, supplies, or pharmaceutical agents were not received by the beneficiary, or there is no documentation to substantiate that the provider performed the services or provided the pharmaceutical agents claimed. (See [Chapter 13](#), if fraud is suspected.)
  
- 3.8** The services, supplies, or pharmaceutical agents were furnished by an unauthorized provider.
  
- 3.9** The TRICARE payment was made to the participating provider and a primary health insurance or pharmacy plan also made a payment to the provider or beneficiary for the same services or supplies, and the combined payments exceed the lower of the amount remaining after the double coverage plan has paid its benefits or the amount TRICARE would have paid as primary payor. See TRICARE Reimbursement Manual (TRM), [Chapter 4](#).
  
- 3.10** The payment was made to the wrong provider or a nonparticipating provider. In such cases, the contractor shall issue payment to the correct payee and concurrently initiate recoupment action against the erroneously paid provider. The contractor shall not postpone issuing payment to the correct provider pending completion of the recoupment.
  
- 3.11** The patient was not eligible at the time the services were provided.
  
- 3.12** The patient had OHI or pharmaceutical coverage primary to TRICARE.

**4.0 BENEFICIARY LIABLE**

Erroneous payment refunds shall be sought from the beneficiary in the following situations:

- 4.1** The overpayment was caused by incorrect application of the deductible or cost-share.
  
- 4.2** The patient was not an eligible beneficiary at the time services were provided and the payment was made to a participating provider for whom a good faith payment has been authorized under [paragraph 6.0](#). When payment was made to a retail network pharmacy based on erroneous eligibility data provided by the Government from Defense Enrollment Eligibility Reporting System (DEERS), the pharmacy may retain the payment as a good faith payment.
  
- 4.3** The beneficiary who received TRICARE payment had OHI or pharmacy coverage primary to TRICARE.
  
- 4.4** The TRICARE payment was made to the beneficiary instead of the participating provider. The contractor shall immediately issue payment to the participating provider and concurrently take recoupment action against the beneficiary.

**32.4** Interest will not be assessed upon previously accrued interest charges. When the debtor and the contractor enter into an installment repayment agreement, interest will be assessed for the period beginning on the date of the initial demand letter and ending on the due date of the first installment payment. The interest shall be assessed at the rate properly reflected in the initial demand letter on that portion of the debt which remained outstanding 30 days after the date of the initial demand letter. The interest so assessed will be collected and applied to the debtor's account before the due date of the first installment payment. Subsequently, interest shall be computed daily on the outstanding principal balance at the rate properly reflected in the initial demand letter, which shall also be reflected in any promissory note sent to the debtor as required by [paragraph 16.2.3](#).

**32.5** Interest collected under installment agreements shall be reported to TMA monthly with unidentified refunds and refunds \$10.00 or less. The rate of interest, as initially assessed, shall remain fixed for the duration of the indebtedness, except that where a debtor has defaulted on a repayment agreement and seeks to enter into a new agreement, a new interest rate may be set which reflects the current value of funds to the Treasury at the time the new agreement is executed.

**32.6** Delinquent installment accounts shall be handled in accordance with the procedures outlined in [paragraph 25.0](#).

### **33.0 OVERPAYMENTS TO VETERANS ADMINISTRATION (VA) FACILITIES**

Overpayments to VA facilities are not subject to the above procedures. When a contractor discovers an overpayment to a VA facility, the contractor must notify the VA facility and request repayment to the TRICARE program. The contractor shall not offset funds due to the VA under any circumstances. The VA may take up to 240 days to make the repayment. Nevertheless, the contractor should obtain an assurance from the VA that repayment is forthcoming. If the VA refuses to provide such a statement or payment is not made within 240 days, the contractor shall contact, by telephone, the Claims Collection Section, OGC, TMA. The contractor shall provide a monthly status report of all VA overpayment cases as described in the CDRL to the Claims Collection Section.

- END -



**2.5.5.8.1** Enrolled members determined to be eligible for pharmacy services based on their primary HCDP code will pay appropriate cost-shares as determined by their primary HCDP code and will submit a paper claim to the pharmacy contractor to seek reimbursement of these costs shares. Enrollment documentation that includes the specific condition for Section 1637 enrollment shall be submitted with their claim. The pharmacy contractor will verify eligibility in DEERS and determine coverage of the prescription based on the specific condition detailed in the supporting documentation.

**2.5.5.8.2** Enrolled members determined to not be eligible for pharmacy services based on their primary HCDP code will pay out-of-pocket for the total cost of the prescription and then submit a paper claim to the pharmacy contractor for reimbursement. The pharmacy contractor shall verify eligibility in DEERS and determine coverage of the prescription based on the specific condition detailed in the supporting documentation.

**2.5.5.8.3** In situations where the supporting document submitted by the member to the pharmacy contractor does not provide sufficient detail of their covered condition, the pharmacy contractor will contact MMSO to obtain appropriate documentation of their covered condition needed to make a coverage determination and process the claim.

## **2.5.6 Definitions**

### **2.5.6.1 Validated Date and Diagnosis**

The date a DoD physician (Military or Civil Service) validates the diagnosis of a service-related condition and validates that the condition can be resolved within 180 days.

### **2.5.6.2 MMSO**

The centralized government office which will be the overall government organization to provide government services to TAMP members that have a service-related condition.

## **2.6 Provisions Of Reproductive Services For The Benefit Of Seriously or Severely Ill Or Injured ADSMs Under The SHCPs**

Assisted reproductive services, including sperm retrieval, oocyte retrieval, In-Vitro Fertilization (IVF), artificial insemination, and blastocyst implantation, are available for seriously or severely ill/injured female and male service members (Category II and III). This is a benefit offered based on the condition of the seriously or severely ill/injured service member not the spouse; therefore, the use of the SHCP is authorized.

### **2.6.1 Policy Guidelines**

**2.6.1.1** The policy applies to service members, regardless of gender, who have sustained a serious or severe illness/injury while on active duty that led to the loss of their natural procreative ability. It is the intent of this policy to provide IVF services only to consenting male members whose illness or injury prevents the successful delivery of their sperm to their spouse's egg and to consenting female members whose illness or injury prevents their egg from being successfully fertilized by their spouse's sperm, but who maintain ovarian function and have a patent uterine

cavity. This includes, but is not limited to, those suffering neurological, physiological, and/or anatomical injuries.

**2.6.1.2** The policy provides for the provision of assisted reproductive technologies to assist in the reduction of the disabling effects of the member's qualifying condition. The authority for this policy for care outside of the basic medical benefit is derived from Section 1633 of the 2008 NDAA. This section allows the ADSM to receive services that are outside the definition of "medical care." This benefit is provided through the authorization of the expenditure of SHCP funds and delivery of the needed services in either MTFs that offer assisted reproductive technologies or in the purchased care sector that are outside the medical benefit. Although purchased care is available for this benefit depending on the service member's circumstances not allowing him or her to travel, the use of MTFs shall be encouraged, with members eligible for this benefit given priority for care at MTFs if there is a waiting list. If the member receives care or medications in the civilian sector, participating network providers must be used if available. Preauthorization for every IVF cycle is required.

**2.6.1.3** The benefit is limited to permitting a qualified member to procreate with their lawful spouse, as defined in federal statute and regulation.

**2.6.1.4** The benefit would apply equally to male and female seriously or severely ill/injured service members (Category II or III). Male members must be able to produce sperm, but need alternative sperm collection technologies as they can no longer ejaculate in a way that allows for egg fertilization. Ill/injured female members require ovarian function and a patent uterine cavity that would allow them to successfully carry a fetus even if unable to conceive naturally (e.g., through damage to their fallopian tubes).

**2.6.1.5** Third party donations and surrogacy are not covered benefits. The benefit is designed to allow the member and their dependent spouse to become biological parents through reproductive technologies where the ADSM's illness or injury has made it impossible to conceive naturally.

**2.6.1.6** Consent must be able to be given by the ADSM and his or her lawful spouse. Third party consent is not authorized under this policy.

**2.6.1.7** The DoD will cost-share the costs of cryopreservation and storage of embryos for up to three years. At the end of three years or when the member separates/retires (whichever comes first), couples are free to continue embryo storage at their own expense if desired. Issues regarding ownership, future embryo use, donation, and/or destruction etc. shall be governed by the applicable state law and shall be the responsibility of the ADSM and his/her lawful spouse and the facility storing the cryopreserved embryos. DoD's role is limited to paying for this benefit when requested by the consenting member. DoD will not have ownership or custody of cryopreserved embryos and will not be involved in the ultimate disposition of excess embryos. Ultimate disposition or destruction of excess embryos will not be cost-shared.

## **2.6.2 Procedures**

**2.6.2.1** Prediction of fertility potential (Ovarian Reserve) will be conducted in accordance with the provider clinic's practice guidelines. (This may include a Clomiphene Citrate Challenge Test (CCCT) and evaluation of the uterine cavity.) Beneficiaries with a likelihood of success, based on the specific clinic's guidelines, will be provided IVF cycles under this benefit. Infertility testing and

treatment, including correction of the physical cause of infertility, are covered in accordance with the TPM, [Chapter 4, Section 17.1](#).

**2.6.2.2** Three completed IVF cycles will be provided for the seriously or severely ill/injured female service member or lawful spouse of the seriously or severely ill/injured male service member. No more than six IVF cycles will be initiated for the seriously or severely ill/injured female service member or legal spouse of the seriously or severely ill/injured male service member. In other words, there may be a total of six attempts to accomplish three completed IVF cycles. If the ill/injured ADSM has used initiated IVF cycles, subsequently remarries and desires this benefit with the new spouse, the number of cycles available is dependent on prior cycles used.

**2.6.2.3** Assisted reproductive service centers with capability to provide full services including alternative methods of sperm aspiration will be invited to participate in the TRICARE network by the contractors. (Membership in the American Society for Reproductive Medicine (ASRM), with associated certification(s), is highly recommended for network providers. Reporting outcomes to the Centers for Disease Control and Prevention (CDC) is mandatory.) When a network provider is not available, the benefits provided under this policy may be provided by any TRICARE-authorized provider, including those authorized pursuant to [32 CFR 199.6\(e\)](#).

**2.6.2.4** IVF cycles shall be accomplished in accordance with the practice guideline for the provider clinic using gonadotropins which are concentrated mixtures of Follicle Stimulating Hormone (FSH) or FSH and Luteinizing Hormone (LH) given as an injection to stimulate the ovary to produce multiple oocytes in preparation for egg retrieval. These medications will be purchased through the TPharm contract, TRICARE Pharmacy Home Delivery Program, or non-network pharmacy, or MTF.

**2.6.2.5** Anesthesia or conscious sedation will be provided for the oocyte retrieval and sperm aspiration in accordance with the TPM, [Chapter 3, Section 1.1](#) and [1.2](#). For males, sperm aspiration through Microsurgical Epididymal Sperm Aspiration (MESA), Percutaneous Epididymal Sperm Aspiration (PESA), or non-surgical fine needle aspiration will be accomplished in conjunction with egg retrieval. Vibratory stimulation or electro-ejaculation may be used if appropriate for the seriously or severely ill/injured service member.

**2.6.2.6** Intracytoplasmic sperm injection will be accomplished for all viable oocytes.

**2.6.2.7** Embryo transfer in accordance with guidelines provided by the ASRM shall be accomplished in accordance with specific clinic practices at either cleavage stage or blastocyst stage of the embryo.

**2.6.2.8** Healthy embryos that progress to an appropriate stage, as assessed by the embryologist, in excess of those used for the fresh embryo transfer may be cryopreserved. Storage of cryopreserved embryos for up to three years will be a covered benefit so long as the member remains eligible for this benefit. Ownership of cryopreserved embryos will be the responsibility of the ADSM and their spouse and documented in accordance with clinic policies.

**2.6.2.9** In the event that frozen embryos are available for transfer, TRICARE will authorize frozen embryo transfer cycles to facilitate the utilization of these embryos. Frozen embryo transfers may be accomplished in fresh ovulatory cycles or in medicated transfer cycles in order to provide the optimal uterine environment for embryo implantation.

### **2.6.3 Process for Participating in Assisted Reproductive Services Program**

**2.6.3.1** For an ADSM to be eligible, there must be documentation of Category II or III illness or injury designation as defined in Department of Defense Instruction (DoDI) 1300.24.

**2.6.3.2** A memorandum must come from the ADSM's PCM or other provider significantly involved in the care of the qualifying condition(s). Certification of the illness or injury category shall be made by the provider and endorsed by the member's service. The memorandum shall include the following:

- ADSM's qualifying diagnosis(es).
- Category (II or III).
- Summary of relevant medical information supporting category designation.
- Name of provider of reproductive services requested to be used.
- Number of initiated IVF cycles.
- Number of cancelled IVF cycles.

**2.6.3.3** The memorandum is sent to the member's service for endorsement, and then sent electronically to TMA, Office of the Chief Medical Officer (OCMO) where verification of the member's eligibility for this benefit will be completed. Please send e-mails to: TMASHCPWaiverRequests@tma.osd.mil.

**2.6.3.4** This authorization (verification of benefits) shall be forwarded to the appropriate MTF or MMSO as well as the TRICARE Regional Office (TRO), TAO, and TOP Office (TOPO). Preauthorization for care by the MTF or MMSO will be requested from the appropriate contractor. This preauthorization will allow the use of SHCP funds for this treatment. All bills for the ADSM and spouse should be coded as SHCP bills.

**2.6.3.5** In order to verify eligibility, number of attempts (and completed attempts), and all other requirements, all IVF cycles must be preauthorized. OCMO will verify the eligibility of each member for each cycle with a memo. This memo will go through the relevant service back to the MTF or MMSO will request a preauthorization for each cycle.

**2.6.3.6** All TED records for this benefit shall include Enrollment/Health Plan Code "SR SHCP - Referred Care" regardless of the enrollment status returned by DEERS. The contractor shall follow all applicable TED coding requirements in accordance with TRICARE System Manual (TSM), [Chapter 2](#).

**2.6.3.7** All SHCP requirements and provisions of [Chapter 16](#) and [17](#) apply to this benefit unless changed or modified by this paragraph. The appropriate chapter for the status of the ADSM shall apply. Contractors shall follow the requirements and provisions of these chapters, to include MTF or MMSO referrals and authorizations, receipt and control of claims, authorization verification, reimbursement and payment mechanisms to providers, reimbursement specifying no cost-share, copay, or deductible to be paid by the ADSM or their lawful spouse, and use of CMACs/DRGs when applicable.

### **2.6.4 Exclusions**

**2.6.4.1** Third party donations or surrogacy cannot be cost-shared.

**2.6.4.2** Cryopreservation of gametes in anticipation of deployment.

**2.6.4.3** Services related to gender selection will NOT be cost-shared.

### **3.0 ENROLLMENT STATUS EFFECT ON CLAIMS PROCESSING**

**3.1** Active duty claims shall be processed without application of a cost-share, copayment, or deductible. These are SHCP claims.

**3.2** Claims for TRICARE Prime enrollees who are in MTF inpatient status shall be processed without application of a cost-share, copayment, or deductible. These are SHCP claims.

**3.3** Claims for services provided under the current MOU between the DoD (including Army, Air Force, and Navy/Marine Corps facilities) and the DHHS (including the Indian Health Service, Public Health Service, etc.) are not SHCP claims. They should be adjudicated under the claims processing provisions applicable to those specific agreements.

**3.4** Claims for services provided under any local MOU between the DoD (including the Army, Air Force, and Navy/Marine Corps facilities) and the DVA are not SHCP claims. They should be adjudicated under the claims processing provisions applicable to those specific agreements. (Claims for services provided under the current national MOA for Spinal Cord Injury (SCI), Traumatic Brain Injury (TBI), and Blind Rehabilitation are covered, see [Section 2, paragraph 3.1.](#))

**3.5** Claims for participants in the Comprehensive Clinical Evaluation Program (CCEP) shall be processed for payment solely on the basis of MTF authorization. There will not be a cost-share, copayment, or deductible applied to these claims. These are SHCP claims.

**3.6** Claims for non-TRICARE eligibles shall be processed for payment solely on the basis of MTF or SPOC authorization. There will not be a cost-share, copayment, or deductible applied to these claims. These are SHCP claims.

**3.7** Outpatient claims for non-TRICARE Medicare eligibles will be returned to the submitting party for filing with the Medicare claims processor. These are not SHCP or TRICARE claims.

**3.8** Claims for TDRL participants shall be processed for payment in accordance with DoD/HA Policy Letter dated March 30, 2009, Subject: Policy Guidance for Use of Supplemental Health Care Program Funds to Pay for Required Physical Examinations for Members on the Temporary Disability Retirement List. There will not be a cost-share, copayment, or deductible applied to these claims. These are SHCP claims. SHCP funds will only be applied to the exam. SHCP funds shall not be used to treat the condition which caused member to be placed on the TDRL or for conditions discovered during the exam.

**3.9** Claims from members enrolled in the FRCP shall be processed without application of a cost-share, copayment, or deductible. These are SHCP claims.

### **4.0 MEDICAL RECORDS**

The current contract requirements for medical records shall also apply to ADSMs in this program, with the additional requirement that ADSMs must also be given copies directly. Narrative

summaries and other documentation of care rendered (including laboratory reports and X-rays) shall be given to the ADSM for delivery to his/her Primary Care Manager (PCM) and inclusion in his/her military health record. The contractor shall be responsible for all administrative/copying costs. Under no circumstances will the ADSM be charged for this documentation. Network providers shall be reimbursed for medical records photocopying and postage costs incurred at the rates established in their network provider participation agreements. Participating and non-participating providers shall be reimbursed for medical records photocopying and postage costs on the basis of billed charges. ADSMs who have paid for copied records and applicable postage costs shall be reimbursed for the full amount paid to ensure they have no out-of-pocket expenses. All providers and/or patients must submit a claim form, with the charges clearly identified, to the contractor for reimbursement. ADSM's claim forms should be accompanied by a receipt showing the amount paid.

## **5.0 REIMBURSEMENT**

**5.1** Allowable amounts are to be determined based upon the TRICARE payment reimbursement methodology applicable to the services reflected on the claim, (e.g., DRGs, mental health per diem, CMAC, Outpatient Prospective Payment System (OPPS), or TRICARE network provider discount). Reimbursement for services not ordinarily covered by TRICARE and/or rendered by a provider who cannot be a TRICARE authorized provider shall be at billed amounts. Cost-sharing and deductibles shall not be applied to supplemental health care claims.

**5.2** Claims with codes on the TRICARE inpatient only list performed in an outpatient setting will be denied, except in those situations where the beneficiary dies in an emergency room prior to admission. Reference the TRM, [Chapter 13, Section 2, paragraph 3.4](#). Professional providers may submit with modifier CA. No bypass authority is authorized for inpatient only procedure editing. Bypass authority is authorized for codes contained on the No Government Pay List (NGPL) when the service is authorized by the MTF.

**5.3** Pending development and implementation of recently enacted legislative authority to waive CMACs under TRICARE, the following interim procedures shall be followed when necessary to assure adequate availability of health care to ADSMs under SHCP. If required services are not available from a network or participating provider within the medically appropriate time frame, the contractor shall arrange for care with a non-participating provider subject to the normal reimbursement rules. The contractor initially shall make every effort to obtain the provider's agreement to accept, as payment in full, a rate within the 100% of CMAC limitation. If this is not feasible, the contractor shall make every effort to obtain the provider's agreement to accept, as payment in full, a rate between 100% and 115% of CMAC. If the latter is not feasible, the contractor shall determine the lowest acceptable rate that the provider will accept and communicate the same to the referring MTF. A waiver of CMAC limitation must be obtained by the MTF from the Regional Director (RD), as the designee of the Chief Operating Officer (COO), TMA, before patient referral is made to ensure that the patient does not bear any out-of-pocket expense. Upon approval of a CMAC waiver by the RD, the MTF will notify the contractor who shall then conclude rate negotiations, and notify the MTF when an agreement with the provider has been reached. The contractor shall ensure that the approved payment is annotated in the authorization/claims processing system, and that payment is issued directly to the provider, unless there is information presented that the ADSM has personally paid the provider. In the case of non-MTF referred care, the contractor shall submit the waiver request to the RD.

**5.4** Eligible uniformed service members and/or referred patients who have been required by the provider to make “up front” payment at the time services are rendered will be required to submit a claim to the contractor with an explanation and proof of such payment. For eligible uniformed service members, if the claim is payable without SPOC review the contractor shall allow the billed amount and reimburse the ADSM for charges on the claim. If the claim requires SPOC review the contractor shall pend the claim to the SPOC for determination. If the SPOC authorizes the care the contractor shall allow the billed amount and reimburse the ADSM for charges on the claim.

- Supplemental health care claims for uniformed service members and all MTF inpatients receiving referred civilian care while remaining in an MTF inpatient status shall be promptly reimbursed and the patient shall not be required to bear any out-of-pocket expense. If such payment exceeds normally allowable amounts, the contractor shall allow the billed amount and reimburse the patient for charges on the claim. As a goal, no such claim should remain unpaid after 30 calendar days.

**5.5** In no case shall a uniformed service member be subjected to “balance billing” or ongoing collection action by a civilian provider for referred, emergency or authorized care. If the contractor becomes aware of such situations that they cannot resolve they shall pend the file and forward the issue to the referring MTF or SPOC, as appropriate, for determination. The referring MTF or SPOC will issue an authorization to the contractor for payments in excess of CMAC or other applicable TRICARE payment ceilings, provided the referring MTF or SPOC has requested and has been granted a waiver from the COO, TMA, or designee.

## **6.0 END OF PROCESSING**

### **6.1 EOB**

An EOB shall be prepared for each supplemental health care claim processed, and copies sent to the provider and the patient in accordance with normal claims processing procedures. For all SHCP claims, the EOB will include the statement that this is a supplemental health care claim, not a TRICARE claim. The EOB will also indicate that questions concerning the processing of the claim must be addressed to the TRICARE Service Center (TSC) or SPOC, as appropriate. Any standard TRICARE EOB messages which are applicable to the claim are also to be utilized, e.g., “No authorization on file.”

### **6.2 Appeal Rights**

**6.2.1** For supplemental health care claims, the appeals process in [Chapter 12](#), applies, as limited herein. If the care is still denied after completion of a review to verify that no miscoding or other clerical error took place and the MTF/SPOC will not authorize the care in question, then the notification of the denial shall include the following statement: “If you disagree with this decision, please contact (**insert MTF name/SPOC here**).” TRICARE appeal rights shall pertain to outpatient claims for treatment of TRICARE eligible patients. The SPOC will handle only those issues that involve SPOC denials of authorization or authorization for reimbursement. The contractor shall handle allowable charge issues, grievances, etc.

**6.2.2** An ADSM will appeal SPOC denials of authorization or authorization for reimbursement through the SPOC—not through the contractor. If the ADSM disagrees with a denial, the first level of appeal will be through the SPOC who will coordinate the appeal with the appropriate RD. The

ADSM may initiate the appeal by contacting his/her SPOC. If the SPOC upholds the denial, the SPOC will notify the ADSM of further appeal rights with the appropriate Surgeon General's office. If the denial is overturned at any level, the SPOC will notify the contractor and the ADSM.

**6.2.3** The contractor shall forward all written inquiries and correspondence related to SPOC or MTF denials of authorization or authorization for reimbursement to the appropriate SPOC or MTF. The contractor shall refer telephonic inquiries related to SPOC denials to the appropriate SPOC or MTF.

## **7.0 TRICARE ENCOUNTER DATA (TED) SUBMITTAL**

The TED for each claim must reflect the appropriate data element values. The appropriate codes published in the TSM are to be used for supplemental health care claims.

## **8.0 CONTRACTOR'S RESPONSIBILITY TO RESPOND TO INQUIRIES**

### **8.1 Telephonic Inquiries**

Inquiries relating to the SHCP need not be tracked nor reported separately from other inquiries received by the contractor. Most SHCP inquiries to the contractor should come from MTFs/claims offices, the Service Project Officers, TMA, or the SPOC. In some instances, inquiries may also come from Congressional offices, patients, or providers. To facilitate responsiveness to SHCP inquiries, the contractor shall provide MTFs/claims offices, the Service Project Officers, TMA, and the SPOC a specific telephone number, different from the public toll-free number, for inquiries related to the SHCP Claims Program. The line shall be operational and continuously staffed according to the hours and schedule specified in the contractor's TRICARE contract for toll-free and other service phone lines. It may be the same line as required in support of TPR under [Chapter 16](#). The telephone response standards of [Chapter 1, Section 3](#), shall apply to SHCP telephonic inquiries.

#### **8.1.1 Congressional Telephonic Inquiries**

The contractor shall refer any congressional telephonic inquiries to the referring MTF or the SPOC, as appropriate, if the inquiry is related to the authorization or non-authorization of a specific claim or episode of treatment. If it is a general congressional inquiry regarding the SHCP claims program, the contractor shall respond or refer the caller as appropriate.

#### **8.1.2 Provider And Other Telephonic Inquiries**

The contractor shall refer any other telephonic inquiries it receives, including calls from the provider, service member or the MTF patient, to the referring MTF or the SPOC, as appropriate, if the inquiry pertains to the authorization or non-authorization of a specific claim. The contractor shall respond as appropriate to general inquiries regarding the SHCP.

### **8.2 Written Inquiries**

#### **8.2.1 Congressional Written Inquiries**

For MTF-referred care, the contractor shall refer written congressional inquiries to the Service Project Officer of the referring MTF's branch of service if the inquiry is related to the

authorization or non-authorization of a specific claim. For non-MTF referred care, the inquiry shall be referred to the SPOC. When referring the inquiry, the contractor shall attach a copy of all supporting documentation related to the inquiry. If it is a general congressional inquiry regarding the SHCP, the contractor shall refer the inquiry to the TMA. The contractor shall refer all congressional written inquiries within 72 hours of identifying the inquiry as relating to the SHCP. When referring the inquiry, the contractor shall also send a letter to the congressional office informing them of the action taken and providing them with the name, address and telephone number of the individual or entity to which the congressional correspondence was transferred.

### **8.2.2 Provider And Service Member (Or MTF Patient) Written Inquiries**

The contractor shall refer provider and service member or MTF patient written inquiries to the referring MTF or the SPOC, as appropriate, if the inquiry pertains to the authorization or non-authorization of a specific claim. The contractor shall respond as appropriate to general written inquiries regarding the SHCP.

### **8.2.3 MTF Written Inquiries**

The contractor shall provide a final written response to all written inquiries from the MTF within 10 work days of the receipt of the inquiry, or if appropriate, refer the inquiry to the SPOC upon receipt of the inquiry.

## **9.0 SHCP AGING CLAIMS REPORT**

The Government intends to take action on all referrals to the SPOC as quickly as possible. To support this objective, the SPOC must be kept apprised of those claims on which the contractor cannot take further action until the SPOC has completed its reviews and approvals.

- END -



## Chapter 18

### Demonstrations

Section/Addendum Subject/Addendum Title

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8	Department Of Defense (DoD) Enhanced Access To Autism Services Demonstration
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## **EXPIRED** - Department Of Defense (DoD) Cancer Prevention And Treatment Clinical Trials Demonstration

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### **1.0 PURPOSE**

The purpose of this demonstration is to improve TRICARE-eligible family member access to promising new cancer therapies, assist in meeting the National Cancer Institute's (NCI) clinical trial goals, and to assist in the formulation of conclusions regarding the safety and efficacy of emerging therapies in the prevention and treatment of cancer. The Department of Defense's (DoD's) financing of these sponsored studies will include Phase II and Phase III protocols approved under the NCI for all types of cancer.

### **2.0 BACKGROUND**

**2.1** On November 16, 1998 (Vol 63, No. 220) the **Federal Register** announced the one year extension of a demonstration project in which the DoD provides TRICARE reimbursement for eligible beneficiaries who receive cancer treatment under approved NCI clinical trials. A **Federal Register** Notice was published on January 5, 2000, extending the DoD Cancer Prevention and Treatment Clinical Trials Demonstration until such time the Interagency Agreement between DoD and the NCI is terminated. Extending the demonstration will allow for an evaluation of costs associated with this demonstration project.

**2.2** The NCI sponsors and actively coordinates an extensive clinical trials program for the evaluation of prevention, early detection, treatment, and supportive care for various types of cancer. The NCI's program includes sponsorship of studies in single institutions, as well as large, multi-center, randomized trials in cooperative networks. The trials encompass studies of cancers occurring in virtually all anatomical sites and in all stages of development. The NCI clinical trials program has been the means by which the oncology community has developed most of the formal clinical evidence for the efficacy of the various prevention, early detection, and management approaches in treating cancer.

**2.3** In support of NCI's efforts to further the science of cancer treatment, the DoD expanded its breast cancer demonstration to include all NCI-sponsored Phase II and Phase III clinical trials. This expanded demonstration will enhance current NCI efforts to determine safety and efficacy of promising cancer therapies by expanding the patient population available for entry into clinical trials and stabilizing the referral base for these clinical activities.

**2.4** On June 21, 1999, the Assistant Secretary of Defense (Health Affairs) (ASD(HA)) expanded the successful partnership with the NCI by allowing TRICARE eligible family members to participate in NCI sponsored clinical trials in cancer prevention in addition to cancer treatment. Cancer prevention clinical trials include screening and early detection clinical trials. This expansion of the current demonstration will enhance continued NCI efforts to determine safety and efficacy of

promising cancer prevention strategies by expanding the patient population available for entry into clinical trials and stabilizing the referral base for these clinical activities.

**2.5** While this demonstration provides an exception to current TRICARE benefit limitations, the DoD hypothesizes that this increased access to innovative cancer strategies will occur at a cost comparable to that which the DoD has experienced in paying for conventional care under the TRICARE Standard program. The results of the demonstration will provide a framework for determining the scope of DoD's continued participation in the NCI's clinical research efforts.

### **3.0 POLICY**

**Note:** Effective June 21, 1999, the DoD expanded the demonstration to include NCI sponsored cancer prevention, screening and early detection clinical trials.

**3.1** Effective January 1, 1996, the cancer demonstration was authorized for those TRICARE-eligible patients selected to participate in NCI sponsored Phase II and Phase III studies for treatment of cancer. NCI sponsorship of clinical trials occurs through the Cancer Therapy Evaluation Program (CTEP), Cooperative Group Studies, NCI Grants or Cancer Center Studies. Evidence of NCI sponsorship in one of these categories will be that it is identified in the NCI comprehensive database, Physicians's Data Query (PDQ), or NCI supplements to that database; formal notification of approval from The Clinical Protocol Review and Monitoring Committee; or verification from the NCI project officer; or through protocols co-sponsored by the NCI and other federal agencies.

**3.2** The DoD will cost-share all medical care and testing required to determine eligibility for an NCI-sponsored trial, including the evaluation for eligibility at the institution conducting the NCI-sponsored study. DoD will cost-share all medical care required as a result of participation in NCI sponsored studies. This includes purchasing and administering all approved chemotherapy agents (except for NCI-funded investigational drugs), all inpatient and outpatient care, including diagnostic and laboratory services not otherwise reimbursed under an NCI grant program if the following conditions are met:

- The provider seeking treatment for a TRICARE-eligible family member in an NCI approved protocol has obtained preauthorization for the proposed treatment before initial evaluation; and
- Such treatments are NCI sponsored Phase II or Phase III protocols; and
- The patient continues to meet entry criteria for said protocol; and
- The institutional and individual providers are TRICARE-authorized providers.

**3.3** The DoD will not provide reimbursement for care rendered in the National Institutes of Health Clinical Center or costs associated with non-treatment research activities associated with the clinical trials. Costs associated with non-treatment research activities may include administrative costs, such as, record keeping costs, publication costs, etc.

**3.4** Cost-shares and deductibles applicable to TRICARE also apply under this Demonstration. For TRICARE Prime enrollees, including those enrolled in Uniformed Services Family Health Plan (USFHP), applicable copays apply.

**Note:** Those patients enrolled in the previous breast cancer demonstration prior to January 1, 1996 (the effective date of the expanded cancer demonstration), will continue to have cost-shares and deductibles waived through the completion of their protocol. Waiver of the cost-shares and deductibles apply regardless of whether they were randomized to the experimental or conventional arm of the protocol.

**3.5** Retroactive authorizations can be authorized in accordance with the provisions outlined in [32 CFR 199.4\(g\)\(19\)](#). A retroactive authorization for coverage of a cancer clinical trial can be issued to those beneficiaries who began participation in such trial before termination of the cancer demonstration. such retroactive authorization for coverage under the cancer demonstration rules can be issued even after termination of the Demonstration.

**3.6** The demonstration will expire on March 31, 2008. Requirements of this chapter as related to cancer demonstration cease at 12:00 midnight on March 31, 2008, except for claims for demonstration enrollees whose treatment is in progress when the Demonstration expires. The Demonstration retains responsibility for these claims until the beneficiary is discharged from the cancer clinical trial. For cancer clinical trials benefit, see TRICARE Policy Manual (TPM), [Chapter 7, Section 24.1](#).

**3.7** The records management requirements described in [Chapter 2](#) apply to cancer demonstration records.

#### **4.0 APPLICABILITY**

**4.1** The Demonstration applies to all TRICARE-eligible beneficiaries. Active duty members continue to be eligible for Direct Care (DC) system services. The demonstration does not apply to Continued Health Care Benefit Program (CHCBP) enrollees.

**4.2** Since demonstration benefits are not the same as TRICARE benefits, all inquiries and claims related to the Demonstration, including claims for conventional therapy under Phase III protocols shall be submitted to the appropriate contractor, referencing the DoD Cancer Prevention and Treatment Clinical Trials Demonstration.

**4.3** Since the DoD has no authority regarding the NCI protocol eligibility for the sponsored study, if a patient does not meet the criteria for enrollment, appeal rights do not apply.

#### **5.0 GENERAL DESCRIPTION OF ADMINISTRATIVE PROCESS**

**5.1** The attending oncologist or physician shall determine the eligible patient's needs and consult with the contractor/NCI to determine which, if any, Phase II or Phase III, NCI-sponsored studies are appropriate for the patient.

**5.2** Following the identification of an appropriate sponsored study within the terms of the Demonstration, the attending oncologist or physician shall apply for Demonstration benefits to the case manager's office specially designated at the contractor.

**5.3** Following a validation of the eligibilities of the patient and the sponsored study under the terms of the Demonstration, the contractor shall issue a written decision to both the patient and the applicant provider.

**5.4** All claims for approved care under the Demonstration shall be submitted to the contractor for adjudication.

## **6.0 TRICARE MANAGEMENT ACTIVITY (TMA) AND CONTRACTOR RESPONSIBILITIES**

**6.1** TMA will provide:

**6.1.1** Demonstrations will be non-financially underwritten transactions and follow vouchering rules set forth in the contract.

**6.1.2** Case management and claims adjudication functions via specific contractual arrangement(s) with one or more Demonstration claims processors.

**6.1.3** Periodic review and evaluation of the Demonstration claims adjudication process.

**6.1.4** Specific written guidance to the Demonstration claims processor(s) regarding case management services and claims adjudication services to be provided by the claims processor under the terms of the Demonstration.

**6.1.5** Public affairs functions to properly inform and periodically update the patient and provider communities regarding the terms of the Demonstration.

**6.2** The contractor shall:

**6.2.1** Provide a registered nurse to serve as case manager for inquiries and actions pertinent to the Demonstration.

**6.2.2** Ensure the provider has submitted a letter on the facility's letterhead certifying:

**6.2.2.1** The protocol is an NCI sponsored study; and

**6.2.2.2** The index patient meets all entry criteria for said protocol; and

**6.2.2.3** Notification will be provided to the contractor's Demonstration case manager of the patient's registration date when treatment actually begins; and

**6.2.2.4** Notification will be provided to the contractor's Demonstration case manager if the patient becomes ineligible for the study prior to treatment.

**6.2.3** Verify the letter from the facility includes the patient's name, sponsor's Social Security Number (SSN), the title and phase of the protocol, and the NCI number of the protocol and/or other appropriate evidence of NCI sponsorship.

**6.2.4** Subscribe to the NCI's Comprehensive Cancer Database known as the PDQ, to assist in determining whether a particular study meets the requirements of the Demonstration and whether the patient is eligible for a particular protocol. For those studies that are not listed on the PDQ, the contractor will work with NCI staff to verify NCI sponsorship.

**6.2.4.1** Unlike the other NCI sponsorship categories listed in [paragraph 3.1](#), protocols for Cancer Center Studies are not individually reviewed by the NCI. Instead, the NCI designates specific institutions as meeting NCI criteria for clinical and comprehensive cancer centers. Cancer center protocols receive approval through an NCI approved institutional peer review and quality control system at the institution. Protocols which have been through this process receive formal notification of approval from The Clinical Protocol Review and Monitoring Committee and, therefore, are considered NCI sponsored, but may not appear in the PDQ. A provider who is seeking to enter a patient into a Cancer Center Study must provide evidence of NCI sponsorship by forwarding the formal notification of approval from this specific committee. Formal notification of approval by the Clinical Protocol Review and Monitoring Committee will be required for approval of treatment in Cancer Center Studies which are not otherwise sponsored through the CTEP program, NCI cooperative groups, or NCI grants.

**6.2.4.2** Certain protocols listed in the PDQ may not be clearly identified in terms of NCI sponsorship. Clinical trials conducted as part of an NCI grant, or those identified with a "V" number, must be verified for NCI sponsorship with the NCI project officer. Physicians who are holders of the grant at the institution must provide written clarification that the proposed treatment is a protocol under their NCI grant. The grant title and number must be specified.

**6.2.4.3** Requests for treatment in clinical trials overseas must be verified as to NCI sponsorship with the NCI project officer.

**6.2.4.4** Protocols that are co-sponsored by the NCI and other Federal Agencies must be verified by the NCI project officer.

**6.2.5** Verify the patient's eligibility on the Defense Enrollment Eligibility Reporting System (DEERS).

**6.2.5.1** If the patient is authorized to receive the care under the Demonstration, but DEERS reflects that the patient is not eligible, a statement shall be added to the authorization letter indicating before benefits can be paid, the patient must be listed as eligible on DEERS.

**6.2.5.2** The patient shall be referred to the pass/ID card section of the military installation nearest their home for an eligibility determination.

**6.2.5.3** If a patient is listed on DEERS as being eligible as of the date the cancer therapy begins, all services provided as a result of participation in an NCI sponsored study shall be covered. This also applies to patients whose treatment is in progress when the Demonstration expires.

**6.2.6** Issue an authorization (Figure 18.2-2) or denial (Figure 18.2-3) letter to the applicant provider and patient once a determination is made regarding a particular protocol.

**6.2.7** Establish and maintain a database of patients participating in the Demonstration. The database shall include the patient's name, sponsor's SSN, name and number of protocol, type of cancer, hospital name, and address and total cost.

**6.2.8** Furnish a list of enrollees in the Demonstration to the contractor's Program Integrity Unit with instructions to run an annual post-payment report to determine if hospitals are receiving additional unlawful payments as a result of also receiving payment under TRICARE. If such payment exists, it shall be the responsibility of the contractor to initiate recoupment action for any Demonstration benefits paid in error. This function will be supervised by the TMA Program Integrity Office (PI).

**6.3** The contractor may at its discretion establish a dedicated toll-free telephone number to receive inquiries from both patients and providers regarding the Demonstration. If a dedicated toll-free telephone number is established for this demonstration, the phone shall be staffed seven hours a day during normal business hours. In the absence of a dedicated toll-free number for Demonstration inquiries, contractors shall use their primary toll-free telephone inquiry system (see Chapter 11, Section 7 and Chapter 20, Section 4).

**6.4** The contractor may at its discretion establish a dedicated mailing address where Demonstration inquiries and claims shall be sent for expedited response and/or claims adjudication. In the absence of a dedicated mailing address for Demonstration inquiries and claims, contractors shall use their primary address(es) for written correspondence and claims (see Chapter 11, Sections 5, 6, and Chapter 20, Section 4).

## **7.0 CLAIMS PROCESSING REQUIREMENTS**

**7.1** Verify TRICARE-eligibility on the DEERS prior to payment.

**7.2** Both institutional and professional charges shall be reimbursed based on billed charges.

**7.2.1** The cancer center shall submit all charges on the basis of fully itemized bills. Each service and supply shall be individually identified and submitted on the appropriate claim forms.

**7.2.2** All claims for medical care required as a result of participation in an NCI sponsored study for cancer prevention or treatment that is not a TRICARE benefit, shall be processed and paid under the demonstration.

**7.3** Cost-shares and deductibles applicable to TRICARE will also apply under the Demonstration. For TRICARE Prime enrollees, including those enrolled in USFHP, applicable copays will apply.

**7.3.1** The contractor shall query the DEERS Catastrophic Cap and Deductible Data (CCDD) to determine the status of deductible and catastrophic cap met amounts for TRICARE-eligible beneficiaries at the time the costs are listed on the voucher for processing and payment.

**TRICARE Operations Manual 6010.56-M, February 1, 2008**

Chapter 18, Section 2

**EXPIRED** - Department Of Defense (DoD) Cancer Prevention And Treatment Clinical Trials  
Demonstration

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**7.3.2** The contractor shall determine what expenses to apply to the deductible and catastrophic cap and reports these to the CCDD. These expenses shall be reported at the same time the costs are listed on the voucher for processing, prior to payment of the claim.

**7.3.3** The contractor shall use query type 80. Type 80 (nonclaim update) is used to request crediting of amounts since this is a manual process.

**7.4** Double coverage provisions apply. Acceptable evidence of processing by the double coverage plan is outlined in TRICARE Reimbursement Manual (TRM), [Chapter 4](#). In double coverage situations, the Demonstration shall pay the balance after the other health insurance has paid.

**7.5** Claims for this demonstration will be paid from the applicable non-underwritten bank accounts (see [Chapter 3](#)), and submitted through normal TRICARE Encounter Data (TED) processing as required in the TRICARE Systems Manual (TSM) with the applicable coding for clinical trials demonstration with enrollment effective before April 1, 2008.

**7.6** Claims for this demonstration may be submitted either by Electronic Media Claim (EMC), through the dedicated demonstration mailing address, or through the appropriate regional claims processing address(es).

**FIGURE 18.2-1 SAMPLE OF AUTHORIZATION LETTER TO BE ISSUED TO INSTITUTION  
VERIFYING TRICARE ELIGIBILITY FOR SAID PATIENT TO BE ENROLLED IN NCI  
SPONSORED STUDIES**

Hospital Name  
Street Address  
City, ST Zip

Dear \_\_\_\_\_:

This responds to your request for TRICARE eligibility verification, prior to enrollment of a TRICARE beneficiary in an NCI sponsored study for the prevention/treatment of cancer.

This is to inform you the following patient is eligible for TRICARE benefits and may be considered for enrollment in the NCI sponsored study. Enrollment in the study is a voluntary decision and can be made only by the patient.

Name of Patient: \_\_\_\_\_

Sponsor's Social Security Number: \_\_\_\_\_

If you have any questions or concerns, you may contact me at the address in the letterhead.

Sincerely,

Title

Enclosure

**FIGURE 18.2-2 SAMPLE OF AUTHORIZATION LETTER FOR DOD CANCER PREVENTION AND TREATMENT CLINICAL TRIALS DEMONSTRATION**

Name of Inquirer

Title

Hospital Name (Phase of cancer prevention or treatment protocol;

Street Address type of cancer; title of protocol)

City, ST Zip

Patient: **(Name of Patient) (Relationship to Sponsor, Sponsor Name, Rank, Branch of Service, Sponsor Status, Sponsor's SSN)**

Dear \_\_\_\_\_:

Our office has completed review of your **(Date of Letter)** application on behalf of **(Name of Patient)** for benefits under the Department of Defense Cancer (DoD) Prevention and Treatment Clinical Trials Demonstration. Based on our finding the proposed protocol **(NCI Number of Approved Protocol)** is an NCI sponsored study, and meets the terms of the Demonstration, we are pleased to authorize this care for **(Name of Patient)**.

The DoD intends to pay institutional and professional charges for cancer prevention and treatment for the patient named above if:

1. The provider seeking treatment for a TRICARE-eligible family member in an NCI approved cancer protocol has obtained preauthorization for the proposed clinical trial before initial evaluation; and
2. Such treatments are provided according to the NCI approved Phase II or Phase III cancer prevention or treatment protocol; and
3. The patient continues to meet entry criteria for said protocol; and
4. The institutional and individual providers are TRICARE-authorized providers.

Both institutional and professional charges will be reimbursed based on billed charges. The cancer center must submit all charges on the basis of fully itemized bills. Each service and supply must be individually identified. All cost-shares and deductibles applicable to TRICARE will also apply under this Demonstration as will copays for TRICARE Prime and USFHP enrollees. Questions regarding claims and reimbursement methodology will be provided by the contractor Demonstration case manager.

Because Demonstration benefits are not the same as TRICARE benefits, claims must be submitted to the appropriate contractor, referencing the DoD Cancer Prevention and Treatment Clinical Trials Demonstration.

A copy of this letter must accompany any claim submitted for Demonstration reimbursement of care related to this patient's cancer prevention and treatment. Any treatment under protocols other than the one specifically approved in this letter must receive preauthorization.

**FIGURE 18.2-2 SAMPLE OF AUTHORIZATION LETTER FOR DOD CANCER PREVENTION AND  
TREATMENT CLINICAL TRIALS DEMONSTRATION**

Name of Facility

Re: Patient Name

Date

Thank you for allowing the DoD to participate in the care of your patient.

Sincerely,

Title

cc:

-Beneficiary's Name and Mailing Address

**FIGURE 18.2-3 SAMPLE OF DENIAL LETTER FOR DOD CANCER PREVENTION AND  
TREATMENT CLINICAL TRIALS DEMONSTRATION**

Name of Inquirer

Title

Hospital Name (Phase of cancer prevention or treatment protocol; type of cancer; title  
Street Address of protocol)

City, ST Zip

Patient: **(Name of Patient) (Relationship to Sponsor, Sponsor Name, Rank, Branch of Service,  
Sponsor Status, Sponsor's SSN)**

Dear \_\_\_\_\_:

Thank you for your **(Date of Letter or Facsimile)** application requesting care for **(Name of Patient)** under the terms of the Department of Defense (DoD) Cancer Prevention and Treatment Clinical Trials Demonstration.

The Demonstration is authorized to fund cancer prevention and treatment when conducted under a Phase II or Phase III, NCI-sponsored study. Following review of the data you submitted for **(Name of Patient)**, we have determined that **(list one or more of the following two reasons for denial)**:

1. **(List Name of Protocol)** is not an NCI sponsored study.
2. **(List Name of Protocol)** is not Phase II or Phase III in design.

Therefore, it is our decision that this patient's proposed care does not qualify for reimbursement under the terms of the Demonstration. Since the Demonstration has no authority regarding the NCI sponsored studies, if a patient does not meet the criteria for enrollment, appeal rights do not apply.

I am sincerely sorry that we are unable to assist **(Name of Patient)** with these expenses.

Sincerely,

Title

cc:

-Patient's Name and Mailing address

**FIGURE 18.2-4 SAMPLE OF NOTIFICATION LETTER TO BE ISSUED TO GEOGRAPHICAL  
CONTRACTOR OF PATIENT'S ENROLLMENT IN THE DOD CANCER  
PREVENTION AND TREATMENT CLINICAL TRIALS DEMONSTRATION**

FI/Contractor Name  
Street Address  
City, ST Zip

Dear \_\_\_\_\_:

This letter is to notify you the following patient has enrolled in the Department of Defense (DoD) Cancer Prevention and Treatment Clinical Trials Demonstration:

Name of Patient: \_\_\_\_\_

Sponsor's Social Security Number: \_\_\_\_\_

All claims associated with this patient's treatment while enrolled in the clinical trial shall be processed by this office, with the exception of individual prescription drug claims. If claims are received for services provided to this patient, please forward the claims to the following address: **(Appropriate Address)**.

If you have any questions or concerns, you may contact me at the address in the letterhead or call **(Appropriate Telephone Number)**.

Sincerely,

Title

- END -

## **EXPIRED** - Department Of Defense (DoD) In-Utero Fetal Surgical Repair Of Myelomeningocele Clinical Trial Demonstration

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### **1.0 PURPOSE**

This demonstration will improve access to patients with fetuses who have a prenatal diagnosis of myelomeningocele; and to assist in meeting clinical trial goals under the Management of Myelomeningocele Study (MOMS) Protocol, in the formulation of conclusions regarding the safety and efficacy of intrauterine repair of fetal myelomeningocele.

### **2.0 BACKGROUND**

**2.1** The current state of the medical literature does not allow for a TRICARE benefit for in-utero surgical intervention for myelomeningocele as it is considered unproven. This determination is based on a Blue Cross Blue Shield (BCBS) technology assessment conducted in February 1999, which examined health outcomes resulting from prenatal correction to fetal malformations known to interfere with organ development (in a potentially fatal manner), and surgical techniques for which prenatal corrections have been developed and applied in humans. Because the evidence for in-utero repair of myelomeningocele was too scant, BCBS did not conduct a detailed analysis. Likewise, TRICARE Management Activity's (TMA's) December 1999 and October 2001 medical reviews of literature did not reveal any new evidence to justify TRICARE coverage for in-utero surgical repair of myelomeningocele.

**2.2** On February 13, 2003 (Vol 68, No 30), the **Federal Register** announced a demonstration project in which the DoD provide TRICARE reimbursement for active duty members, former members, and their dependents to receive prenatal and postnatal surgical intervention for the repair of myelomeningocele under approved National Institute of Child Health and Human Development (NICHD) clinical trial.

**2.3** The NICHD agreed to sponsor and actively coordinate an unblinded randomized controlled clinical trial program for the evaluation of the safety and efficacy of intrauterine repair of fetal myelomeningocele. Two hundred eligible patients whose fetuses have been diagnosed with myelomeningocele at 16 to 25 weeks' gestation who are at the age of 18 years or older would be screened for enrollment via telephone by the Biostatistics Center (BCC) at George Washington University in Rockville, Maryland, to undergo an initial evaluation. The NICHD program includes sponsorship in three participating MOMS Centers (Vanderbilt University Medical Center in Nashville, the University of California at San Francisco, and Children's Hospital of Philadelphia) where final evaluation and screening will be performed.

**2.4** Approximately 60,000 TRICARE births occur at the Military Treatment Facilities (MTF) each year. Approximately 40,000 TRICARE births occur in the civilian hospitals. According to the Center of Disease Control, in 2001 there were 20.09 cases of spina bifida per 100,000 births; approximately 19 cases would occur annually in TRICARE. This Demonstration Project is projected to have approximately 6 to 16 TRICARE patients that has a fetus with a prenatal diagnosis of spina bifida participating in the protocol each year. DoD financing of this procedure will assist in meeting clinical goals and arrival at conclusions regarding the safety and efficacy of intrauterine repair of fetal myelomeningocele.

### **3.0 POLICY AND ELIGIBILITY**

**3.1** Effective March 17, 2003, the myelomeningocele demonstration is authorized for all eligible DoD beneficiaries including Active Duty Service Members (ADSMs) selected to participate in the NICHD-sponsored clinical trial for the treatment of myelomeningocele as outlined in the Myelomeningocele Clinical Trial Demonstration Protocol (MCTDP) (Figure 18.3-1).

**3.2** The DoD will cost-share all medical care and testing required to determine eligibility for the NICHD-sponsored clinical trial, including the evaluation of eligibility at the institution conducting the NICHD-sponsored study, except to the extent that these services are covered by Other Health Insurance (OHI) of the beneficiary, or through grant support from the NICHD to participating institutions.

**3.3** DoD will cost-share all medical care required as a result of participation in NICHD sponsored clinical trials. This includes purchasing and administering all approved pharmaceutical agents, perioperative, preoperative and postoperative x-ray or magnetic resonance imaging procedures and ultrasound procedures, physical examination, laboratory investigations, surgical interventions, postoperative management, and peripartum medical or surgical interventions including management of complications not otherwise reimbursed under NICHD grant program or beneficiaries' OHI if the following conditions are met:

**3.4** The providers have obtained preauthorization for the proposed treatment before initial evaluation. If a preauthorization was not obtained before the initial evaluation, preauthorization can take place once the referral sheet from the MOMS Centers is received. A preauthorization for enrollment will suffice to cover each incidental expense or claim related to participation in the NICHD sponsored trial extending through the duration of the clinical trial. A preauthorization is required even when the beneficiary has OHI and must include verification with the NICHD that the patient has been enrolled in the NICHD-sponsored trial; and such treatments are those indicated in NICHD sponsored protocols; and the patient continues to meet entry criteria for said protocol.

**3.5** The DoD will not provide reimbursement for costs associated with any non-treatment research activities associated with the clinical trial. This includes, but is not limited to:

- Data collection activities;
- Management and analysis of the data;
- Salaries of the research nurses;
- Travel to and from participating fetal surgery centers, per diem and hotel accommodation cost.

**Note:** These research costs will not be the responsibility of the patient participating in the trial but will be covered by NICHD grant program or the grantee Institution. If travel costs to and from the participating fetal surgery centers are not covered by NICHD grant program, DoD beneficiaries may receive any travel entitlements they are entitled to under the Joint Travel Regulations, the Joint Federal Travel Regulations, or the TRICARE Prime specialty care travel benefit as the case may be.

**3.6** Cost-shares and deductibles applicable to TRICARE will also apply under this Demonstration. For TRICARE Prime enrollees, including those enrolled in Uniformed Services Family Health Plan (USFHP), applicable copays will apply, if any.

**3.7** The Assistant Secretary of Defense (Health Affairs) (ASD(HA)) approved this DoD Demonstration commencing on the effective date of participation, which is the date 30 calendar days after publication of the Notice in the **Federal Register**, with those enrolled having periodic examinations during a three year follow-up period.

#### **4.0 APPLICABILITY**

**4.1** The provisions of this demonstration are limited to those TRICARE-eligible beneficiaries and ADSMs whose fetuses have been diagnosed with myelomeningocele at 16 to 25 weeks' gestation and who are at the age of 18 years or older (on the date of enrollment). The demonstration does not apply to those TRICARE-eligible beneficiaries enrolled in the Continued Health Care Benefit Program (CHCBP).

**4.2** Inquiries and claims related to the Demonstration's prenatal protocol, excluding claims for the post-natal protocol, shall be submitted to the South Region referencing the DoD In-Utero Fetal Surgical Repair of Myelomeningocele Clinical Trial Demonstration. All inquiries and claims related to the Demonstration's post-natal protocol shall be submitted to the appropriate regional Managed Care Support (MCS) contractor, as these services are covered under the Basic Program. The DoD has no authority regarding the NICHD protocol eligibility for the sponsored study. Therefore, if a patient does not meet the criteria for enrollment, appeal rights do not apply.

#### **5.0 GENERAL DESCRIPTION OF ADMINISTRATIVE PROCESS**

The regional MCS contract shall verify the TRICARE eligibility of the patient on the Defense Enrollment Eligibility System (DEERS). Patient selection will be made by the BCC at George Washington University in Rockville, Maryland in accordance with the protocol. Those patients remaining eligible and interested will be assigned by the BCC to one of the three participating MOMS Centers. The contractor will not be involved in medical necessity or clinical review of the Demonstration claims. Claims for approved care under the Demonstration shall be submitted to the South Region for adjudication.

#### **6.0 ASD(HA) RESPONSIBILITIES**

ASD(HA) is the designated Executive Agent for the Demonstration project. They shall designate a project officer in the Office of the DASD (Clinical Services) for the Demonstration. The project officer shall provide clinical oversight and resolve any clinical issue among DoD, NICHD, and MCTDP.

## 7.0 THE BCC

For the myelomeningocele clinical trial, the BCC will serve as a referral center for patients and coordinate the outcome evaluations, including both the review of the Magnetic Resonance Imaging (MRI), and ultrasounds, as well as the infant follow-up examinations. The BCC may be contacted at:

Dr. Catherine Shaer, Program Manager  
Management of Myelomeningocele Study (MOMS)  
The Biostatistics Center, The George Washington University  
6110 Executive Boulevard, Suite 750  
Rockville, MD 20852

Call toll-free: 1-866-ASK-MOMS (1-866-275-6667)

Fax toll-free: 1-866-458-4621

<http://www.spinabifidamoms.com>

## 8.0 PARTICIPATING MOMS CENTERS

**8.1** Participating MOMS Centers will be responsible for obtaining information regarding possible Third Party Liability (TPL) and OHI coverage of the TRICARE beneficiary. The MOMS Centers shall collect from third party or the OHI and bill any remaining balance of the total amount to the appropriate regional contractor within 30 calendar days of the receipt of the payment from the OHI. The MOMS Centers shall ensure proper entry regarding the OHI on the Centers for Medicaid and Medicare Services (CMS) 1450 UB-04 claim form before submitting the claim form to the contractor.

**8.2** In the event that the MOMS Centers are unable to collect from a third party or the OHI for health care services that would be covered under the TPL or by the OHI if provided by a private provider, no bill shall be presented by the MOMS Centers to the DoD contractor. The MOMS Centers shall determine patient acceptance for participation in the Demonstration in accordance with the protocol outlined in [Figure 18.3-1](#).

**8.3** Participating MOMS Centers shall request reimbursement for inpatient services provided under the Demonstration completing a CMS 1450 UB-04 and submitting the form to the appropriate regional contractor. Reimbursement will be based on billed charges, which will cover all professional and institutional services. The MOMS Centers shall be responsible for collecting the beneficiary cost-shares from TRICARE patients. The participating MOMS Centers shall submit all charges on the basis of fully itemized bills.

**8.4** The MOMS Centers shall establish a POC to respond to inquires related to participation in the Demonstration and for coordination with the regional contractors. Unless otherwise agreed to between NICHD and DoD/TMA, the coordination support by the MOMS Centers shall be provided for up to 12 months after termination of the demonstration.

## **9.0 TMA AND CONTRACTOR RESPONSIBILITIES**

### **9.1 TMA will provide:**

- A special fund for the purpose of the demonstration.
- Periodic review and evaluation of the Demonstration claims adjudication process.
- Beneficiary Education and Support Division (BE&SD) functions to properly inform and periodically update the patient and provider communities regarding the terms of the Demonstration.

### **9.2 The contractor shall:**

**9.2.1** Verify the patient's eligibility on DEERS. If the patient is authorized to receive the care under the Demonstration, but DEERS reflects that the patient is not eligible, a statement shall be added to the authorization letter indicating before benefits can be paid, the patient must be listed as eligible on DEERS. If a patient is listed on DEERS as being eligible as of the date enrollment begins, all services provided as a result of participation in an NICHD sponsored study shall be covered. This also applies to patients whose treatment is in process when the Demonstration expires.

**9.2.2** Issue an authorization to the applicant provider and patient once a determination is made regarding eligibility and/or a particular protocol.

**9.2.3** Refer eligible patients to BCC for initial screening and protocol information for participation in the study.

**9.2.4** Furnish a list of enrollees in the Demonstration to the contractor's Program Integrity Unit with instructions to run an annual post-payment report to determine if hospitals are receiving additional unlawful payments as a result of also receiving payment under TRICARE. If such payment exists, it shall be the responsibility of the contractor to initiate recoupment action for any Demonstration benefits paid in error. This function will be supervised by the TMA Program Integrity Office (PI).

**9.2.5** Establish and maintain a database of patients participating in the Demonstration. The database shall include the patient's name, sponsor's Social Security Number (SSN), name and number of protocol, treatment, hospital name and address and total cost. The database shall also include the date the TRICARE beneficiary was either accepted, or denied enrollment into the clinical trial and the patient shall be carried in the database until the Demonstration ends.

## **10.0 CLAIMS PROCESSING REQUIREMENTS**

**10.1** Claims under the NICHD clinical trial demonstration project shall be processed by the South Region. Jurisdiction edits shall not apply thereby ensuring that claims are paid and submitted to the TMA in accordance with current requirements for not at risk funds.

**10.2** Verify TRICARE-eligibility on the DEERS prior to payment.

**10.3** Both institutional and professional charges shall be reimbursed based on billed charges.

**10.3.1** The NICHD participating MOMS Centers shall submit all charges on the basis of fully itemized bills. Each service and supply shall be individually identified and submitted on the appropriate claim forms.

**10.3.2** Claims for medical care required as a result of participation in an NICHD sponsored study for in-utero fetal repair of myelomeningocele or treatment that is not a TRICARE benefit (i.e., the Demonstration's pre-natal protocol portion), shall be processed and paid under the South Region.

**10.3.3** Cost-shares and deductibles applicable to TRICARE will also apply under the Demonstration. For TRICARE Prime enrollees, including those enrolled in USFHP, applicable copays will apply.

**10.3.4** The contractor shall query the DEERS Catastrophic Cap and Deductible Data base (CCDD) to determine the status of deductible and catastrophic cap met amounts for TRICARE-eligible beneficiaries at the time the costs are listed on the voucher for processing and payment. The contractor shall determine what expenses to apply to the deductible and catastrophic cap and report these to the CCDD. These expenses shall be reported at the same time the costs are listed on the voucher for processing, prior to payment of the claim.

**10.4** Double coverage provisions apply. Acceptable evidence of processing by the double coverage plan is outlined in the TRICARE Reimbursement Manual (TRM), [Chapter 4](#). In double coverage situations, the Demonstration will pay the balance after the OHI has paid.

**10.5** Claims shall be paid from the applicable non-underwritten bank accounts, see [Chapter 3](#), and submitted through normal TRICARE Encounter Data (TED) processing as required in the TSM with the applicable coding for clinical trials.

**10.6** Once in-utero fetal surgical repair of the myelomeningocele becomes a TRICARE benefit, claims for treatment shall be processed and paid based on the regional contractor's implementation date for the change. If a claim spans the implementation date, the contractor shall process and pay those charges on the claim that are prior to the implementation date and the regional contractor shall process the remaining charges under its at-risk contract. The contractor shall notify the provider the claim has been split for processing of charges as of the date of implementation for the TRICARE benefit. If the patient is an inpatient at the time in-utero fetal surgical repair of the myelomeningocele becomes a TRICARE benefit, and the claim is subject to the DRG-based payment, then the claim cannot be split. Under these circumstances, the entire claim shall be processed and paid under the Demonstration.

**10.7** A Non-Availability Statement (NAS) is not required under the Demonstration.

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**FIGURE 18.3-1 DEMONSTRATION PROTOCOL**

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**MANAGEMENT OF MYELOMENINGOCELE STUDY  
(MOMS)  
A RANDOMIZED TRIAL OF PRENATAL VERSUS  
POSTNATAL REPAIR OF MYELOMENINGOCELE**

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**PROTOCOL**

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**The National Institute of Child Health and Human Development  
Fetal Surgery Units Group**

Prepared by the

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**September 1, 2002**

## 1 INTRODUCTION

### 1.1 Study Abstract

In the last five years, repair of myelomeningocele in utero has become an established technique. The rationale is that early prenatal intervention may preserve neurological function that would otherwise be lost during gestation. Indeed, data from the first 180 fetuses undergoing this procedure since its inception in 1997, suggest that the incidence of shunt-dependent hydrocephalus may be reduced and the cerebellum and brainstem may be restored to more normal configuration. However, the evidence is far from convincing in that comparisons were made with historical controls and there is very little follow-up data from the children who received the surgery prenatally. A randomized trial, with follow-up of the infants to determine neurological functioning is described. Two hundred pregnant women in the second trimester with the diagnosis of myelomeningocele will be randomized either to prenatal or postnatal repair at one of three fetal surgery units, with follow-up to be conducted by an independent team of examiners.

### 1.2 Primary Hypotheses

Mid-trimester intrauterine repair of fetal myelomeningocele reduces the risk of death or ventricular decompressive shunting compared with standard postnatal repair.

Mid-trimester intrauterine repair of myelomeningocele results in an improvement in neurologic and neuro-motor function compared with standard postnatal repair.

### 1.3 Purpose Of The Study Protocol

This protocol describes the background, design and organization of the study and may be viewed as a written agreement between the study investigators. It is reviewed by the Advisory Board, and is approved by the Steering Committee, the Data and Safety Monitoring Committee and the Institutional Review Board (IRB) of each clinical center and of the data and study coordinating center (DSCC) before recruitment begins. Any changes to the protocol during the study require the approval of the Steering Committee.

A manual of operations supplements the protocol with detailed specifications of the study procedures.

## 2 BACKGROUND

### 2.1 Introduction

Open neural tube defects are a group of congenital abnormalities that arise by day 28 post-conception when some portion of the neural tube fails to close. These defects are the most common and most severe of the congenital abnormalities affecting the central nervous system. Approximately 2,000 fetuses annually are affected with some sort of open neural tube defect in the United States, about half of which are open spina bifida.<sup>1</sup> Health care costs are estimated by the Centers for Disease Control at \$200 million per year. Open spina bifida can occur either with a flat defect without a fluid filled sac covering (myeloschisis), with a membranous covering (meningocele), or membranous covering with extrusion of the cord into the sac (myelomeningocele). In most cases it is also associated with hydrocephalus and the Chiari Type II malformation (hindbrain herniation).

Open spina bifida is frequently diagnosed prenatally through the combined results of second trimester maternal serum alpha-fetoprotein screening and obstetrical ultrasonography. Until recently, the only options available to parents once a diagnosis was made prenatally were expectant management with delivery and postnatal therapy for the child, or pregnancy termination. Current neonatal management consists of prompt closure of the defect in an attempt to prevent infection or further injury to the exposed neural elements.

### 2.2 Sequelae Of Spina Bifida

Infant death related to open spina bifida in the United States is estimated at 10% and remains about 1% per year.<sup>2,3,4</sup> Those who survive are likely to experience significant life-long disabilities. Botto and colleagues note, "Medical problems may result from the neurologic defect or from its repair (e.g., paralysis, hydrocephalus, Arnold-Chiari type II malformation, endocrine abnormalities, tethered cord, syringomyelia, and syringobulbia) or may be sequelae of the neurologic deficit (e.g., deformations of the limbs and spine, bladder, bowel, and sexual dysfunction, and learning disabilities)."<sup>5</sup> These deficits and problems are related to the spinal cord level of the lesion and the degree of damage to the cord itself during the pregnancy, delivery, and the neonatal period.

The first year of life in a spina bifida child is dominated by neurosurgical interventions, in particular, ventricular peritoneal shunting to control the effects of hydrocephalus, itself a result of hindbrain herniation. Untreated, severe hydrocephalus can lead to brain damage and death. Complications of shunting include blockage or under-drainage, causing the symptoms of hydrocephalus to return, over-drainage that can lead to hemorrhage, and infection. Complications are relatively common and lead to the necessity for shunt revision surgeries.

Later, orthopedic and urologic considerations tend to preoccupy these patients. Nearly 90% of infants with spina bifida have some type of foot deformity such as clubfoot, vertical talus deformity or calcaneovalgus which requires splinting and/or casting followed by surgical repair once weight bearing activities are achieved.<sup>6</sup> Hip surgery in the form of muscle-tendon releases, open reduction of the hip, and proximal femoral osteotomy with or without acetabuloplasty and muscle balancing, is often necessary if the "verticalization" process of the child is inhibited. In addition, the majority of patients with myelomeningocele are afflicted with some degree of leg weakness resulting from

damage to the spinal cord at lumbar and upper sacral levels. The neurologic deficit is usually at or slightly above the level of the last intact vertebral segment. In a study of 101 spina bifida patients by Cochrane,<sup>7</sup> 90% of patients with a thoracic level lesion used wheelchairs and 45% and 17% of patients with a lumbar and sacral level lesion, respectively, used wheelchairs.

Only two to three percent of children with spina bifida achieve urinary continence and spontaneous voiding without urologic intervention. However 70% of patients can achieve urinary continence with conservative medical therapy. This generally entails intermittent catheterization rather than spontaneous voiding to empty the bladder, medications to improve bladder capacity and compliance, and in approximately one-quarter of patients, surgical intervention.<sup>8</sup>

Numerous studies have documented that children with spina bifida are at increased risk for a variety of neuropsychological and behavioral problems. These include impairments in cognitive, perceptual-motor, memory, fine and gross motor, language, and attention skills, as well as academic achievement and psychosocial functioning. Intelligence quotients (IQ) of children who have myelomeningocele and a common complication, hydrocephalus, vary widely but tend to cluster in the borderline to low average range, i.e., IQ's of 70-90. Difficulties with memory and attention are also frequently reported, particularly in children with hydrocephalus.<sup>9,10</sup> Given the multiple areas of cognitive function that may be affected, it is not surprising that academic performance is often adversely impacted. Children with spina bifida are also at risk for poorer psychosocial adjustment in relation to the general population.<sup>11</sup> More specifically, children with spina bifida have been found to have higher rates of internalizing and externalizing behavior problems than unaffected children based on parental reports.<sup>11</sup>

### **2.3 Rationale For Prenatal Repair of Myelomeningocele**

In a fetus with myelomeningocele, there is evidence that neurologic function deteriorates during gestation. First, sonographic evaluation suggests that both the central and peripheral nervous system insults may be progressive. The Chiari malformation and ventriculomegaly are often seen to progress during fetal development. Lower extremity movement can be seen early in gestation (before seventeen to twenty weeks) and is not seen later. Clubbing of the feet associated with myelomeningocele also appears to be progressive throughout gestation. Secondly, experimental and clinical work in other areas of nervous system development suggest that plasticity is greatest in the young brain and nervous system.<sup>12</sup> Recovery of function after CNS damage from traumatic and hypoxic insults is better in neonatal animals than it is in adult animals. In summary, if the myelomeningocele can be safely repaired in utero, relatively early in gestation, it is plausible that neurologic function could be substantially improved.

### **2.4 Animal Studies**

Animal studies have demonstrated that prenatal coverage of the lesion may preserve neurological function. Michejda created a spina bifida-like lesion in eight Macaca mulatta fetuses by performing intrauterine lumbar laminectomy and displacing the spinal cord from the central canal.<sup>13</sup> This condition was repaired in utero in five monkeys. At delivery, the five animals whose lesion was covered developed normally, while those with open lesions were paraplegic with lower extremity somatosensory loss and incontinence. Studies performed in the rat model showed that those animals in which the defect remained uncovered were born with a severe deformity and weakness

of the hind limbs and tail.<sup>14</sup> In contrast, repaired rats were normal at birth. Histological studies of the exposed spinal cord revealed findings similar to those described in children with myelomeningocele. Similar studies have been performed in fetal pigs and lambs with identical results.<sup>15,16,17</sup> It has recently been shown in an open spinal canal fetal lamb model that hindbrain herniation can be prevented by mid-gestational repair of the surgically created myelomeningocele.<sup>18</sup> It is now hypothesized that the neurological defects seen in children with myelomeningocele result from both the congenital myelodysplasia as well as from intrauterine spinal cord injury resulting from prolonged exposure of neural elements to the intrauterine environment.

## 2.5 Clinical Studies

Starting in 1994, the first cases of myelomeningocele repair in utero were performed using a fetoscopic approach. This approach did not result in satisfactory repair of the lesion and was abandoned quite quickly. In 1997, the first cases were carried out by hysterotomy. As of April 1, 2002, 212 women had received open fetal repair of myelomeningocele at three centers: University of California San Francisco (UCSF), Children's Hospital of Philadelphia (CHOP), and Vanderbilt University Medical Center.

**TABLE 1: FETAL REPAIR OF MMC (OPEN REPAIR ONLY) BY YEAR OF SURGERY AS OF 04/01/2002**

YEAR	CHOP	VANDERBILT	UCSF
1997	0	3	0
1998	4	26	1
1999	9	45	1
2000	18	39	6
2001	15	30	2
2002	3	9	1
<b>TOTAL</b>	<b>49</b>	<b>152</b>	<b>11</b>

The CHOP cases include two fetal and one neonatal death. At Vanderbilt, there were two fetal deaths, two neonatal deaths, and one infant death at 10 months of age. In addition, one child died at three years of age due to complications of ventriculostomy (not included in the table). At UCSF, there was one fetal death and two deaths from complications of prematurity. The current ages of the surviving infants are as follows:

**TABLE 2: CURRENT AGE OF INFANTS/STATUS OF PREGNANCIES WITH OPEN FETAL REPAIR OF MMC AS OF 04/01/2002**

	CHOP	VANDERBILT	UCSF
<b>Died</b>	3	5	3
<b>Not born yet</b>	2	7	1
<b>&lt; 12 months</b>	15	28	1
<b>12 - &lt; 24 months</b>	17	40	5
<b>24 - &lt; 36 months</b>	8	44	1
<b>36+ months</b>	4	28	0
<b>Total</b>	<b>49</b>	<b>152</b>	<b>11</b>

### 2.5.1 Shunt-Dependent Hydrocephalus

The table below describes the experience at the three centers for the fetal surgery patients who reached one year of age as of April 2002. As a comparison, at CHOP, of 416 patients followed in the Spina Bifida Clinic, 84% had a shunt by one year of age. The distribution of lesion levels among the fetal surgery patients was similar to these clinic patients.

**TABLE 3: 1 YEAR SHUNT RATES FOR SURVIVING FETAL SURGERY PATIENTS**

	CHOP	VANDERBILT	UCSF
<b>Shunt by 12 mos</b>	13	61	3
<b>No shunt by 12 mos</b>	16	50	3
<b>Missing outcome</b>	0	1	0
<b>Total</b>	<b>29</b>	<b>112</b>	<b>6</b>
<b>Shunt rate</b>	44.8%	55.4%	50.0%

Although the shunt rates differ somewhat between the centers, this may be explained by differences in gestational age at repair, which, like lesion level, was shown in the Vanderbilt series to be associated with the hydrocephalus outcome. All of the repairs at CHOP were performed early in gestation, at 21-24 weeks. At Vanderbilt, 25/58 fetuses (43.1%) of surviving fetuses repaired at less than 25 weeks compared with 37/54 (68.5%) of those repaired later required a shunt.

### 2.5.2 Hindbrain Herniation

Investigators at Vanderbilt compared the postnatal MRIs of 26 of their original 28 patients who underwent in utero surgery with MRIs or ultrasounds in 22 historical controls. They found the following results:<sup>19</sup>

**TABLE 4: HINDBRAIN HERNIATION IN FETAL SURGERY PATIENTS AND CONTROLS AT VANDERBILT**

GRADE	0-1	2-3	4-5
<b>Fetal Surgery</b>	17	9	0
<b>Control</b>	1	18	3

Using a different grading scale, the CHOP group similarly demonstrated a marked improvement in the degree of hindbrain herniation following in utero repair. All nine of the patients had scored a grade 3 on MRIs done between weeks 19 and 24 gestation. MRIs done three weeks after fetal closure of myelomeningocele showed improvement in all nine and, on the MRI obtained six weeks postnatally, all nine were Grade 1 (normal).<sup>20</sup> This result has subsequently been confirmed in that every single delivered patient at CHOP by August 2001 (36 excluding deaths) has demonstrated improvement in hindbrain herniation.

### 2.5.3 Leg Function

An analysis of the leg function of the first 26 patients to undergo in utero repair of myelomeningocele at Vanderbilt revealed no significant difference from a set of historical controls

who were treated in the conventional fashion (postnatal repair).<sup>19</sup> The average anatomic level in the prenatal surgery group was L5 while that in the control group was L2/L3. However, the neurologic level in the prenatal surgery group was L4/L5 while that in the control group was L2/L3. Thus as a group, the upper anatomic level of the lesion closely matched the neurological level. The average age at the time of this neurological examination was approximately six months. All intrauterine repairs were performed at more than 25 weeks' gestation.

In 34 patients with in utero repair at CHOP, several had neurological function substantially better than might have been expected after conventional repair. Fifteen of 34 patients evaluated as newborns had lower extremity function better than expected by at least two spinal levels based on anatomic level as determined by the initial MRI. Interestingly, all of these patients were operated on at less than 25 weeks gestation, suggesting that earlier repair of the myelomeningocele may result in improved lower extremity function.

A follow-up on 30 infants from Vanderbilt who have reached age two and for whom data are available, indicates that 80% were ambulatory (15 were 'cruising', 3 walking with long leg braces, 1 with ankle orthotics and 5 unaided).

These results suggest that in utero surgery does not worsen and may improve leg function in infants so treated. Other issues, such as an improved ability to detect pain and temperature, could clearly improve quality of life even in the absence of normal motor function by allowing the individual, for example, to prevent burns or avoid pressure sores.

#### **2.5.4 Bowel And Bladder Function**

The effect of fetal myelomeningocele repair on urologic function remains largely unknown at this time. In a preliminary study of 26 patients who had undergone fetal myelomeningocele repair at Vanderbilt, no significant improvement in urologic function could be appreciated as compared with patients treated in the conventional fashion.<sup>19</sup> However, the population had an average age of six months, and urologic testing is relatively unreliable at this age. An update on those from Vanderbilt who reached two years by August 2001 (30 patients with available data), revealed that all were 'socially continent' of bladder and bowel, although 37% were catheterized, 73% had been treated for a bladder infection and 57% demonstrated typical management of bowel symptoms (on oral medications, altered diet, requiring assistance with evacuation).

#### **2.5.5 Cognitive Function**

Of the 19 infants who had reached one year of age by August 2001 at CHOP, eleven returned for a developmental assessment. The Bayley Scales of Infant Development and the Preschool Language Scales (PLS) were conducted. The mean MDI was 86 and PDI was 56. The mean total PLS was 85. All three scores have a standardization mean of 100, and standard deviation of 15. Overall, two of the children were demonstrating a significant global delay.

Developmental data were collected and reported on the first group of 26 infants aged 2 to 18 months who underwent fetal surgery at Vanderbilt.<sup>21</sup> Their average MDI was 100, with a range from 80 to 118. More recent data are not available, since the quality of the Bayley data collected from the many different clinics was felt to be too variable.

## 2.6 Potential Risks Of Fetal Surgery

### 2.6.1 Maternal Risks

Not only does the fetus face the potential risks of the intrauterine surgery, but also the mother's health may be threatened without the possibility of any direct benefit. She undergoes two laboratory incisions during the index pregnancy, one at the time of fetal surgery and the other with cesarean delivery at birth. Thus, she is at risk for the standard operative morbidities incurred by any major abdominal surgery including: bleeding, perhaps requiring transfusion; wound infection or breakdown; uterine infection; damage to adjacent organs such as the bowel or bladder; immediate damage to the uterus requiring hysterectomy; pulmonary edema in the immediate postoperative period; allergic reactions to medications; and even death. Pulmonary edema in the immediate postoperative period has occurred in approximately 8% of the patients in the Vanderbilt series and has responded promptly to medical management. None required intubation or admission to the ICU. In the combined experience at UCSF, CHOP and Vanderbilt with over 200 open fetal surgeries for a variety of fetal diseases, there have been no intra-operative maternal complications or maternal deaths<sup>22,23</sup> In one instance at Vanderbilt, the mother aborted during surgery, requiring intraoperative delivery of the 28-week fetus who survived. If this were to occur prior to 24 weeks' gestation, it would be unlikely that the baby would survive.

Due to the extent and type of uterine surgery required for access to the fetus for open repair, the mother is at increased risk of uterine rupture during that pregnancy and with all subsequent deliveries. The mother is also at risk for significant adhesions resulting in difficulty in performance of the cesarean section, development of bowel obstruction and postoperative pain. As with any previous uterine surgery, there can be abnormal implantation of a placenta in a subsequent pregnancy over the scar from the hysterotomy, resulting in a placenta accreta or placenta percreta.

In the Vanderbilt series, no catastrophic uterine ruptures have occurred, although in one case the fetal foot extruded through the incision at about 34 weeks requiring urgent delivery and uterine repair with good maternal and fetal outcomes.

A study of 45 women who underwent open fetal surgery at UCSF for a variety of indications over a 15-year period was recently published.<sup>24</sup> There were 35 attempted pregnancies. Thirty-two were successful resulting in 31 live births. Of the three that have not conceived, two had a strong history of infertility, and one had only been trying for three months. This suggests that even open hysterotomy, fetal manipulation, and suture closure of the hysterotomy has a minimal impact on maternal fertility.

Finally, there are potential psychological risks such as the mother feeling "coerced" into having prenatal surgery performed. There are few mothers who will not do "everything" for their child(ren). It is critical that the perioperative counseling for these women and their partners/families legitimize and give "permission" to the woman to decide against surgery, or in this case, the randomized trial. The woman is likely to be on medical leave from work for the duration of her pregnancy and, as such, there is potential for financial harm as well as psychosocial complications.

### **2.6.2 Fetal Intraoperative Risks**

The fetus also undergoes intraoperative risks including asphyxia from cord occlusion when the amniotic fluid is drained which is addressed via monitoring of the fetal heart rate during the surgery. Damage to the fetal spinal cord or adjacent structures during the surgery is a risk during any myelomeningocele repair, but may be more likely with intrauterine repair due to the small size of the preterm fetus, and the reduced exposure associated with surgery through a hysterotomy. Infection is a significant risk of any surgical procedure, but carries greater significance in an obstetrical patient in whom chorioamnionitis requires prompt delivery. There is a risk of intrauterine infection requiring delivery secondary to premature labor and oligohydramnios. Intrauterine infection requiring preterm delivery has been reported twice in the Vanderbilt series. Oligohydramnios of uncertain etiology has occurred at least transiently in about one third of the patients in the Vanderbilt series although only one significant neonatal problem has been noted. One fetus developed pulmonary hypoplasia secondary to longstanding oligohydramnios and died shortly after delivery.

### **2.6.3 Preterm Birth**

Preterm labor remains an unsolved problem. Avoiding a long hysterotomy by operating earlier in gestation may decrease the incidence of preterm labor by decreasing uterine injury. Nevertheless, the fetus is at increased risk of premature birth and its sequelae including sepsis, intraventricular hemorrhage, respiratory distress syndrome, necrotizing enterocolitis and death. In August 2001, the average gestational age at delivery was 33.9 weeks at CHOP, 33.7 at Vanderbilt and 32.5 at UCSF. It should be noted that many of the 34-37 week deliveries were planned cesarean births after documentation of pulmonary maturity in order to preempt the risk of uterine rupture in the last few weeks of pregnancy. The neonate's risks of prematurity complications after 34 weeks are fairly minimal.

## **2.7 Rationale For The Clinical Trial**

Enthusiasm for fetal intervention must be tempered by reverence for the interests of the mother and her family, by careful study of the disease in experimental fetal animals and untreated human fetuses, and by a willingness to abandon therapy that does not prove effective and safe in properly controlled trials.

To date, clinical results of fetal surgery for myelomeningocele are based on comparisons with historical controls and address efficacy rather than safety. Historical controls are problematic due to constantly improving postnatal management and the problem of ascertainment bias. For example, parents may cause distortion of outcome assessment by avoiding postnatal shunting. Only a properly designed and conducted randomized trial will be sufficient to overcome bias.

Some have argued that randomization of treatment for such an emotionally charged disease is difficult and will not be accepted by families.<sup>25</sup> However, a randomized, controlled trial of fetal surgery for diaphragmatic hernia sponsored by the NIH has enjoyed better than expected enrollment. Many families are relieved, once they know that the best treatment is truly unknown, to have the choice taken out of their hands. A randomized trial for myelomeningocele is clearly difficult but it must be done to determine whether fetal repair of myelomeningocele, with its

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attendant maternal and neonatal morbidity, is warranted. It is important to launch a trial before more centers begin doing the procedure.

### 3 STUDY DESIGN

#### 3.1 Primary Research Questions

1. Does intrauterine repair of fetal myelomeningocele at 19<sup>0</sup> to 25<sup>6</sup> weeks gestation using a standard multi-layer closure improve outcome, as measured by death or the need for ventricular decompressive shunting by one year of life, compared with standard postnatal repair?
2. Does intrauterine repair of myelomeningocele improve neurologic function at 30 months corrected age as measured by a combined rank score of the Bayley Scales of Infant Development mental development index and the difference between the motor level and lesion level?

#### 3.2 Secondary Research Questions

Secondary research questions this study will address include:

- Does intrauterine repair of myelomeningocele improve the degree of the Chiari II malformation as measured by magnetic resonance imaging (MRI)?
- Does intrauterine repair of myelomeningocele improve the postnatal course and neurologic outcome of the infant? Neurologic function will be assessed by detailed neuromotor function analysis, cognitive testing, and evaluation of neurodevelopmental status at twelve and thirty months of age.
- What are the long-term psychological and reproductive consequences for the parents?

#### 3.3 Design Summary

The study is an unblinded randomized controlled clinical trial of 200 patients. Patients diagnosed with myelomeningocele at 16 to 25 weeks gestation will be referred to the Data and Study Coordinating Center (DSCC) for initial screening and information. Those eligible and interested will be assigned by the DSCC to a Fetal Surgery Unit (MOMS Center) where final evaluation and screening will be carried out. Patients who satisfy the eligibility criteria and consent to randomization will be centrally randomized to one of the following two management protocols:

- Intrauterine repair of the myelomeningocele at 19<sup>0</sup> to 25<sup>6</sup> weeks, discharge to nearby accommodation on tocolytics when stable for preterm labor, weekly prenatal visits and monthly ultrasounds conducted at the MOMS Center; cesarean delivery at 37 weeks following demonstration of lung maturity.
- Return to local perinatologist for prenatal care, with monthly ultrasounds reported to the MOMS Center; return to the MOMS Center at 37 weeks gestation for cesarean delivery following demonstration of lung maturity; neonatal repair of the myelomeningocele.

### **3.4 Eligibility Criteria**

#### **3.4.1 Inclusion Criteria**

1. Myelomeningocele (including myeloschisis) at level T1 through S1 with hindbrain herniation. Lesion level will be confirmed by ultrasound and hindbrain herniation will be confirmed by MRI at the MOMS Center.
2. Maternal age  $\geq$  18 years
3. Gestational age at randomization of 19<sup>0</sup> to 25<sup>6</sup> weeks gestation as determined by clinical information and evaluation of first ultrasound. If the patient's last menstrual period is deemed sure and her cycle is 26 to 32 days, and if the biometric measurements from the patient's first ultrasound confirm this LMP within  $\pm$  10 days, the LMP will be used to determine gestational age. In all other cases (i.e., if the LMP is unsure, if she has an irregular cycle or her cycle is outside the 26-32 day window or if the measurements from her first ultrasound are more than 10 days discrepant from the ultrasound), the ultrasound determination will be used. Once the EDC has been determined for the purposes of the trial, no further revision is made.
4. Normal karyotype with written confirmation of culture results. Results by fluorescence in situ hybridization (FISH) will be acceptable if the patient is at 24 weeks or more.

#### **3.4.2 Exclusion Criteria**

1. Non-resident of the United States
2. Multifetal pregnancy
3. Insulin dependent pregestational diabetes
4. Fetal anomaly not related to myelomeningocele. A fetal echocardiogram will be conducted before randomization and if the finding is abnormal, the patient will be excluded.
5. Kyphosis in the fetus of 30 degrees or more
6. Current or planned cerclage or documented history of incompetent cervix
7. Placenta previa
8. Short cervix  $<$  20mm measured by ultrasound. The patient may be excluded based on an ultrasound report during initial screening or based on the cervical length measurement performed at the MOMS Center as part of the final evaluation.
9. Obesity as defined by body mass index of 35 or greater
10. Previous spontaneous singleton delivery prior to 37 weeks
11. Maternal-fetal Rh isoimmunization, Kell sensitization or a history of neonatal alloimmune thrombocytopenia

12. Maternal HIV or Hepatitis-B status positive because of the increased risk of transmission to the fetus during fetal surgery. If the patient's HIV or Hepatitis B status is unknown, the patient must be tested and found to have negative results before she can be randomized.
13. Known Hepatitis-C positivity. If the patient's Hepatitis C status is unknown, she does not need to be screened.
14. Uterine anomaly such as large or multiple fibroids or mullerian duct abnormality.
15. Other maternal medical condition which is a contraindication to surgery or general anesthesia.
16. Patient does not have a support person (e.g., husband, partner, mother).
17. Inability to comply with the travel and follow-up requirements of the trial.
18. Patient does not meet other psychosocial criteria (as determined by the psychosocial interviewer using a standardized assessment) to handle the implications of surgery.

### 3.5 Informed Consent Criteria

Written consent will be obtained from patients after their initial contact with the DSCC to permit further contact and review of their medical records. The consent form is included in Appendix B.1 'Consent Form for Screening'. Upon arrival at a participating MOMS Center, the pregnant woman (and her partner) will be informed about the entire process of counseling and evaluations. The actual steps leading up to randomization will be discussed, and consent to undergo the evaluations will be signed by the patient. The reasons for randomized controlled trials, and the necessary elements for a well-conducted trial as well as the particular requirements for this trial will be discussed. Also, the patients will be told that they can, at any time, decline continued participation in the evaluation or the trial. Full disclosure of the nature and potential risks of participating in the trial will be made. A common consent form is included in Appendix B.2 The patient will also be asked to sign a consent form for follow-up of her infant as part of the study. A common consent form for this part of the trial is included in Appendix B.3 Minor modifications will be made to these consent forms at each center as necessitated by the requirements of each individual institutional review board.

Women who are not fluent in English will be enrolled by a person fluent in their language. Both verbal and written informed consent will be obtained in that language; if this is not possible the patient will not be included. She will also be asked to sign a release for her medical records. Following the guidelines of the local IRB, the father's consent will also be obtained.

### 3.6 Randomization Method and Masking

Randomization assignment will be based on a randomization sequence prepared using the simple urn model, stratified by center, and maintained centrally by the DSCC.<sup>26</sup> The advantage of the urn model is that it provides a good probability of balance, and future assignments are unpredictable, in addition to allowing an explicit randomization analysis to be conducted with relative ease. Stratification by center assures balance between the two treatment groups with respect to possible differences in patient management. Because this is an unmasked trial, central randomization via a secure Internet procedure will be used.

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Although the trial is unmasked, independent consultants who will be blinded to the infant's randomization group will perform primary outcome assessment.

## **4 STUDY PROCEDURES**

### **4.1 Pre Screening for Eligibility**

Patients from the United States with prenatally diagnosed fetal spina bifida who are interested in trial participation will contact the DSCC. Publicity about the study will be coordinated by the DSCC, and will be directed to patients, physicians and other health care providers.

If a patient appears to meet minimal eligibility criteria, basic rules for participation in the trial will be discussed with the patient. To minimize noncompliance and loss to follow-up, patients who appear unwilling to accept any portion of the trial, including randomization to either group, and delivery and follow-up at the assigned MOMS Center, will not be considered eligible for trial participation.

For patients who remain interested in trial participation, eligibility will be verified and the patient will also be asked to make arrangements for an amniocentesis for karyotyping. A standardized packet of information will then be mailed to the patient, containing material describing spina bifida, including prenatal and neonatal development, general outcomes expected, and management options in pregnancy and the newborn period. The packet will also contain information describing the study, including the rationale and general study design.

### **4.2 Assignment to MOMS Center**

If the patient remains eligible and interested, she will be directed to one of the three participating centers. To eliminate selection bias, patients will be assigned to a MOMS Center based on geography to ensure that each center is assigned equal numbers of patients. The number of patients assigned to each MOMS Center will be monitored quarterly by the DSCC, and if necessary the patient distribution will be shifted to ensure equal numbers of patients at each center. Patients must agree to the assignment of MOMS Center or they will not be enrolled in the study.

### **4.3 Final Screening**

Once the patient is referred to a participating MOMS Center, she will contact that site for intake. The study coordinator will assist the patient and her family in obtaining suitable transportation and lodging for the scheduled evaluation. Patient evaluation for study participation will consist of the following procedures.

- 1.** Comprehensive obstetrical ultrasound examination, including documentation of cervical length, fetal gestational age, lesion level, ventricular size, leg and foot positioning, and lower extremity movement, in addition to a fetal echocardiogram.
- 2.** Fetal MRI to document hindbrain herniation.
- 3.** Maternal physical examination and clearance for surgery by anesthesia and the OB/GYN staff.
- 4.** Psychosocial evaluation to identify family dynamics and social issues that will impact the family's strategies for the remainder of the pregnancy and after the birth of the child. The social worker will also develop interventions if such issues are identified.

5. Teaching about neural tube defects, community resources, information regarding prenatal and postnatal surgery, management following prenatal surgery, and recommendations for continued care for the postnatal group.
6. An ethics focused interview to afford potential participants a formal opportunity to examine what they have learned about the study in the course of their evaluation and to discuss how they feel about enrolling in the study.

#### **4.4 Informed Consent**

When it has been determined that the patient meets all of the inclusion criteria and has none of the exclusion criteria, and the patient indicates a willingness to undergo randomization (i.e., will accept either pre- or post-natal surgery), she will be asked to sign both the informed consent form for the study and for follow-up.

#### **4.5 Psychological Testing**

Once the patient has given consent but prior to randomization, she and her partner will be asked to complete the psychosocial questionnaires listed below. These are administered prior to randomization so that surgery group assignment will not affect the baseline results. The data from these questionnaires will provide indications for the parents' emotional functioning, subjective well-being, subjective opinion of met and unmet needs, levels of optimism/pessimism and stress.

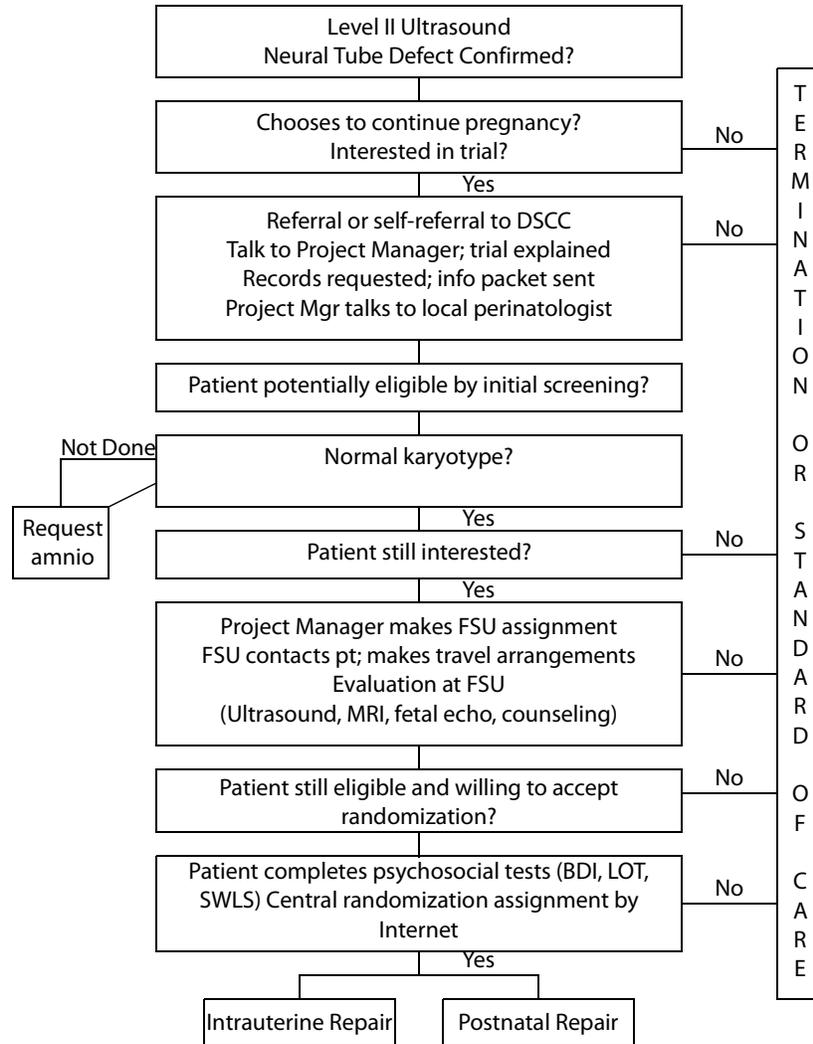
1. Satisfaction with Life Scale (SWLS) - The SWLS measures life satisfaction as a cognitive-judgmental process, using a seven-point Likert scale. This scale has high test-retest reliability with correlation coefficients of 0.54 to 0.80.<sup>27</sup> Pavot compared the SWLS to other related scales and found it was valid and reliable and could be used in a variety of age groups and applications.<sup>28</sup>
2. Life Orientation Test (LOT) - The LOT is an eight item instrument measuring "dispositional optimism", the degree to which individuals expect favorable outcomes, rated on a five point Likert scale. The LOT includes items such as "every cloud has a silver lining", wherein such optimistic slogans are endorsed or denied. According to Scheier and Carver, the LOT has a Cronbach's alpha of 0.76 and a reliability coefficient of 0.79.<sup>29</sup>
3. Beck Depression Inventory (BDI) - The BDI is a widely used 21-item self report measure of depressive symptoms which has been shown to be a reliable and valid measure of severity of depressive symptomatology in clinical populations.<sup>30</sup> Internal consistency ranges from 0.73 to 0.92, with a mean of 0.86 and has a reliability coefficient of 0.93.<sup>31</sup> The BDI takes approximately 10 minutes to complete and requires a fifth to sixth grade reading level. The BDI has been translated into several languages, including Spanish, and the reliability and validity of these translated versions has been verified.

#### **4.6 Randomization**

The randomization assignment will then be obtained via the central Internet randomization system. Patients assigned to the fetal surgery group will be scheduled for surgery no less than one working day later and no more than three working days or 25<sup>6</sup> weeks gestation, whichever is earlier.

Screening and randomization procedures are summarized in the figure below.

**FIGURE 1. SCREENING AND ENROLLMENT**



## 4.7 Patient Management And Follow-Up

### 4.7.1 Prenatal Surgery Group

Patients randomized to the prenatal surgery group will be scheduled for surgery no sooner than the following working day, and No Later Than (NLT) three working days after randomization or 25<sup>6</sup> weeks gestation, whichever is sooner. Patients will undergo open fetal surgical repair of the myelomeningocele with standardized intraoperative techniques, post-operative care and cesarean delivery performed by each of the three fetal surgery teams (including the surgeons, perinatologists and neurosurgeons). A description of the surgery is presented in Appendix C. All

surgeries will be performed by open hysterotomy since the previous experience with the endoscopic approach was unsatisfactory.

Since prenatal surgery patients are at increased risk of preterm labor, use of tocolytics is planned until 366 weeks gestation. All patients will stay in the hospital until they are on a regular diet, have return of bowel function, are able to ambulate to the bathroom without assistance, demonstrate good tocolytic control, and have good postoperative pain management on oral medications. All discharged patients (and their support person) will stay close to the MOMS Center in accommodations provided to permit standardized postoperative management, ultrasound evaluation, and delivery. They will be on modified bedrest for the first two weeks, but subsequently allowed to graduate to moderate activity if the uterus is quiescent.

Outpatient follow-up will be scheduled every week. In addition to the usual content of a prenatal visit, maternal assessment will include the degree of postoperative discomfort, wound healing, and premature labor/delivery risks. A brief "targeted" ultrasound will be performed to assess amniotic fluid volume and membrane status since oligohydramnios and chorioamniotic separation are the most frequent complications following fetal surgery and their presence may directly impact pregnancy management. Fetal well-being will be determined at every visit after 28 weeks by means of a biophysical profile.

Comprehensive ultrasonography will be performed monthly to measure: biparietal diameter, head circumference, femur length, humerus length, abdominal circumference, amniotic fluid index and maximum vertical pocket, status of the chorion, diameter of the posterior horn of the lateral ventricles, lateral ventricular width/hemispheric width ratio, and appearance of the third ventricle.

If staying near the MOMS Center becomes a cause for considerable hardship for a patient and if she is cleared for travel, she may return home. Before her departure, the team perinatologist or Principal Investigator will contact the local perinatologist directly to facilitate a smooth transfer of patient information and follow-up plans, and to ensure that patient management guidelines are clear, as outlined in a standardized letter which will be sent at the same time. This will include ultrasound specifications. The monthly ultrasound examinations on videotape will be forwarded by express mail, (or transferred by internet if the technology is available at the local center) to the MOMS Center, as well as prenatal records. Upon reaching 320 weeks gestation undelivered, and if she is cleared to travel, including to fly if applicable, the patient and her support person will return to the participating MOMS Center for elective cesarean delivery at 37 weeks, given fetal lung maturity.

#### **4.7.1.1 Use Of Antenatal Steroids**

Steroids will not be used at the time of antenatal surgery, but only in the case of threatened preterm delivery prior to 34 weeks. If preterm labor is diagnosed and the likelihood of delivery is high (e.g., there is premature membrane rupture, vaginal bleeding, or nonreassuring antepartum fetal surveillance), a course of steroid therapy will be given to minimize any complications of prematurity. The steroid course is two doses of 12 milligrams of betamethasone 24 hours apart, and will be given once between 24 weeks and 34 weeks of gestation. This regimen was developed for the prenatal surgery group, but would also apply to patients in the postnatal group who present with threatened preterm delivery.

#### **4.7.1.2 Use Of Tocolytics**

Magnesium sulfate will be started postoperatively in the operating room and will be continued for the first 24 to 48 hours following surgery. Indomethacin will be given as a 50 mg suppository preoperatively, followed by 50 mg (p.r. or p.o.) every 6 hours for the first 24 hours following surgery and 25 mg every 6 hours on the second day. During the time that the mother is on indomethacin, two fetal echocardiograms will be conducted. Maintenance therapy will consist of p.o. nifedipine (10-20 mg every 4-6 hours) and will be continued until 36 weeks 6 days. If nifedipine fails, i.e., the patient experiences more than eight contractions per hour, or if it is not tolerated, a terbutaline pump will be used.

First line tocolysis will be re-initiated for fetal surgery patients or initiated for patients assigned to postnatal surgery when there have been palpable, uncomfortable contractions occurring preterm for longer than one hour, and at a frequency of greater than or equal to 4 per 20 minutes. Magnesium sulfate will remain the primary tocolytic in such cases.

#### **4.7.1.3 Management Of Oligohydramnios And Intrauterine Growth Restriction**

Oligohydramnios will be managed by bed-rest with bathroom privileges when the AFI is less than the 5th percentile and, for in-hospital management, with fetal heart rate or NST assessment every nursing shift when the AFI is less than the 2.5th percentile. The only indication for amnioinfusion will be severe oligohydramnios with evidence of cord compression. Written guidelines will be developed and also provided to the community physicians who may be involved in monitoring these patients. Intrauterine growth retardation (IUGR) is defined as a fall off in fetal size and weight to less than the 10th percentile by ultrasound biometry. This has occurred only rarely in fetal surgery patients and would be managed as any other pregnancy complicated by IUGR (bed rest, maternal nutrition, frequent fetal surveillance, and umbilical artery Doppler velocimetry).

#### **4.7.1.4 Management Of Fetal Distress**

Recurrent late, prolonged or severe variable fetal heart rate decelerations, or a sinusoidal pattern, or prolonged bradycardia are sufficient grounds for delivery if conservative measures, such as maternal position change, administration of oxygen, and intravenous fluid hydration are unsuccessful.

#### **4.7.1.5 Membrane Separation**

When membrane separation is seen by ultrasound, patients will be placed on bed rest with bathroom privileges only. If the membrane separation progresses and extends to the placental cord insertion site, patients will be admitted to the antepartum service on bed rest, and a fetal heart rate strip will be collected every shift and if decreased fetal movement is observed.

#### **4.7.2 Delivery**

Upon documentation of fetal lung maturity at 370 weeks gestation, delivery will occur via cesarean section. If fetal lung maturity is not demonstrated, delivery will be delayed five to seven days. Delivery by cesarean section is necessitated by the presence of the fundal hysterotomy scar. If the

patient experiences preterm labor at less than 340 weeks gestation unresponsive to tocolytic therapy, rupture of membranes at less than 340 weeks gestation, chorioamnionitis, suspected uterine rupture, placental abruption or a non-reassuring fetal status, she will be delivered via cesarean section.

Although the same abdominal incision will usually be used for the cesarean section as for the prenatal surgery, the fetus is preferably delivered via a lower uterine segment incision. The uterine and abdominal incisions will be closed in routine fashion. A full description of the hysterotomy site will be recorded.

Babies will be stabilized and routine neonatal evaluation will be performed. If the fetal repair of the myelomeningocele was unsuccessful, standard postnatal operative repair of the myelomeningocele will be performed as soon as the baby is stable, usually within 48 hours of delivery, by the MOMS Center surgical team.

#### **4.7.3 Postnatal Surgery Group**

Patients randomized to the postnatal surgery group will return to their community of origin for prenatal care under the direct supervision of a perinatologist. The team perinatologist or PI will contact the local perinatologist directly to facilitate a smooth transfer of patient information and follow-up plans. A standardized letter will be sent to the local perinatologist detailing the patient management guidelines. Obstetrical ultrasonography will be obtained monthly at the closest prenatal diagnosis center. All prenatal records, and ultrasound tapes will be regularly forwarded to the participating MOMS Center where the patient was randomized, as outlined above.

At 370 weeks, if the patient is undelivered, the woman and her support person will return to the participating MOMS Center for delivery. Once at the center, the MOMS Center team perinatologist will perform an amniocentesis for pulmonary maturity studies, if necessary. Demonstration of fetal lung maturity may be made by appropriate interpretation of LS, FLM, TDX, or PG. If fetal lung maturity is not demonstrated, delivery will be delayed by 5 to 7 days. If the amniocentesis results indicate a low risk of pulmonary immaturity, or if performance of an amniocentesis is not technically possible, she will be assessed preoperatively, and cesarean birth will be performed. Patients will be delivered operatively because of evidence suggesting that children with myelomeningocele have increased neurologic deficits if not delivered by cesarean section.<sup>32,33</sup>

If the patient experiences preterm labor before 370 weeks gestation unresponsive to tocolytic therapy, rupture of membranes before 370 weeks gestation, chorioamnionitis, suspected uterine rupture, placental abruption or a nonreassuring fetal status, she will be delivered at her community of origin via cesarean section.

Postnatal repair of the myelomeningocele is not an emergency procedure. Babies will be stabilized and routine neonatal evaluation will be performed. Standard postnatal operative repair of the myelomeningocele will be performed when the baby is stable by the same MOMS Center surgical team that completes the prenatal repairs. Infants with myelomeningocele usually have a one- to two-week hospitalization during which time growth and development as well as the development of hydrocephalus is monitored and baseline assessments of the genitourinary and musculoskeletal systems are performed.

#### **4.8 Adverse Event Reporting**

Detailed information concerning adverse events will be collected and evaluated throughout the conduct of the protocol. The NICHD Program Scientist will be notified immediately by telephone of any maternal, fetal or neonatal deaths. An Adverse Event Report Form will be sent by fax within twenty four hours to the DSCC and the NICHD. If the patient is in the fetal surgery group, a copy should also be forwarded to the appropriate local Oversight Committee. A copy of the patient's medical record should be made and sent to the DSCC.

Any event that is serious and/or unexpected in nature, severity, or frequency will also be reported promptly by completing an Adverse Event Report Form to be sent to both the NICHD and the DSCC. A copy of the patient's medical record will be made, as the DSCC may request this at a later date for review by the Data and Safety Monitoring Committee (DSMC).

The DSMC will review all Adverse Event Report Forms and other interim safety data and will provide a report to the principal investigators, to the local Oversight Committees and to the IRBs.

#### **4.9 Neonatal Magnetic Resonance Imaging And Ultrasound**

MRI of the head and the spine, and an ultrasound of the head will be obtained before discharge. The MRI films and ultrasounds will be forwarded to the DSCC for blinded central review by an independent committee of radiologists. (the Radiology Review Committee).

#### **4.10 Psychological Testing**

All mothers will be asked to complete the SWLS, LOT, and BDI within one month of delivery. For those women randomized to the postnatal surgery group, the psychosocial assessments should be obtained after surgical repair of the myelomeningocele. For those mothers not delivering at the participating MOMS Centers, the questionnaires will be mailed to their homes for completion. If the BDI indicates that the mother is depressed, she will be referred to a mental health professional.

#### **4.11 Infant Neurosurgical Management**

For all patients delivered at the assigned MOMS Center, postnatal management of the neonate will be provided by the neonatologists at the MOMS Center and by the neurosurgeon of the multidisciplinary MOMS Center team. For patients who deliver at their community of origin, postnatal neurosurgical management will be conducted in consultation with the MOMS Center team neurosurgeon. This will include a request for an MRI to be done at neonatal discharge. The team neurosurgeon will contact the local neurosurgeon directly to facilitate smooth transfer of patient information, management guidelines and follow-up plans. All neonatal and infant records will be regularly forwarded to the assigned MOMS Center.

When the infant is discharged from the MOMS Center, postnatal neurosurgical management for the first year of life will be conducted in consultation with the MOMS Center team neurosurgeon. The infant will receive serial physical examinations, measurement of head circumference and ultrasound or CT assessments of hydrocephalus. Most often the need for shunting becomes manifest in the first six weeks of life as indicated by increasing head circumference, bulging

fontanelles, and increasing hydrocephalus on serial imaging studies. Strict criteria for shunting will be applied (below). Any decision to shunt made at the home institution will be done in consultation with the team neurosurgeon from the assigned MOMS Center using the established criteria, with the other center neurosurgeons as additional consultants if necessary. It is not feasible to expect patients to return to the MOMS Center if the need for shunting develops, as transportation could significantly delay needed decompression.

#### **4.12 Interim Infant Follow-up**

The study coordinator at each participating MOMS Center will be responsible for maintaining contact with the patient throughout the three-year follow-up period. Successful follow-up depends on continuing and regular interaction of the study coordinator with the patients. For example, telephone calls, reminder notes, cards, arrangements for transportation and regularly scheduled visits all impact on the success of the follow-up.

All patients will be contacted at least every three months by phone and questioned regarding any medical developments that might have occurred over that period of time. A detailed history of neurologic function will be taken including a history of neurological procedures, neurologic signs and symptoms and overall neurologic function. The study coordinator will also obtain a detailed history of urologic function including a history of continence or incontinence, urinary tract infection, need for catheterization, and catheterization schedule as well as information regarding fecal continence or incontinence. Once the infant is of walking age, data regarding ambulation status will be obtained. If infants underwent a Brain Stem Auditory Evoked Response test, swallowing profile, video urodynamic studies, renal sonography and/or an ophthalmologic examination, a copy of the records of these examinations will be forwarded to the participating MOMS Center. Copies of radiographs of the feet, lower extremities, hips and spine will also be forwarded to the participating MOMS Center.

#### **4.13 Twelve And Thirty Month Follow-Up Visits**

All patients and their infants will be required to return to the assigned MOMS Center for purposes of follow-up at twelve months chronological age and thirty months corrected age. Outcome Evaluation Teams each comprised of a developmentalist, a psychologist or psychometrist, and DSCC staff, will travel to the participating MOMS Centers to conduct neurologic, muscle strength and developmental examinations. The developmentalist and psychologist will be independent investigators not associated with the MOMS Centers. If a patient and her infant cannot return to her assigned MOMS Center, arrangements will be made for her to either have her follow-up visit at one of the other MOMS Centers or for the Outcome Evaluation Team to go to her home Spina Bifida clinic to conduct the examinations.

To assure standardization, all examiners will receive central training and certification prior to the start of the follow-up examinations. Only examiners who have been centrally certified will conduct the follow-up exams. To retain certification, each examiner will submit a videotape of a study exam annually and the accompanying data forms.

The examiners will be blinded as to which surgery group the patient was randomized to. Thus, the examiners will be instructed to refrain from asking the mother about her pre- or post-natal

experiences. In addition, the parents will also be asked to refrain from revealing this information. Both written guidelines and verbal instructions will be provided to the families in advance of the follow-up visits. DSSC personnel will be present to monitor compliance.

The study coordinators will compose summaries of the evaluations, which can then be sent to the families, their physicians, or both. The following procedures will be conducted.

#### 4.13.1 Imaging

A plane x-ray of the spine and a MRI of the head and spine will be obtained at the one-year follow-up visit. This will be used to determine the anatomic level of the lesion for the primary outcome.

#### 4.13.2 Neurological Exam

A neurological examination will be conducted at the 12 and 30 months follow-up visits. This will include measurement of tone, deep tendon reflexes, coordination and movement (not including eye movement). The Gross Motor Function Classification System will be conducted at 30 months.<sup>34</sup> The Gross Motor Function Classification System is based on self-initiated movement with particular emphasis on sitting (truncal control) and walking. The primary criterion in the design of the system is that the distinctions in motor function between levels are clinically meaningful. Distinctions between levels of motor function are based on functional limitations, the need for assistive technology including mobility devices and wheeled mobility, and to a much lesser extent quality of movement.

#### 4.13.3 Muscle Strength Testing

At each evaluation, patients will receive the Manual Muscle Test, a standardized test of muscle strength and lower extremity function graded on a 0-5 scale that enables assignment of a specific neurological level to each leg of a patient. Individual muscles or muscle groups are tested at the hip, knee and ankle bilaterally. These can, in turn, be related to radicular level (L1-S1) using a standard form.<sup>35,36</sup> In instances where there is a discrepancy between legs, the more rostral ("worse") level will be used. Additional parameters tested will include range of motion and general tone.

#### 4.13.4 Developmental Testing

Psychological/developmental assessments will be conducted on all infants at each study visit. Direct administration of standardized measures to the children will be combined with parent interviews at each level to obtain information about the children's skills and behavior across multiple domains of development. A summary of the developmental examinations is presented below:

**TABLE 5: DEVELOPMENTAL TESTING**

	TEST	VISIT
<b>Gross Motor</b>	Mullen Scales of Early Learning	12 and 30 months
	Bayley Scales of Infant Development	12 and 30 months
	Gross Motor Classification System	30 months only

**TABLE 5: DEVELOPMENTAL TESTING (CONTINUED)**

	TEST	VISIT
<b>Fine Motor</b>	Mullen Scales of Early Learning	12 and 30 months
	Bayley Scales of Infant Development	12 and 30 months
<b>Cognitive</b>	Bayley Scales of Infant Development	12 and 30 months
<b>Behavior</b>	Behavior Rating Scale of the Bayley	12 and 30 months
	Child Behavior Checklist for ages 2-3	30 months only
<b>Language</b>	Mullen Scales of Early Learning	12 and 30 months

At twelve months and at thirty months corrected age, the Mullen Scales of Early Learning will be conducted. This scale has five subscales: gross motor, visual receptor, fine motor, expressive language and receptive language. The Bayley Scales of Infant Development-II (BSID) has two subscales, the mental scale and the motor scale, and a Behavior Rating Scale, which is completed by the examiner after the mental and motor scales. The mental scale includes an assessment of sensory/perceptual acuities, discriminations and response; acquisition of object constancy; memory, learning and problem solving; and vocalization. It also includes an assessment of the beginning of verbal communication, basis of abstract thinking, habituation and mental mapping. The motor scale includes an assessment of the degree of body control, large muscle coordination, finer manipulatory skills of the hands and fingers, dynamic movement, dynamic praxis, postural imitation and stereognosis. The Bayley Behavior Rating Scale rates the child's test taking behaviors and measures attention/arousal, orientation/engagement, emotional regulation and motor quality. The Child Behavior Checklist will be administered at the 30-month follow-up exam. It provides the parents' ratings of the child's behavior including what concerns the parent most about their child, and the best things about their child.

**4.13.5 Video Urodynamics And Renal Sonography**

If video urodynamic studies have not been conducted as part of the routine follow-up care at the infant's home Spina Bifida clinic in the previous year, these studies will be completed at the thirty-month follow-up examination for study purposes. This study is routinely performed with video fluoroscopy so that a voiding study can be performed in the same sitting. A specially designed catheter is passed per urethra through which irrigant is carefully infused into the bladder at a slow and steady rate. Pressures are electronically measured as the bladder fills. A similar catheter is placed in the rectum to measure external abdominal pressure, which is subtracted from the bladder measurements to determine the true pressure generated by the native bladder alone. Once full, bladder emptying is assessed both in terms of bladder pressure, urinary flow rate, and the completeness of emptying. Electrical activity in the sphincters is measured as well.

Likewise, if sonography of the urinary tract has not been completed as part of routine follow-up care at the infant's home Spina Bifida clinic in the previous year, it will be completed at the thirty-month follow-up examination for study purposes. Images will be obtained in the longitudinal and transverse planes. The length of both kidneys will be measured and correlated with established normal size for age. The presence or absence of hydronephrosis and ureteronephrosis will be determined and classified as mild, moderate, or severe and bladder wall thickness will be assessed.

#### 4.14 Parental Follow-Up

Mothers and their partners (fathers) will complete the SWLS, LOT and BDI at the 12 and 30-month follow-up visits and the mothers will be evaluated for reproductive function at the 30-month follow-up visits. If the results of the BDI indicate that the either parent is depressed, he or she will be referred to a mental health professional.

#### 4.15 Outcome Measures

##### 4.15.1 Primary Outcomes

1. Death or the need for ventricular decompressive shunting by one year of life. This composite outcome was chosen to avoid the problem of competing risks, which can be a source of bias.<sup>37</sup> This concern arises when the assessment of the desired outcome cannot be made because of the competing risk of another outcome; in this case an infant that dies cannot be assessed for shunt placement. However, by including death as a component, the primary outcome can be evaluated for all patients. This is intuitively reasonable, since if one treatment improves the shunt rate at the expense of an increased death rate, it should not be judged superior. It should be noted that all fetal and neonatal deaths, including terminations, would qualify for this outcome. There is also a potential for assessment bias in the need for shunting. This is avoided by the use of objective criteria for shunting as follows:
  1. Cerebral spinal fluid leakage from the myelomeningocele wound  
or
  2. Bulging at the myelomeningocele wound  
or
  3. Any two of the following:
    - An increase in the greatest occipital-frontal circumference at a rate of greater than one centimeter per week
    - An evaluation of the fontanelle as bulging and pulsating or bulging and hard using the following scale: sunken and soft, flat and soft, bulging and soft, bulging and pulsating, and bulging and hard
    - Increasing hydrocephalus on two consecutive ultrasounds or CTs determined by increase in ratio of biventricular diameter to biparietal diameter measured at the foramen of Monro  
or
  4. In infants less than one week old, a fontanelle evaluated as bulging and hard, together with ventriculomegaly and any of apnea, bradycardia or lethargy  
or
  5. Development of marked syringomyelia by imaging studies. For this criterion, the MOMS Center neurosurgeon should contact the other two neurosurgeons to review the case.

The necessity for a shunt will be assessed using a blinded adjudication process. Copies of medical records and imaging studies for all infants will be sent to the DSCC, which will be responsible for ensuring that the medical records do not reveal the assigned surgery group of the infant. The MRI obtained at the twelve-month visit to the MOMS Center will be included in the medical records to be reviewed. The records of all infants in the trial will be reviewed by two members of the Shunt Outcome Review committee to determine whether they did or did not meet the criteria for shunt placement. If the two members do not agree, the third member of the committee will review the records and the whole committee will adjudicate the case.

**2.** A composite outcome of two measures:

- Bayley Scales of Infant Development: The outcome score, evaluated at thirty months corrected age, will consist of the Mental Development Index (MDI) or a score of zero for death. Death is included so that the outcome is measurable in all patients. The MDI scores will be ranked and deaths will receive the lowest rank. The Bayley Scales will be administered by independent trained evaluation teams, who will be unaware of the child's assigned surgery group.
- Distal somatosensory function and motorsensory assessment of level of lesion, evaluated in relation to anatomic level. This can be expressed as the difference between the anatomic and the functional level. The plane x-ray obtained at the 12 month visit will be used to determine the anatomic level. These scores will also be ranked and deaths will receive the lowest rank.

The composite outcome consists of the sum of these two ranks.

#### **4.15.2 Secondary Outcomes**

Secondary outcome measures for this study include the following:

##### **4.15.2.1 Maternal/Paternal**

1. Gestational age at delivery
2. Maternal death
3. Oligohydramnios
4. Uterine rupture
5. Maternal and paternal psychosocial status as measured by the SWLS, LOT and BDI at delivery, 12 and 30 months after delivery
6. Maternal reproductive functioning at 30 months post delivery

##### **4.15.2.2 Neonatal**

Neonatal morbidity and mortality including:

1. Neonatal death or stillbirth
2. Bronchopulmonary dysplasia,

3. Pulmonary interstitial emphysema
4. Retinopathy of prematurity
5. Pulmonary hypoplasia
6. Necrotizing enterocolitis
7. Patent ductus arteriosus
8. Seizures
9. Intraventricular hemorrhage
10. Periventricular leukomalacia
11. Sepsis

#### 4.15.2.3 Infant

1. Radiographic appearance of the Chiari II malformation - measured in millimeters of cerebellar herniation below the foramen magnum. Copies of the head MRIs will be forwarded to the DSCC for central reading by the Radiology Review Committee. Since there is no uniform grading scale available, the Radiology Review Committee in consultation with the pediatric neuroradiologists from the MOMS Centers will develop a grading system for the Chiari malformation based on:

- Location of cerebellar tonsils in relation to the foramen magnum
- Presence and location of a cervicomedullary kink
- Size and location of the fourth ventricle
- Additional secondary criteria, including the presence of hydrocephalus

Review of the MRIs will be conducted by the Radiology Review Committee, blinded to the assigned surgery group of the infant.

2. Number of shunt revisions
3. Number of surgical procedures for related conditions such as tethered cord, hydrosyringomyelia, feeding problems, gastrointestinal reflux, urinary or fecal control, genitourinary reflux, and orthopedic deformities including kyphoscoliosis by 30 months
4. Locomotion - independent ambulation vs. braces vs. wheelchair bound at 30 months'
5. Brain stem function as measured by swallowing profile and BSAER tests
6. Motor scales from the Bayley Scales of Infant Development
7. Rating of functional impairment from the Gross Motor Function Classification System
8. Number of days of total hospitalization for the infant (through 30 months)

**5 STATISTICAL CONSIDERATIONS**

**5.1 Sample Size And Power**

Although there are two primary outcomes, an adjustment for two comparisons to type I error was not included in the calculation of sample size. The outcomes may well be correlated and they may be of differing clinical significance.

**5.1.1 Death Or VP Shunt**

Among 416 children followed at the Spina Bifida Clinic at CHOP, the overall shunt rate at one year of age was 84%. However, it is very possible that the shunt rate observed in the trial for the postnatal surgery group will be lower; therefore a range of shunt rates are considered. A 30% reduction in shunt rate (among survivors) would be considered clinically significant. Although higher apparent reductions from historical shunt rates have been shown among the surgeries performed before 25 weeks at both CHOP and Vanderbilt, it is possible that a smaller reduction will be observed in the trial, since many potential confounding factors and biases will be removed.

Table 6 below shows total sample sizes required for power 80%, type I error 5% 2-sided, using the method of Casagrande, Pike and Smith.<sup>38</sup> The primary outcome rates were calculated assuming 0, 5% and 10% death rate in both groups, a shunt rate in survivors of 70-80% in the postnatal group and at least a 30% reduction in the prenatal surgery group. The sample size was adjusted for a loss to follow-up rate of 5%.

**TABLE 6: SAMPLE SIZES FOR VARIOUS SHUNT RATES AND DEATH RATES BY 1 YEAR OF AGE; POWER 80%, TYPE I ERROR 5% 2-SIDED, WITH 5% LOSS TO FOLLOW UP**

1-year death rate in postnatal and prenatal surgery groups	1-year shunt rate in survivors - postnatal surgery group	1-year shunt rate in survivors - prenatal surgery group (30% reduction)	Primary outcome rate in postnatal surgery group	Primary outcome rate in prenatal surgery group	Reduction in primary outcome	Total sample size	Sample size adjusted for loss to follow-up
0%	70%	49.0%	70.0%	49.0%	30.0%	188	198
	75%	52.5%	75.0%	52.5%	30.0%	158	168
	80%	56.0%	80.0%	56.0%	30.0%	132	140
5%	70%	49.0%	71.5%	51.6%	27.9%	204	216
	75%	52.5%	76.3%	54.9%	28.0%	171	180
	80%	56.0%	81.0%	58.2%	28.1%	142	150
10%	70%	49.0%	73.0%	54.1%	25.9%	222	248
	75%	52.5%	77.5%	57.3%	26.1%	185	206
	80%	56.0%	82.0%	60.4%	26.3%	154	172

Given a death rate in both groups of 5% (fetal and neonatal deaths), the actual reduction in the composite outcome would be about 28%. In the fetal surgery cases to April 2002, the one-year death rate is 5.2% (11/212). Overall, assuming a primary outcome rate in the postnatal surgery group of 80%, a total of 100 patients per group will yield over 90% power to detect a 28% reduction, with 5% loss to follow-up.

### 5.1.2 Composite Outcome Of Bayley Scales Of Infant Development MDI Score And Motor Function

The second primary outcome is a composite of:

- a) Bayley Scales of Infant Development mental developmental index MDI, and
- b) Motor function, calculated as the difference between anatomic and functional level.

The anatomic and function level will be measured as described in Luthy, et al.<sup>35</sup> Functional and anatomic lesion level are scored from 1 (C1) to 29 (S5) with 30 indicating no motor impairment. Due to the inclusion criteria, anatomic lesion level can range from T1 (scored as 9) to S1 (scored as 26). Motor function will be scored as functional level - anatomic level. The highest score possible mathematically would be in a child with an anatomic lesion level of T1 and no motor impairment, or  $30-9 = 21$ . Negative scores are possible for the child with lower functional level than predicted by lesion level. The lowest negative score possible mathematically would be in a child with an anatomic lesion level of S1 and a functional level of T1, or  $9-26 = -17$ . Death can be assigned a score of -18. For the Bayley MDI, death can be represented by zero.

As proposed by O'Brien<sup>39</sup> a composite measure of both factors (the Bayley MDI and functional minus anatomic level) will be created by ranking the measurements for each factor separately and calculating the sum of the ranks for each individual. For example, if an infant has the highest Bayley MDI and the most improvement in functional level compared with the anatomic level, his or her rank sum will be 200. The advantage of using a method based on ranks is that death is taken into account by assigning the lowest rank: an infant that dies will receive a rank sum of 2. Under the null hypothesis that there is no difference between the two groups and if the two measures are independent (i.e., the Bayley Mental Developmental Index is independent of the improvement in expected motor function level) the mean and variance of the rank sum is a constant depending only on sample size. Under the alternative hypothesis that there is a difference between the prenatal and postnatal surgery groups, however, the mean and variance of the rank sum depends on the probability that an observation drawn at random from one group (say, fetal surgery) is larger than an observation drawn from the other group (postnatal surgery) as well as similar joint probabilities based on the relationship between several observations. Death can be taken into account when calculating these probabilities. For example, if X is an observation from the prenatal surgery group and Y an observation from the postnatal surgery group then the probability that X is greater than Y,  $P(X > Y)$ , is given as follows:

$$P(X > Y) = P(X \text{ is a survivor}) \cdot P(Y \text{ is a death}) + P(X > Y \text{ given } X \text{ and } Y \text{ both survivors}) \cdot P(X \text{ is a survivor}) \cdot P(Y \text{ is a survivor})$$

since if X represents a death it is assigned the lowest possible score and cannot be greater than Y. If death rate d is observed in both groups, this becomes

$$P(X > Y) = (1 - d) d + (1 - d)^2 P(X > Y \text{ given } X \text{ and } Y \text{ are both survivors}).$$

Although the rank sum does not have a normal distribution and the rank sums for individuals are correlated, the central limit theorem can be invoked<sup>39</sup> and the normal distribution used to

calculate power and sample size. O'Brien showed that a test based on this rank sum performs reasonably well.

There is more than 90% power to show a difference in rank sum, or effect size, of 0.5 standard deviations. However, this does not have intuitive meaning and it is useful to relate this to the differences which might be observed in the Bayley MDI and the functional minus anatomic level. Under the assumption that for survivors the Bayley MDI and the functional minus anatomic level have a bivariate normal distribution and that the two groups have equal variances, it is possible given various death rates and correlations between the two measures among survivors to calculate the power to show a difference between the two treatment groups given a sample size of 95 in each group, to account for 5% loss to follow up.

From data on 34 infants born following fetal surgery at CHOP, the mean and standard deviation of the difference between the anatomic and functional levels was 1.65 and 2.3 segments, respectively. Therefore 2.5 segments is a reasonable estimate of the standard deviation and is also consistent with Luthy et al.<sup>32</sup> The table below shows the power for mean differences of 1 segment or 0.4 standard deviations and 1.25 segments or 0.5 standard deviations. The Bayley MDI is assumed to have a standard deviation of 15. Thus a mean difference of 5 points is equivalent to one third of a standard deviation, and 10 points to two thirds.

As can be seen in the table below, both the correlation between the two measures and increasing the death rate tend to reduce the power.

**TABLE 7. POWER FOR VARIOUS DIFFERENCES IN BAYLEY MEAN MDI AND FUNCTIONAL MINUS ANATOMIC LEVEL (ASSUMING A NORMAL DISTRIBUTION) AND THE CORRESPONDING STANDARDIZED DIFFERENCE IN MEAN RANK SUM**

1-year death rate in postnatal and prenatal surgery groups	Correlation between Bayley MDI and functional - anatomic level among survivors	Difference in mean Bayley MDI	Difference in mean functional - anatomic level		
			No difference	1 segment 0.4 sd	1.25 segments 0.5 sd
0%	0	No difference		47.5%	65.8%
		5 points: 0.33sd	35.3%	93.9%	97.9%
		10 points: 0.67sd	88.1%	99.9%	99.9%
	0.25	No difference		40.0%	56.6%
		5 points: 0.33 sd	29.6%	88.4%	94.8%
		10 points: 0.67sd	80.6%	99.6%	99.9%
	0.5	No difference		34.5%	49.4%
		5 points: 0.33sd	25.5%	82.2%	90.6%
		10 points: 0.67sd	73.3%	98.7%	99.6%

**TABLE 7. POWER FOR VARIOUS DIFFERENCES IN BAYLEY MEAN MDI AND FUNCTIONAL MINUS ANATOMIC LEVEL (ASSUMING A NORMAL DISTRIBUTION) AND THE CORRESPONDING STANDARDIZED DIFFERENCE IN MEAN RANK SUM**

1-year death rate in postnatal and prenatal surgery groups	Correlation between Bayley MDI and functional - anatomic level among survivors	Difference in mean Bayley MDI	Difference in mean functional - anatomic level		
			No difference	1 segment 0.4 sd	1.25 segments 0.5 sd
5%	0	No difference		34.8%	49.5%
		5 points: 0.33sd	25.8%	81.7%	90.0%
		10 points: 0.67sd	72.7%	98.4%	99.4%
	0.25	No difference		30.5%	43.7%
		5 points: 0.33sd	22.7%	75.6%	85.2%
		10 points: 0.67sd	66.0%	96.8%	98.7%
	0.5	No difference		27.2%	39.0%
		5 points: 0.33sd	20.3%	69.8%	80.2%
		10 points: 0.67sd	60.2%	94.7%	97.4%
10%	0	No difference		25.7%	36.7%
		5 points: 0.33sd	19.3%	66.2%	76.6%
		10 points: 0.67sd	56.5%	92.4%	95.9%
	0.25	No difference		23.3%	33.3%
		5 points: 0.33sd	18.2%	61.2%	71.8%
		10 points: 0.67sd	55.2%	89.4%	93.9%
	0.5	No difference		21.4%	30.4%
		5 points: 0.33sd	16.3%	56.8%	67.4%
		10 points: 0.67sd	47.8%	86.3%	91.5%

For example, if the Bayley MDI and the difference in functional and anatomic levels have a correlation as high as 0.25, the death rate is 5% and in the fetal surgery group there is a 5 point increase in mean MDI and 1 segment improvement in mean difference between the anatomic and functional level, there would be 85% power to show a difference. If the Bayley score and the motor function score were independent, then there would be over 90% power to show a difference. The latter combination would be equivalent to an overall effect size of 0.5 standard deviations.

### 5.1.3 Secondary Outcomes

A sample size of 200 patients will also yield reasonable power for the secondary outcomes. For the rating scale of Chiari malformation, which is an ordered categorical outcome, power may be calculated based on the proportional odds model.<sup>40</sup> If in the postnatal surgery group, 5%, 50%, 30% and 15% had Chiari grades 0-1, 2, 3 and 4+ respectively (see Table 4), there would be between 70% to 80% power to detect an odds ratio of 2.0 (as was observed) for fetal surgery to yield a given grade or better versus worse than that grade.

## 5.2 Analysis Plan

### 5.2.1 Interim Analysis Of Outcomes

During the trial, the external Data and Safety Monitoring Committee will meet periodically to review trial results. Interim reports analyzing the primary outcome pose well-recognized statistical problems related to the multiplicity of statistical tests conducted on the accumulating data. The timing of the interim analyses is at the discretion of the Data and Safety Monitoring Committee. The group sequential method of Lan and DeMets will be used to characterize the rate at which the type I error is spent. The chosen spending function is the Lan-DeMets<sup>41</sup> generalization of the O'Brien-Fleming boundary. This method is flexible with regard to the timing of the interim analyses.

The Data and Safety Monitoring Committee may also be consulted at any time if safety concerns arise during the conduct of the study. In this trial the primary outcome determinations are remote from delivery yet the perinatal period is probably the time of greatest risk of death for fetuses undergoing the experimental treatment. The DSCC will continuously monitor cases of fetal/neonatal mortality during the trial, i.e., whenever an adverse event notice of death is received. If Fisher's exact test were to show evidence of harm with a nominal p-value < 0.1, the coordinating center would contact the NICHD representative on the DSMC and the Chair of the DSMC who would then decide whether to suspend recruitment and/or call a meeting or conference call to review the data. Alternatively, the DSMC may consider it desirable to set up a stopping boundary for this outcome as suggested by Bolland and Whitehead.<sup>42</sup> The fact that fetal or neonatal death would be included as a component of the primary outcome complicates the statistical interpretation, but as the authors note, "the ethical requirement to monitor safety is of far greater importance than the preservation of the mathematical purity of the efficacy analyses." However, p-values for efficacy calculated ignoring the safety rule would, if anything, be conservative.

Even though recruitment will end before virtually any primary outcome data is available, a formal interim analysis will take place before the final follow-up data are accrued but after seven months of follow-up to determine if the boundary has been crossed. Conditional power analyses will be calculated under various hypotheses. The DSMC may then be able to make a recommendation to the MOMS Centers regarding offering fetal surgery to patients outside of the trial.

Before each DSMC meeting, a formal detailed statistical report will be written based on all existing study data as of four to six weeks before the meeting (recruitment updates and other updated information can be brought to the meeting, as required). The report presents the results of every aspect of the study,<sup>43</sup> including baseline variables, protocol adherence, outcome variables, adverse events reported and MOMS Center performance in terms of recruitment, data quality, loss to follow-up and protocol violations. For the evaluation of the primary outcome, a different cohort of patients is chosen consisting of all patients randomized before a certain date so that selection bias does not directly or indirectly affect the study results.

### 5.2.2 Primary Analysis Plan

All statistical analyses will be based upon the total cohort of patients randomized into the trial. Although data on some patients may be missing at points in time, all relevant data available from each patient will be employed in all analyses. Patients will be included in the surgery group to

which they are randomly assigned regardless of compliance. It is generally agreed that analysis according to this "Intention to Treat" principle provides the most unbiased assessment of the true therapeutic benefits of a treatment.<sup>37,44,45</sup>

The primary analysis of the shunt/death outcome will consist of a simple comparison of binomial proportions. The relative risk and confidence interval will be reported. The individual components of this composite outcome will also be examined in addition to an analysis of the actual placement of the shunt as opposed to the need for a shunt. Although as stated above, the intent to treat principle should be applied, in the presence of losses to follow-up this is not possible unless an assumption is made regarding the outcome of those lost. Thus, the primary comparison will not include the lost to follow-up patients. However, a sensitivity analysis will be performed including these patients, with different assumptions regarding their outcome, to determine whether the results are robust. A sensitivity analysis will also be performed to examine whether actual placement of the shunt versus meeting criteria for a shunt affects the study conclusions. Stratified analyses will be conducted, in particular by lesion level, gestational age and center, all of which have been shown in previous analyses to be related to the outcome. Interactions will be evaluated.

A similar strategy will be employed for the Bayley MDI/Motor Function composite score. Although the power analysis is based on a parametric analysis, the Mann-Whitney (Wilcoxon) test will be used to compare the two groups. The Wei-Lachin<sup>46</sup> method will be used to conduct stratified analyses, adjusting for environmental factors such as parent education level and socioeconomic status.

### 5.2.3 Secondary Analysis

Many of the baseline and outcome measurements are qualitative. For example, biodemographics, complications of the antenatal, intrapartum, postpartum and neonatal period are predominantly dichotomous responses (i.e., yes, no). For these measurements, standard statistical methods for rates and proportions are appropriate.<sup>47</sup> For baseline and outcome measures that are quantitative (e.g., anthropometrics, blood pressure) and, standard parametric and nonparametric statistical methods, such as the Wilcoxon Rank Sum test, are appropriate. Time elapsed to the occurrence of an event is another type of variable encountered, such as latency of the pregnancy or time to shunt failure. For such measurements, life-table analyses are used to compare differences between groups<sup>48</sup> and the logrank test or related statistics<sup>49</sup> can be employed to test differences between survival curves. An extension of survival analysis or time to a single event is the possibility for multiple recurrent events over time in each patient, such as surgeries for shunts or preterm labor episodes. A family of statistical methods based on the theory of counting processes can be applied to such data.<sup>50</sup> For variables that are ordinal such as rating of functional impairment and functional level from the Manual Muscle test, the Mantel-Haenszel test of trend will be used.

For some outcomes, response of each study participant may be observed on two or more occasions. Standard linear models for repeated measures data will be applied to these data.<sup>51</sup> For Gaussian random variables, these include the linear model with structured covariance matrices<sup>52</sup> and the random-effects model.<sup>53</sup> For non-parametric analysis, the methods of Wei and Lachin,<sup>46</sup> may be used. Binary repeated measures, for example the presence or absence of a certain symptom, may be analyzed using the generalized estimating equation (GEE) model.<sup>54,55</sup>

In the analysis of clinical trials it has been traditional first to perform an overall assessment of treatment effect on the total cohort of patients, and then to perform various other analyses aimed at obtaining an adjusted assessment of treatment effectiveness, for example, adjusting for stratification factors used in randomization (clinical center) or other baseline patient characteristics (covariates). The objectives of these analyses include estimating the influence of covariates on the outcome and using covariates to improve the estimated difference of treatment groups.<sup>56</sup> The simplest such adjustment is a stratified adjustment, such as the Mantel-Haenszel procedure. A regression model, such as linear, logistic, or proportional hazards, depending on the type of outcome variable and on the fit, may be used to provide an interpretable adjustment for multiple baseline covariates simultaneously. The proportional odds logistic regression model may be used for ordinal measures such as the grading scale for the Chiari malformation or the Gross Motor Function scale.

A stepwise procedure for model building can be employed to select a subset of covariates that appear optimal but, because there is considerable ambiguity as to the statistical confidence one can have in the results of such selection procedures, split-half, jackknife or other model validation methods would also be applied.<sup>57</sup> These analyses are considered exploratory in nature and are not viewed as providing confirmatory tests of hypotheses or as describing causal associations. Rather, findings observed in such analyses are viewed with caution and used as a basis for consideration of future studies designed to test specific hypotheses.

Models that employ baseline covariates can be directly interpreted because of the temporal relationship between the observation of the baseline covariate, the initiation of the randomly assigned treatment, and the observation of the outcome. An important class of analysis concerns confounding factors arising post randomization, or time dependent covariates. If the covariate may be considered as an inherent patient characteristic, independent of surgery group allocation, then it can be included as a time dependent covariate in the models above, but it is quite plausible that for example, a factor measured at delivery, is correlated with the surgery group allocation, and including both in a linear model may result in invalid results. Analysis involving time dependent covariates must be carefully interpreted.

#### **5.2.4 Racial/Ethnic Subgroup Analysis**

Power is limited to detect moderate differences in the primary outcomes within the racial/ ethnic subgroups; however, this analysis is planned and if, for example shunt outcome is as dramatic as preliminary data suggest, there will be sufficient power (86%) with type I error 5% 2-sided, using Fisher's Exact test to detect a difference from 80% to 30% among Hispanics, if there are as many as 40 Hispanic patients. This kind of difference was seen at CHOP when compared with historical controls. Even for the other minorities, of whom about 27 patients are expected, there is 68% power.

## 6 DATA COLLECTION

### 6.1 Data Collection Forms

Data will be collected on standardized forms on which nearly all responses have been precoded. Forms will be mailed in on a weekly basis. The Randomization Form will, however, use a web-based data entry system since it will be linked to the Internet randomization procedure. The data collection forms are described briefly below. The first two forms are completed at the DSCC before referral to the MOMS Center; the remaining forms are completed at the MOMS Centers.

- SCR0: Initial Contact Form (completed for all interested parties at initial contact with the DSCC)
- SCR1: Central Screening Log (completed by the DSCC staff during central screening process)
- SCR2: Central Screening Form (completed by the DSCC after screening consent obtained and medical records reviewed)
- MOM1: Patient Evaluation Form (screening information completed for a patient referred to the MOMS Center; result of randomization assignment and reason for non-randomization, if applicable).
- MOM2: Psychosocial Evaluation Form (provides data on psychosocial evaluation and psychological testing prior to randomization)
- MOM3: Baseline Data Form (includes baseline demographics, medical history and current pregnancy history)
- MOM4: Previous Pregnancy Log (lists previous pregnancies and the general outcome of each)
- MOM5: Maternal/Fetal Surgery Form (for patients assigned to fetal surgery group, details of the surgery and hospital course)
- MOM6: Monthly Prenatal Visit Form (documents ultrasound parameters, tocolysis etc.)
- MOM7: Maternal Hospital Admission form (hospital admissions for complications)
- MOM8: Labor and Delivery Form (documents delivery information, including intrapartum or postpartum complications through discharge)
- MOM9: Neonatal Baseline Form (records anthropometric measures, Apgar scores and specific neonatal complications detectable at birth)
- MOM10: Neonatal Outcome Form (records specific neonatal complications and problems requiring admission to the NICU)
- MOM11: Postnatal Surgery Form (for infants repaired postnatally)
- MOM12: Infant Hospital Admission Form (documents rehospitalizations and emergency outpatient visits since discharge following birth)
- MOM13: Protocol Deviation/Withdrawal Form
- MOM14: Adverse Event Form
- MOM15: CNS MRI/Ultrasound/X-ray Log (documents imaging studies performed for the trial and sent for review)
- MOM16: Shunt Placement Form (documents specific indications for shunt placement and the consultation process)
- MOM17: Quarterly Infant and Parental Follow-up Form
- MOM18: Twelve Month Examination Form
- MOM19: Thirty Month Examination Form

Additional forms will be developed in-house for recording the results of the Shunt Outcome Review Committee and the Radiology Review Committee.

## **6.2 Central Data Entry System**

Data will be keyed at the DSCC into PC based data entry software set up to require validation of out of range values. Corrections or 'updates' received in writing at the DSCC in response to edit or audit messages (see below), are keyed together with incoming data forms. The core system is written in Visual FoxPro 6.0, with object-oriented design. Case report forms are keyed once and then independently re-keyed by the data entry operator.

## **6.3 Centralized Data Management System**

Once the data are keyed, they will be uploaded to the server on a weekly basis. The data processing entails both the addition of new data to the study database on the central server and the editing of new or replaced records. The newly entered records are added to permanently stored SAS data sets containing all data for the study. These will constitute the permanent study database. Records replaced in the updating procedure are added to a secondary file to form an 'edit trail' within which changes to the data over time may be traced.

The new and updated data are automatically edited using software developed in SAS on an intra-form basis. Intra-form edits include checks for items that should have been answered but are missing, items that should have been skipped but were completed instead, values that are out of range, and any other logical inconsistencies between items on a form. After review at the DSCC, edit printouts are returned to the center for correction or clarification on a weekly basis. At regular intervals, audit programs (also in SAS), which compare data across forms are run by the DSCC on the entire database or on a specific subset of data. Inter-form audits include checks for inconsistencies in a study participant's clinical profile, in date sequences, or on unlikely values for repeated measurements. These include longitudinal checks that compare forms over time (e.g., forms completed at an earlier visit with forms completed at a subsequent one). Audit reports are also submitted to the centers for correction.

Any problems detected by the software are logged into a permanent database which records the forms, fields, and values that were involved, the nature of the problem as well as information that allows the software to track the edit or audit until it is resolved.

## **6.4 Performance Monitoring**

The Steering Committee will assume overall responsibility for the management and conduct of the trial. This includes monitoring the performance of their own centers in terms of data quality, protocol adherence and recruitment.

The DSCC will make the following tools available to the Steering Committee for performance monitoring.

- **Data Quality Reports:** The DSCC will report to the Steering Committee on the volume of edits and audits (presented as the number per 1000 fields keyed), the time to edit

- resolution and the number of overdue forms. Data quality tables will be presented by center and time period, to identify both center and temporal problems. Data quality reports will be included in the Steering Committee reports that are generated quarterly.
- **Performance Reports:** The DSCC will generate reports of study progress on a monthly basis (recruitment reports) and on a quarterly basis (Steering Committee reports). The recruitment report will include enrollment efforts (screening numbers, reasons for ineligibility, recruitment numbers) by MOMS Center and will be distributed by e-mail. Full Steering Committee reports will be prepared quarterly to coincide with the meetings and conference calls. These reports will be more extensive than recruitment reports and will include recruitment data, protocol adherence data such as study participants apparently lost to follow-up or overdue, protocol violations, baseline characteristics, and data quality assessment.

In addition, the DSCC will report on center performance to the Data and Safety Monitoring Committee. For every meeting of the DSMC, a report is prepared which includes patient recruitment, baseline patient characteristics, center performance information with respect to data quality, timeliness of data submission and protocol adherence, in addition to analysis of outcomes.

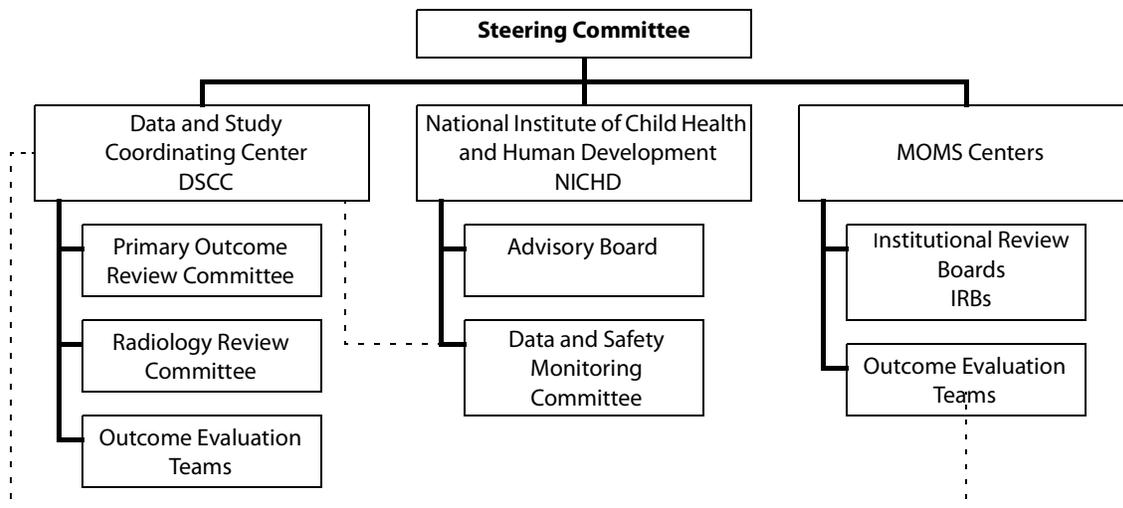
**7 STUDY ADMINISTRATION**

**7.1 Organization And Funding**

The study is being funded by the National Institute of Child Health and Human Development (NICHD). The study will be conducted by three MOMS Centers, the Data and Study Coordinating Center and NICHD, and is administered under cooperative agreements between each of the centers and NICHD. The study will be conducted under the auspices of the NICHD MFMU Network, although the three MOMS Centers do not coincide with any of the MFMU Network clinical centers. However, the data coordinating center of the Network will function as the DSCC for the Fetal Surgery Units Group; the MFMU Network Advisory Board and the Data and Safety Monitoring Committee will also serve the group.

A Principal Investigator represents each of the funded institutions. A diagram of the study organization is presented and each component described below.

**FIGURE 2. STUDY ORGANIZATION**



**7.1.1 Participating Clinical Centers**

The Principal Investigators of the three MOMS Centers have agreed to abide by the study protocol, to have comparable staff, facilities and equipment and to ensure the proper conduct of the study at each of their centers including: recruitment and treatment of patients as specified in the protocol, accurate data collection and the transmission of information to the Steering Committee.

**7.1.2 Data And Study Coordinating Center**

The Data and Study Coordinating Center (DSCC) is responsible for all aspects of biostatistical design, analysis and data management of the study, in addition to the interim and final statistical analyses and preparation of publications based on the study results. For this trial, the DSCC will also be responsible for advertising the trial, serving as a referral center for interested patients or the

public, and for coordinating the outcome evaluations, including both the review of MRIs and ultrasounds, as well as the infant follow-up examinations. The Principal Investigator of the DSCC reports to the Steering Committee and the Data and Safety Monitoring Committee.

### **7.1.3 NICHD**

In addition to its role as funding agency, the NICHD participates in the activities of the Network, including the development of the protocol, administration and conduct of the study and preparation of publications.

### **7.1.4 MFMU Network Advisory Board**

Appointed by the NICHD, the members of the MFMU Network Advisory Board consist of a group of experts representing the disciplines of maternal-fetal medicine, neonatology, biostatistics and epidemiology who are not affiliated with research being conducted by the Network. Additional ad-hoc members with expertise in neonatal/fetal surgery and perinatal ethics will be added for this trial. The role of the board includes reviewing the proposed study, in addition to identification of scientifically and clinically important questions that the study could feasibly be modified to answer. The NICHD program officer convenes and attends the meetings.

## **7.2 Committees**

### **7.2.1 Steering Committee**

The Steering Committee will be the policy and decision-making group, and assume overall responsibility for the management and conduct of the trial. This committee consists of five members. The Principal Investigator from each of the three MOMS Centers and the Data and Study Coordinating Center, and the NICHD MFMU Network Program Scientist are all voting members. Dr. Mary D'Alton, who is not affiliated with any participating center chairs the Steering Committee. The Chairman of the Steering Committee may vote to break a tie. Steering Committee meetings will be held twice per year during recruitment, once per year thereafter, with interim videoconference calls quarterly. The committee receives recommendations from the Data and Safety Monitoring Committee and the Network Advisory Board.

Unlike the MFMU Network, there will be no separate Publications Committee. However, the Publications Policy developed by this committee will be used as basis for a publications policy for this study group (see publication policy, below).

### **7.2.2 Data And Safety Monitoring Committee**

The DSMC is a group of individuals not affiliated with any of the participating MOMS Centers and free of real or apparent conflict of interest. This committee is established by the NICHD for the MFMU Network and represents expertise in ethics, clinical trial design, perinatology, neonatology and basic science. Ad-hoc members with expertise in pediatric/fetal surgery and perinatal ethics will be included for this trial. The DSMC is charged with reviewing the protocol with respect to ethical and safety standards and making recommendations as necessary. This committee will monitor the emerging results for safety and efficacy. The DSMC will also review the performance of

the trial in terms of recruitment, protocol adherence and data quality. The interval and timing of DSMC meetings after the initial review of the protocol is at the discretion of the committee itself.

### **7.2.3 Local Oversight Committees**

Each MOMS Center will form a multidisciplinary local Oversight Committee, including local expertise in the areas of adult/obstetric intensive care, obstetrics/maternal fetal medicine, neonatology, neurology/neurosurgery, nursing, pediatric surgery, and social work. Membership of the committees will include IRB appointees and they will meet on a monthly basis to review local fetal surgery cases, and progress of previous cases. The DSCC will create a monthly report for each committee consisting of patient information at a case-by-case level, in addition to any adverse event reports received. Each committee would make recommendations to the local PI and Institutional Review Board (IRB) and would be housed in the Chief of Staff Office (Quality Assurance). Both this committee and the IRB will receive reports of all DSMC meetings.

### **7.2.4 Shunt Outcome Review Committee**

The Shunt Outcome Review Committee will review clinical notes, case report forms and imaging studies of all infants to determine if they did or did not meet the criteria outlined in the protocol for shunt placement. The committee will be comprised of three independent pediatric neurosurgeons. One of the members of the Radiology Review Committee will also take part.

### **7.2.5 Radiology Review Committee:**

The Radiology Review Committee will review the MRIs obtained at enrollment, discharge or term, and one year of age to determine the grade of the Chiari II malformation and the presence of a tethered cord. The committee will be comprised of two independent pediatric neuroradiologists with the addition of a pediatric radiologist who specializes in prenatal diagnosis.

### **7.2.6 Outcome Evaluation Teams:**

Three or more Outcome Evaluation Teams will be set up, each comprised of an independent developmentalist and psychologist/psychometrist, and DSCC staff. These teams will conduct the infant neurologic and developmental examinations in a standardized manner and ensure the follow-up data are collected completely and accurately.

## 8 STUDY TIMETABLE

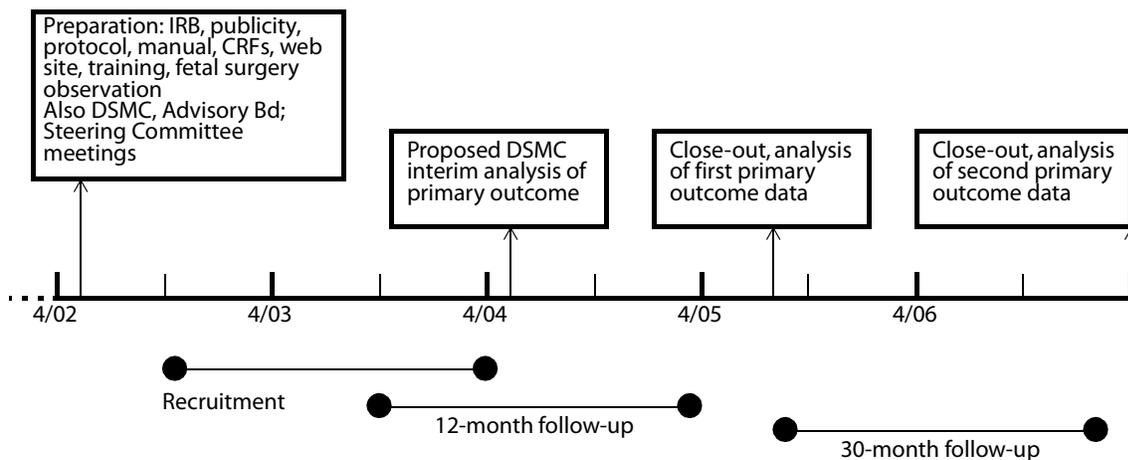
### 8.1 Training And Certification

Prior to the start of the trial, training of research personnel on the contents of the manual of operations will take place. Each center will be required to fulfill certification requirements, including a demonstration of familiarity with the protocol procedures, eligibility criteria and definitions for the case report form fields.

### 8.2 Recruitment And Data Collection Period

The timeline for the trial is summarized in the figure below.

**FIGURE 3. TIMELINE**



Funding began in April 2002 and the first Steering Committee meeting was held in May 2002. Randomization is scheduled to begin in October 2002.

A Steering Committee meeting is proposed shortly after the start of recruitment to evaluate study progress and implement solutions to any problems. During this year final preparations will be made for the neurologic and neurodevelopmental follow-up, including development of the case report forms and the manual of operations and training of the Outcome Evaluation teams.

Overall, it is anticipated that randomization of 200 patients will take 18 months to April 2004. From the CDC data of 1999, by which year the effects of folic acid supplementation had become apparent, it is estimated that during an interval of this length there would be about 1100 births with spina bifida across the United States. If this represents the number of women diagnosed with myelomeningocele and committed to maintaining their pregnancy, then less than 20% will be needed to complete randomization in 18 months.

It is proposed that a formal interim analysis of the first primary outcome be conducted in May 2004, after seven months of follow-up, to be presented to the DSMC. Closeout and analysis of the first primary outcome will take place in July 2005.

The thirty month exams should be completed by January 2007.

### **8.3 Final Analysis**

Closeout and analysis of the primary outcome results will be initiated in January 2007. The last three months of the project will be used for closeout and final analysis and manuscript preparation of the follow-up results.

### **8.4 Publication Policy**

Publication of individual results by the participating centers is unacceptable. All publications will be under the auspices of the "Fetal Surgery Network".

Press releases, announcements, and other publicity will be handled by NICHD. All of the PIs and major co-investigators will be invited to any press conferences. The Program Scientist at NICHD will be the primary study representative at this press conference. At the conclusion of the initial press conference, the PIs will be free to respond to inquiries from local and regional media.

There will most likely be several manuscripts resulting from this study. The first author for each publication will be randomized among the four centers (the three MOMS Centers and the Biostatistics Center). The order of the remaining authors will randomized.

## APPENDIX A. DESIGN SUMMARY

A Randomized Trial of Prenatal and Postnatal Myelomeningocele Repair

### OBJECTIVE

To determine if intrauterine repair of fetal myelomeningocele (MMC) at 180 to 25<sup>6</sup> weeks gestation improves infant outcome as measured by 1) death or the need for ventricular decompressive (VP) shunt by 12 months and 2) death or a composite of the Bayley Scales of Infant Development (BSID) Mental Developmental Index (MDI) and the difference between the anatomic and the functional level of the lesion by 30 months corrected age as compared with standard postnatal repair

### ORGANIZATION

Clinical Centers/ MOMS Centers • University of California-San Francisco; Vanderbilt University, Children's Hospital of Philadelphia  
 (MOMS Centers):  
 Data and Study Coordinating Center (DSCC) • George Washington University Biostatistics Center  
 Steering Committee: • Dr. Mary D'Alton (chair), Dr. Michael Harrison, Dr. Joseph Bruner, Dr. Scott Adzick, Dr. Elizabeth Thom, Dr. Catherine Spong

### DESIGN

Type: Randomized clinical trial  
 Major Eligibility Criteria: • MMC at T1-S1 w/ hindbrain herniation by MRI  
 • 9<sup>0</sup>-25<sup>6</sup> weeks gestation  
 • Singleton pregnancy  
 • Normal karyotype  
 • Maternal age at least 18 years  
 • Informed consent  
 Groups: • Experimental: Prenatal repair of the MMC  
 • Standard care: Postnatal repair of the MMC  
 Random Allocation: Standard urn design  
 Level of Masking: Unblinded  
 Stratification: Clinical center  
 Trial goal = 200 (100/group)  
 Assumptions:  
 1) Type 1 error = 5% (2-sided); Power >= 90%  
 2) Outcome event = death or shunt at 12 mths  
 • Standard care group event rate = 80%  
 • Experimental event group rate = 28% reduction  
 3) Outcome score = BSID MDI rank + functional - anatomic level rank or death at 30 mths; where death=minimum score  
 • Difference in mean outcome score = 0.5 standard deviations  
 Interim Analysis: Group sequential method

### SCHEDULED EVALUATIONS / DATA COLLECTION

Pre-randomization: • History, level II U/S, amnio/CVS, MRI, counseling, psychosocial evaluation, physical exam  
 Post-randomization: • Psychosocial evaluation at delivery, 12, 30 months; (Maternal) Reproductive functioning at 30 months  
 (Infant) • Gestational age at delivery; neonatal morbidity  
 • MRI at delivery, at discharge or 37 wks, 12 months  
 • Neurologic exam, leg strength test and developmental testing at 12, 30 months corrected age  
 • Brain stem evaluation (BSAER/ swallowing profile), urologic evaluation (urodynamics, renal sonography) at 30 mths, orthopedic, ophthalmologic evaluations

### MANAGEMENT PROTOCOLS

Prenatal surgery group: • Post operative care; discharge on tocolysis; bi-weekly ultrasounds and weekly prenatal visits  
 • Stay nearby MOMS Center until delivery or return to assigned MOMS Center at 32 weeks gestation; lung maturity studies and cesarean delivery at 37 weeks  
 Postnatal surgery group: • Standard prenatal care; monthly ultrasounds  
 • Return to assigned MOMS Center at 37 weeks gestation for lung maturity studies and cesarean delivery  
 • Repair of spina bifida when stable

### OUTCOME MEASURES

Primary: • Infant death or ventricular shunt by 1 year of life  
 • Bayley Scales of Infant Development MDI and functional - anatomic level of lesion at 30 months corrected age  
 Secondary: • Chiari II malformation  
 • Neurodevelopmental status  
 • Ambulation status, neuromuscular defects  
 • Maternal psychological and reproductive functioning

### TIMETABLE

Randomization 10/2002 - 04/2004  
 Data Collection 10/2002 - 01/2007  
 Closeout/final analysis 01/2007 - 04/2007

## APPENDIX B. INFORMED CONSENT FORMS

### B.1 Consent Form For Screening

#### Screening Informed Consent Form

Research Study	Myelomeningocele Repair Randomized Trial (MOMS)
Investigator	Elizabeth Thom, PhD.
Telephone Number	301-881-9260
Project Manager	Catherine Shaer, M.D.
Telephone Number	1-866-ASK-MOMS (866-275-6667)

#### I. Introduction

You have contacted us because you have heard about this research study and you might be interested in participating. We think you may be eligible, but before we can decide, we will need more information about you and your baby and we will need to review your medical records and may need to speak to your doctor. This process is called screening. This consent form provides information about the screening process for this research study. Dr. Catherine Shaer, the Project Manager, will be available to answer your questions and provide further information about the study. If you agree to be screened, you are asked to sign this consent form. Signing this form does not mean that you have made any decision, just that you will allow us to contact you and talk to your doctor and obtain and review your medical records. Later, if we find that you are eligible and you decide that you want to take part in the study, you will be asked to sign another consent form which will give you more details about the possible risks and benefits of participating in the study. This process is known as informed consent.

Your decision to let Dr. Shaer contact you with more information about the study and to allow Dr. Shaer to review your medical information and speak to your doctor if necessary is voluntary. Please do not hesitate to ask questions. You are free to choose whether or not you will be screened.

#### II. Purpose

The George Washington University Biostatistics Center is coordinating a research study to find out whether closure of spina bifida (myelomeningocele) while the baby is still in the mother's uterus (womb) is better for the baby's outcome than closure done soon after birth. The person in charge of coordinating this research study is Dr. Elizabeth Thom.

This research is funded by the National Institute of Child Health and Human Development (NICHD), a part of the National Institutes of Health (NIH).

## APPENDIX B. INFORMED CONSENT FORMS

### III. Procedures

Three clinical centers (Vanderbilt University Medical Center in Nashville, Tennessee, the University of California at San Francisco in San Francisco, California, and Children's Hospital of Philadelphia in Philadelphia, Pennsylvania) are doing this research study together with the George Washington University Biostatistics Center in Rockville, Maryland. The study is being done to find out whether it is better to close a spina bifida defect before the baby is born or shortly after birth. Until recently, the only way to treat a baby with spina bifida was to do the surgery soon after birth. Now, at a very few places in the United States, there are specialized teams of doctors who are able to do surgery on a baby with spina bifida while the baby is still in the uterus (womb). They do this by opening her womb as though they were doing a C-section and closing the baby's spina bifida defect. The mother's womb is then sewn up, as for a C-section, and the mother and baby continue the rest of the pregnancy. The doctors think that they may be able to stop some damage to the baby's spinal cord and brain by doing the closure early in the pregnancy, but they don't know for sure. The purpose of this trial is to find out the answer to this question.

A total of 200 pregnant women over the age of 18 years, in the middle part of their pregnancy, will be enrolled. To qualify for the trial, their fetuses must have been diagnosed with spina bifida that is not too high up or too low down the back and the baby must have the Chiari II malformation, an abnormality of the brain which is commonly found in babies with spina bifida. Patients or their doctors will contact the Biostatistics Center for information. They will talk to Dr. Shaer, a trained pediatrician and expert in spina bifida, who will tell them about the study. Patients who consent to have their medical records reviewed by Dr. Shaer will be sent a package of information about the trial. Dr. Shaer will contact them to let them know if they seem to be eligible and to answer any questions they may have. If they are eligible and are still interested in participating, they will be assigned to one of the three clinical centers for further evaluation and for treatment if eligibility is confirmed. Women will not be able to select which clinical center they will be assigned to. They will be assigned to one of the three centers based on convenience to them as well as the need to evenly divide the participants between the three centers.

The patient will then contact their assigned center to arrange a date for further screening. She will travel to the center with the baby's father or another support person. Travel to the center and meals and lodging while they are there will be paid for. During this final screening process, they will get a lot of counseling to make sure that they understand the trial as well as to help them understand what the baby will need later in life. If the screening determines that they are still eligible and if they still want to take part in the study, they will be asked to sign an informed consent form. Then the staff at the clinical center will find out whether the patient will get either surgery before the baby is born (prenatal surgery), or surgery after the baby is born (postnatal surgery). There is a 50:50 chance being assigned to either group, like the chances of getting a heads or tails when flipping a coin. Because prenatal surgery is experimental, it will not be offered at the participating centers or other facilities in the United States outside the study once it begins.

Patients assigned to have prenatal surgery will have the surgery done soon after the assignment is made and they will stay at nearby accommodations until the baby is born by C-section. They need to stay near the MOMS Center to make sure that they get the best care and so that they may be watched for any signs of premature labor. They will be able to go home with the baby once the child is stable. This usually takes seven to 10 days.

## **APPENDIX B. INFORMED CONSENT FORMS**

Patients assigned to postnatal surgery will return home until three weeks before their due date when they will come back to the center for delivery by C-section and subsequent closure of their baby's spina bifida defect by the MOMS team neurosurgeon. The spina bifida defect will be closed at the MOMS Center as soon as the baby is stable enough for surgery.

In both groups, the patients will travel back to the MOMS Center when the baby is one year old and two and a half year old for exams to find out how the baby is doing. By comparing the babies who had prenatal surgery with those who had postnatal surgery we may be able to find out whether prenatal surgery improves the babies' outcome.

### **IV. Possible Risks**

Detailed information about the possible risks of the study is outlined in the brochure that comes with this form. Dr. Shaer is available to discuss these risks with you in detail and to answer any questions you may have. If you get as far as going to one of the MOMS Centers for further screening, the risks will again be discussed with you in depth before you make a decision.

The main risk to the fetus or infant is the risk of being born too early (prematurely). This can result in lung problems, brain damage, or even death. So far, babies who have had this surgery before birth were born about 6 weeks early on average (34 weeks). About 1 in 10 were born more than 10 weeks early (earlier than 30 weeks). So far, seven babies have died due to premature birth out of 192 fetal surgeries. By staying close by the center to be monitored closely, and following the instructions of your health care team, the risk of delivering prematurely will be reduced as much as possible.

For mothers, the main risk comes from cutting the womb twice in the same pregnancy. This means that she will most probably have to have a C-section for all future deliveries. Rupture of the womb and the loss of amniotic fluid are also risks. The risks of wound infection and of complications from anesthesia are the same as they would be for any C-section. The mother will have to stay near the MOMS Center after surgery until she is ready to deliver, possibly for as long as 20 weeks. This could have a serious effect on all members of her family.

### **V. Possible Benefits**

Again, the possible benefits will be discussed in more detail if you decide to find out more about this trial. If you are assigned to prenatal surgery, it may improve your baby's neurologic outcome. This means that your baby may have more function in the legs and more bowel and bladder control than if the surgery were not done. Babies in both the prenatal and postnatal surgery groups will get care from very experienced neurosurgeons at the three participating centers. The staff at the centers will also continue to monitor your baby's progress after you go home. They can also help you find doctors in your area who can take care of your baby's special needs. By taking part in the one-year and two and a half year exams, any problems that your baby has can be diagnosed and you will get help in finding care in your home area. Also, in the future, families facing this situation may benefit from information obtained from this study.

### **VI. Alternatives**

One alternative to participating in this study is for your baby to have postnatal surgery. Prenatal surgery for spina bifida is not offered in the United States except in this study. Some women choose pregnancy termination. You have the right to refuse all treatment.

## **APPENDIX B. INFORMED CONSENT FORMS**

### **VII. Costs**

If you do choose to take part in the study, there will be no additional costs for prenatal care beyond those you would normally have. If you are in the prenatal surgery group, the travel, meal and lodging costs for you and a relative or friend will be covered until delivery and after delivery until you take the baby home. If you are in the postnatal surgery group, travel back to the center for you and a support person will be covered, as well as meals and lodging before and after delivery until your baby is able to go home with you. In addition, if you have insurance, the cost of all medical care associated with the study not covered by your insurance will be covered by the study. The cost of returning with your baby at one year and two and a half years of age will also be covered. Meals and lodging will be covered for those visits as well.

### **VIII. Compensation**

No financial compensation (no payment) is available for participants in this study.

### **IX. Right To Withdraw From The Study**

Your participation in this research study is voluntary. You may decide not to begin or to stop this study at any time.

### **X. Confidentiality Of Medical And Research Records**

Your medical information will be kept as confidential as possible while you are deciding about the trial as well as later if you take part in the study. Your phone calls to and from the Biostatistics Center will be private because they will not go through the main switchboard. Dr. Shaer will have a separate FAX machine to get medical records from your doctors. Personal and medical information will be kept in a locked filing cabinet on a zip disk which will be locked away when Dr. Shaer is not in the office. If you decide you do not want to proceed with screening for this trial or if you are not eligible, all of your medical and personal information will be destroyed.

You have the right to privacy. All information obtained from this research that can be identified with you will remain as confidential as possible. Representatives of governmental agencies may review and photocopy your medical and research records to assure the quality of the information being used in the research.

If you do decide to take part in the trial, your medical data collected for this study will be sent to the George Washington University Biostatistics Center to be put into a database consisting of information from all of the participants in this study. The information in the database about you and your child will only be used for statistical analysis. The information or analysis may appear in scientific publications without identifying you. The medical data sent to the central database does not include your name, address, Social Security Number, hospital number, date of birth or any other personal identifiers.

To help us protect your privacy, we have obtained a certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.



**XIII. Investigator's Statement**

I certify that the screening process for this research study has been explained to the above individual by me or my research staff including the purpose, the procedures, the possible risks and the potential benefits associated with participation in the screening process for this research study. Any questions raised have been answered to the individual's satisfaction.

\_\_\_\_\_  
Investigator's Name (Print Name)

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

## **B.2 Sample Study Informed Consent Form**

### **Consent to Participate in the Management of Myelomeningocele Study (MOMS)**

#### **I. Introduction**

You are being evaluated for voluntary participation in this research study. In order to fully understand what the study involves and what will be required of you, you need to understand the risks and benefits associated with participating. This process is known as informed consent. This form explains the study and what it requires. Please ask your study doctor or nurse to explain any words or points you do not understand.

#### **II. Background And Purpose**

Myelomeningocele, also called spina bifida, is a condition which occurs in the fetus when a part of the developing spinal cord and its coverings do not close properly. As a result, the undeveloped spine is open onto the back of the fetus. Babies with myelomeningocele are born with some degree of nerve damage which causes varying degrees of leg and foot weakness and paralysis, as well as poor or absent bowel and bladder control. In addition, they also have a problem with brain development called the Chiari II malformation. Individuals with the Chiari II most often have to have a tube (called a shunt) placed into the brain cavities (ventricles) after birth to relieve a build-up of fluid. This condition of fluid build-up in the brain cavities is called hydrocephalus.

You and your unborn child are being asked to participate in this research study because you are carrying a fetus with myelomeningocele that could possibly be treated by one of two methods: standard care which involves closure of the defect after birth (called postnatal repair) or closure before birth (called prenatal repair). At this time it is not known if either therapy is better, although surgery after birth has been the standard for many years. However, an operation has been developed which may benefit your unborn child. This operation is performed on a pregnant woman and her unborn child between the 19th and 25th week of pregnancy.

The goal of the prenatal operation is to protect the exposed spinal cord from further damage and prevent, reduce or reverse development of the Chiari II malformation. The doctors involved in this study have experimental and clinical evidence showing that, by closing the spinal cord before birth, development of the Chiari II malformation may be prevented or its severity reduced, and leg weakness may be improved. This treatment requires prenatal (fetal) surgery. The pregnant woman's abdomen and womb must be opened to close the exposed fetal spinal cord. Because this operation is new, we do not know if it is safe for pregnant women or unborn babies, or if it is effective in preventing or reducing the brain damage or nerve damage in an unborn child with spina bifida.

The other way to treat myelomeningocele is the standard method that does not involve surgery before birth. After a baby with spina bifida is born, standard postnatal care involves surgery to close the baby's exposed spinal cord. In addition, insertion of a shunt into the ventricles to relieve build-up of fluid within the brain is usually needed. Shunt placement is most often done during a second surgery.

The effectiveness of closing the spinal cord before birth in babies with myelomeningocele is not known. We do not know if the fetal surgical procedure is worth the risks involved, or if the results will be any better than those obtained with the standard postnatal surgery. Because of the many questions regarding these procedures, we are performing this study to determine whether prenatal surgery improves outcome compared to the standard of repair after birth.

In this study we will examine whether unborn children who have their exposed spinal cords closed using fetal surgery techniques do better, the same, or worse than unborn children treated for myelomeningocele after birth. If you chose to participate in the study, your baby will have either prenatal surgery or postnatal surgery performed by **(Name of Principal Investigator)** and the MOMS Center team at **(Name of Institution)**.

### **III. Procedures**

#### **A. Assignment Procedures**

If you voluntarily agree to be enrolled in this research study, you will be assigned to a MOMS Center and you will travel there with your baby's father or another support person. You and the baby's father will be asked to take three brief psychological tests. You will then be randomly assigned to one of two groups, surgery before birth (prenatal surgery) or surgery after birth (postnatal surgery). This means that you and your unborn child have a 50% chance of being in either group, like the odds of getting a heads or a tails when flipping a coin. Neither you nor the doctors will make the choice of which group you and your unborn child are assigned to. Instead, the Data and Study Coordinating Center (DSCC) at the George Washington University Biostatistics Center will randomly assign you to surgery before birth or surgery after birth. Further surgery on your baby's spinal cord or surgery to place a shunt may be needed regardless of which group you are assigned to.

#### **B. Surgical Procedures**

**Surgery before birth group:** If you are assigned to the prenatal closure group, you and your unborn baby will have surgery under general anesthesia when the fetus is between 19 and 25 weeks old. You will be admitted to the hospital on the day of surgery and asked to sign a separate consent form for surgery. An IV (a needle placed into a blood vessel under your skin to give fluids and/or medications) will be started in your arm. Prior to the operation, an epidural catheter will be placed in your back for use in controlling pain after the operation. You will be given general anesthesia, and that anesthesia will put your baby to sleep as well. In addition, your unborn baby will be given an injection of pain medication during the fetal surgery. After surgery, pain medication will be administered to you and will reach your unborn baby through the placenta.

- a. Before the surgery begins you will be given one dose of indomethacin, a tocolytic drug, (see page 5) to prevent premature uterine contractions. The surgery involves making a horizontal incision (cut) in your abdomen. A vertical incision may be used if medically necessary or if you have a previous vertical scar. Ultrasound will be used to determine where it is safe to make the incision in your uterus. Magnification by special lenses or a microscope will be used to help the doctors perform the operation on your unborn baby's back. Antibiotics will be put into the amniotic fluid remaining in your uterus and the opening in your uterus will be closed after the fetal surgery is completed.

- b. You will be kept in the hospital until you are well enough to leave and your unborn baby is stable. This usually requires 3-7 days but may last as long as the pregnancy continues. For the first few days after surgery, you will be closely monitored. You will receive intravenous (IV) fluids and will have to stay in bed during most of this time. You will also be given magnesium sulfate (another tocolytic drug) for 48 hours to prevent premature labor which is a consequence and major complication of fetal surgery. You will also be given additional indomethacin. A special sonogram of your baby's heart (fetal echocardiogram) will be done once a day while you are on the indomethacin.
- c. After you are discharged, you will need to stay at **(Name of Facility or Hotel)** until you deliver. You will be at bed rest for one week. After the first week, you will be allowed to engage in light activity for the remainder of your pregnancy. You will return to the MOMS Center at least weekly so that your pregnancy can be monitored, the progress of your unborn baby followed closely by sonogram and your delivery planned. In addition to the usual examinations and tests that are done at a routine obstetrical visit, you will be assessed for the degree of discomfort you experienced after surgery, wound healing, and risks for premature labor and/or delivery. A complete obstetrical ultrasound will be done monthly.
- d. If and when you are well enough to leave the hospital after the fetal surgery is performed, you will take a drug called "nifedipine" to prevent premature labor. You will take this medication for the duration of your pregnancy. If the nifedipine is not effective in preventing significant premature contractions or you are unable to tolerate the side effects of this medication, you will be placed on a terbutaline pump. A tiny needle is placed under the skin on your thigh to allow the pump to give small doses of terbutaline (another tocolytic drug) 24 hours a day. If placed on the terbutaline pump, you will remain on this medication for the duration of your pregnancy. A nurse will visit you regularly and you will have telephone access to a nurse and perinatologist (a doctor who monitors fetuses) who are supervising your progress.
- e. When you are ready to deliver your baby (or when you have completed 36 weeks of your pregnancy), you will be readmitted to **(Name of MOMS Center)** facility to deliver your baby by C-section. If you go into preterm labor before you have completed 34 weeks of your pregnancy and delivery is imminent, you will be given betamethasone or dexamethasone, steroid medications which will help your unborn baby's lungs mature. If you reach 37 weeks of pregnancy, an amniocentesis (removal by needle of a small amount of amniotic fluid for study) will be performed to assess the maturity of your baby's lungs. If they are not mature, delivery will be delayed for 5 to 7 days to allow for further lung development. The abdominal incision will be made in the same location used for the fetal surgery. The uterine incision used to deliver your baby will be in a location that is safest for your baby's delivery. It is probable that the uterine incision will be located in an area of your uterus that will not allow vaginal deliveries for future pregnancies. Therefore, all of your future deliveries will probably be by C-section.
- f. At delivery, your baby will be cared for at **(Name of Institution)** using standard postnatal therapies until he/she is fully recovered. That time period is variable and although it averages 7-14 days, it can be several weeks to several months. This means that you may have to stay in the **(Name of Area)** area for an extended amount of time or return home without your baby.

**Surgery after birth group:** If you are assigned to the standard postnatal surgery group, you will return home and will undergo routine obstetrical care in your home area. Your doctor will do monthly ultrasounds in addition to the usual prenatal care procedures. You will need to return to **(Name of MOMS Center)** facility after you have completed 36 weeks of pregnancy, provided written medical clearance to travel (including to fly if indicated) is obtained from your obstetrician/perinatologist. Once you are at **(Name of MOMS Center)** facility, a sample of amniotic fluid will be removed from your uterus using a small thin needle (amniocentesis) to find out if your unborn baby's lungs are mature enough for delivery. If they are not, delivery will be delayed 5 to 7 days to allow for further lung development. The baby will be delivered by C-section to prevent any further damage to the exposed spine. The baby's spina bifida defect will be closed as soon as possible after birth (usually within 48 hours).

### C. Follow-Up For Both Groups

Within one month of delivery, you will be asked to complete the three psychological tests you took before you were assigned to prenatal or postnatal surgery. After you go home, information about both your and your baby's health will be collected through medical reports, letters, and/or phone calls for several years. You will be asked to sign a separate consent form for follow-up. You will be contacted at least every three months by phone and questioned about any medical developments that might have taken place since you were last contacted for follow-up. You will be expected to return to **(Name of MOMS Center)** when your baby is 12 months and 30 months of age. Your baby's development and medical status will be assessed at those visits. It is possible that a grant extension will be requested and granted and in that case another follow-up visit will take place after the 30 month visit.

### IV. Risks And/Or Discomforts

There is the possibility that one procedure is better than the other for you and for your baby and the one you are assigned to may be the poorer of the two. Nearly all the risks and discomforts discussed below are based on information gained from over two hundred (200) fetal operations. There may be other unforeseen risks.

#### Risks Of Fetal Surgery

##### Maternal Risks

- 1. Wound infection after fetal surgery:** This has occurred in less than 5% of cases and is usually superficial.
- 2. Chorioamnionitis (infection in the uterus):** This has been a rare complication of the fetal surgery cases done for closure of spina bifida. If it does occur, preterm delivery and death of the baby may occur.
- 3. Amniotic fluid leak (leak of fluid from the uterus at the incision site):** This has been a rare complication of fetal surgery done for closure of spina bifida, but if it does occur it is likely to result in too little amniotic fluid in the uterus. This is known as oligohydramnios. If it is diagnosed, you will probably be admitted to the hospital and treated with bed rest and IV (intravenous) fluids, maybe until delivery. A long-term lack of amniotic fluid can damage the unborn baby's lungs and could lead to death of the baby.

- 4. Prolonged hospitalization:** It is possible that you will need to be hospitalized from the time of the fetal surgery until delivery. That could be as long as 20 weeks. This could have a serious effect on all members of your family.
- 5. Loss of future reproductive potential:** An inability to have more babies should occur very rarely. One study of 45 women who had fetal surgery and no pre-existing fertility problems found that 32 of 35 who attempted pregnancy were able to conceive and deliver a full-term baby.
- 6. Necessity of C-section for future pregnancies:** The fetal surgery is almost certain to make it necessary for your future deliveries to be by C-section.
- 7. Significant bleeding during fetal surgery or during delivery:** All surgery carries a risk of blood loss. Bleeding that requires a blood transfusion after fetal surgery is extremely rare.
- 8. Side-effects from tocolytic agents:** The side-effects should be no different for mothers whose babies have undergone fetal surgery for myelomeningocele than for mothers who experience preterm labor for any other reason. The possible side-effects of the drugs used in this study to prevent pre-term labor after fetal surgery are:  
  
Magnesium sulfate: flushing, sweating, muscle weakness, nausea and vomiting, blurred vision, excess fluid in the lungs leading to a need for oxygen  
Indomethacin: intestinal cramping, decreased amniotic fluid production  
Terbutaline: fast heart rate, nausea, constipation, headache, high blood sugar  
Nifedipine: low blood pressure, flushing, rash, headache
- 9. Complications and side-effects of general anesthesia and epidural analgesia:** The fetal surgery procedure requires you to undergo an operation under general anesthesia that you would not have if you were assigned to the postnatal surgery group.  
  
General anesthesia: nausea and vomiting, aspiration (inhaling material into the lung), inability to maintain normal breathing requiring placement of a breathing tube into the trachea (windpipe)  
Epidural analgesia: headache, incomplete pain control, infection, hematoma formation (blood collecting around the tube), nerve injury, drug side-effects (itching, nausea and vomiting, inability to urinate, slow breathing, seizure, low blood pressure)
- 10. Death:** This is extremely unlikely due to the intensive monitoring both during and after surgery and the fact that the physicians involved are very experienced obstetrical anesthesiologists and perinatologists. There has never been a maternal death at any of the centers participating in this study during or after any fetal surgical procedure.

#### Fetal Risks

- 1. Fetal/Neonatal death:** To date, the perinatal death rate after fetal surgery for fetal myelomeningocele is approximately 5%.
- 2. Injury after surgery:** It is possible that fetal surgery might increase injury to the baby by worsening the hydrocephalus before delivery. This has not been observed in any case so far.

3. **Side-effects from tocolytic drugs:** Significant narrowing of your baby's ductus arteriosus (blood vessel near the heart). If this occurs, this drug will be discontinued.
4. **Prematurity:** Fetal surgery can cause premature delivery resulting in severe problems associated with prematurity including but not limited to bleeding in the brain, cerebral palsy, difficulty with breathing because of immature lungs, severe infection, damage to the retina of the eyes, and an increased risk of infection of the premature intestines.
5. **Chorioamniotic separation:** This occurs in approximately 20% of cases of fetal surgery. MOMS Center doctors believe this to be due to tearing and separation of the membranes surrounding the baby during the opening of the uterus. This may lead to premature rupture of the membranes (PROM), amniotic band syndrome (strings of tissue that can wrap around and injure fingers, toes or limbs), and umbilical cord compression resulting in either poor fetal growth or fetal death. To date, there have been no known complications as a result of chorioamniotic separation. PROM has occurred with and without the presence of a chorioamniotic separation seen on ultrasound.
6. No improvement in your unborn baby's condition after fetal surgery for myelomeningocele.

#### **Risks of Standard Postnatal Care**

There are no risks to you. Risks to your baby are the progression of the Chiari II malformation prior to birth and subsequent need for placement of a shunt. Babies born with myelomeningocele may have a variety of medical complications including but not limited to breathing and swallowing difficulties, failure to thrive and grow well due to chronic illness, paralysis or weakness of the legs and or feet, and complications of prematurity including bleeding in the brain, difficulty with breathing due to immature lungs, and an increased risk of infection in the premature intestines.

#### **V. Treatment And Compensation For Injury**

If you or your baby are injured as a result of taking part in this study, treatment will be available. The costs of such treatment may be covered by **(Name of MOMS Center)** facility, depending on a number of factors. **(Name of facility)** does not usually provide any other form of compensation for injury. The National Institute of Child Health and Human Development will not provide care or coverage for care for injury suffered as a result of taking part in this study. For further information about this, you may call **(Name of Appropriate Office)** at **(Name of MOMS Center)** facility at **(Phone Number of Office)**.

#### **VI. Benefits**

Either prenatal or postnatal repair of myelomeningocele may prove to be a more effective treatment for your baby's myelomeningocele. By "effective treatment", the doctors involved in this study mean that your baby may have the best chance of normal nerve function in the area affected by the spina bifida as well as the least number of short and long-term complications. After the study is completed and the data is analyzed, the doctors involved in the trial will learn whether one treatment is better than the other. This information is not presently known.

**VII. Alternatives**

You can decide not to participate in this study or terminate the pregnancy. You can decline fetal surgery but still allow study of your baby's outcome by signing a separate consent form. In that case, you can choose to return to your referring doctor and hospital or be cared for at **(Name of MOMS Center)** facility.

**VIII. Financial Considerations**

If you do choose to take part in this study, there will be no additional costs for prenatal care beyond those you would normally have. If you are in the fetal surgery group, the travel, meal and lodging costs for you and a relative or friend will be covered until delivery and after delivery until you take your baby home. If you are in the postnatal surgery group, your travel back to the center will be covered, as well as food and accommodation before and after delivery until your baby is able to go home with you. In addition, the cost of all medical care associated with the study not covered by your insurance will be covered by the study. For both the prenatal and postnatal surgery groups, the cost of returning with your baby at one year and two and a half years will also be covered by the study. Meals and lodging will be covered as well.

**IX. Compensation**

You will not be compensated (paid) for your participation in this study.

**X. Right To Withdraw From The Study**

Your participation in this research study is voluntary. You may decide not to begin or to stop your participation in this study at any time.

**XI. Confidentiality Of Medical And Research Records**

Participation in this study will cause some loss of privacy. However, all of your records and your baby's records will be handled as confidentially as possible. The details of what happens to you and your baby will be recorded by the doctors participating in the study. If you do decide to take part in the trial, your medical data collected for this study will be sent to the George Washington Biostatistics Center and put into a central database consisting of information from all of the participants in the study. The medical data sent to the central database will not include your name, address, Social Security Number, hospital number, date of birth or any other personal identifiers. Your information in the database will only be used for statistical analysis and may appear in scientific publications. You will not be identified in any publications. Authorized staff from the National Institute of Child Health and Human Development may review your medical data to evaluate the progress of the study.

To help us protect your privacy, we have obtained a certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal U.S. Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

**XII. Questions**

The above information has been explained to you by **(Name of Doctor)** and members of the MOMS Center. They have answered your questions concerning participation in the study. You may reach them at any time at **(Name of MOMS Center)** facility or by calling **(Name of Appropriate Contact Person)** at **(Phone Number of Appropriate Contact Person)**.

**XIII. Consent**

Participation in this study is voluntary and you may withdraw at any time. Declining to participate or withdrawing from the study will not jeopardize your treatment or your baby's treatment. The investigators may end your participation in the study prior to undergoing surgery if they deem it medically advisable.

You will be given a copy of this consent form to keep.

If you wish to participate you should sign below.

\_\_\_\_\_

Mother's signature

\_\_\_\_\_

Date

\_\_\_\_\_

Father's signature (if appropriate)

\_\_\_\_\_

Date

\_\_\_\_\_

Person obtaining consent

\_\_\_\_\_

Date

### **B.3. Sample Study Follow-up Consent Form**

Consent for Follow-up by the Management of Myelomeningocele Study (MOMS)

#### **I. Purpose And Background**

The National Institute of Child Health and Human Development (NICHD) has funded a multicenter study to investigate whether closure of myelomeningocele (spina bifida) while the baby is in the mother's womb (prenatal surgery) is better for the baby's outcome than closure after the baby is born (postnatal surgery). This consent applies to follow-up studies which will be done to gather additional data to be used to determine if either surgery is more safe and/or effective.

#### **II. Procedures**

If you agree to participate in this study, the following will occur:

1. After your child is discharged from the hospital, you will be contacted at least every three months for two and a half years so that study staff can obtain updates of both your and your child's condition.
2. Your child will undergo two follow-up evaluations at **(Name of MOMS Center)** facility. He/she will be evaluated at one year of age and two and a half years of age. The one-year evaluation will include an MRI of the head and spine and both the one-year and two and a half year evaluation will include a physical examination and developmental testing. Special testing of the kidneys and bladder (standard in the care of babies with spina bifida) will be done at the two and a half year visit if the testing has not been done as part of your child's routine follow-up care in the previous year.
3. At both the one-year and two and a half year follow-up visits, you and your partner will again complete the three psychological tests which you completed previously.
4. It is possible that, if additional funding is made available through a grant extension, you will be contacted about attending an additional follow-up visit beyond the one currently planned at two and a half years.

#### **III. Risk/Discomforts**

1. Some of the questions asked may make you uncomfortable or upset.
2. Some of the testing may upset your child. However, all of the planned tests are part of the routine care of a child with spina bifida.
3. As with participation in any research study, you may lose some privacy. However, your medical records will be handled as confidentially as possible. No individual names or other identifiers such as birthday or Social Security Number will be used in any reports or publications that may result from this study.
4. You will be required to return to the MOMS Center for follow-up testing and this may be inconvenient for you and your family.

#### **IV. Benefits**

There is no direct benefit to you from participating in the follow-up portion of this study. However, you may receive advice on management of the problems which affect babies with myelomeningocele. The information that you provide may provide essential information as to whether prenatal or postnatal surgery provides a better outcome for babies with myelomeningocele.

#### **V. Costs**

If you do choose to participate in the follow-up portion of this study, there will be no additional costs to you. All evaluations done as part of the follow-up portion of this study not covered by your insurance will be covered by the study. The costs of travel to **(Name of Facility)** for you, your partner and your baby will be covered by the study, as will costs for meals and lodging.

#### **VI. Compensation**

You will not be compensated (paid) for your participation in the follow-up portion of this study.

#### **VII. Confidentiality Of Medical And Research Records**

You have the right to privacy. All information obtained from this research that can be identified with you will remain as confidential as possible. Representatives of governmental agencies may review and photocopy your medical and research records to assure the quality of the information being used in the research.

To help us protect your privacy, we have obtained a certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal U.S. Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

#### **VIII. Questions**

You have the right to have all of your questions about participation in the follow-up portion of this study answered. You should direct any questions to **(Name of Study Doctor and/or Nurse)**. If you do not wish to do this you can contact **(Name of Appropriate Office at MOMS Center)** facility at **(Phone Number of Appropriate Office at MOMS Center)** facility.

#### **IX. Consent**

You will be given a copy of this consent form to keep.

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**Participation in research is voluntary.** You are free to decline to be in the study. Your decision as to whether or not to participate will have no influence on your present or future status as a patient at **(Name of MOMS Center)** facility.

If you agree to participate, sign below.

\_\_\_\_\_  
Mother's signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Father's signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of witness

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of person obtaining consent

\_\_\_\_\_  
Date

### APPENDIX C. PRENATAL SURGERY PROCEDURE

A combination of general and epidural anesthesia is used because of evidence suggesting that this combination is superior to either individually in preventing unwanted uterine contractions.<sup>1</sup> The indwelling epidural catheter also enables administration of continuous postoperative analgesics. The gravid uterus will be exposed via a low transverse laparotomy incision and exteriorized. A vertical skin incision will be used in obese patients (BMI>30) or those with a previous vertical skin scar. The fetus and placenta are then located by ultrasound and the hysterotomy location chosen by the primary surgeon. Initial uterine entry is accomplished through a 1-2 cm hysterotomy. The foot plate of a US Surgical CS-57 autostapling device is passed into the uterine cavity. The stapler is examined manually and with color Doppler ultrasonography to exclude the presence of fetal tissue, and then used to create a 6-8 cm uterine incision. The fetus is directly visualized and manually positioned within the uterus such that the myelomeningocele sac is in the center of the hysterotomy. The fetus is given an injection of fentanyl. During the procedure the fetal heartbeat is monitored by continuous electronic fetal monitoring (EFM).

The myelomeningocele is closed in a standardized manner under magnification regardless of the gestational age. The neural placode is sharply dissected from surrounding tissue and allowed to drop into the spinal canal. The dura is then identified, reflected over the placode and then closed using a fine running suture. If there is insufficient dura for closure, Duragen may be substituted. If it is not possible to obtain skin closure, relaxing incisions are made. Finally, the skin is mobilized and closed using a fine running suture.

The uterus is closed in two layers. The first layer incorporates the absorbable polyglycolic acid staples left by the autostapling device. As the last stitches of this layer are placed, warmed Ringer's lactate, mixed with 500 mg of Nafcillin or vancomycin, is added to the uterus until the amniotic fluid index is normal. Finally, an imbricating layer of suture is placed. The abdominal fascial layer and dermis are closed in routine fashion.

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- END -



## EXPIRED - Department Of Defense (DoD) Weight Management Demonstration

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### 1.0 PURPOSE

This demonstration will allow the Department of Defense (DoD) to determine the efficacy and acceptability of pharmacotherapy and distance behavioral interventions in producing and maintaining clinically significant weight loss in an at-risk overweight or obese individual. The Weight Management Demonstration (hereby referred to as the Demonstration) will also provide information that will enable DoD to determine whether to seek a change in statute to authorize, as part of the TRICARE benefit, behavior modification either alone or with pharmacotherapy for the treatment of patients that are overweight or obese.

### 2.0 BACKGROUND

**2.1** Obesity is the seventh leading cause of preventable death in the United States contributing to more than 112,000 deaths annually. All segments of the DoD population demonstrate upward weight trends with approximately 13% of active duty, 34% of non-active duty, and 19% of dependent DoD adolescents classified as obese according the National Institutes of Health (NIH). Many high volume, high cost medical conditions, including diabetes, heart disease, back and joint pain, asthma, some cancers, and sleep apnea are related to obesity.

**2.2** According to the Centers of Disease Control and Prevention (CDC) in the four demonstration states, there are 315,000 eligibles in total. Out of the 315,000 eligibles, approximately 71,000 Prime enrollees are age 18 and older, and approximately 45,000 Prime enrollees meet the definition for overweight or obese.

**2.3** Under TRICARE, the treatment of obesity, as a sole medical condition, is excluded by law [10 USC 1079(a)(11)]. As a result, TRICARE policy is limited to proven surgical interventions for individuals with associated medical conditions (i.e., hypertension, cholecystitis, narcolepsy, diabetes mellitus, pickwickian syndrome (and other severe respiratory diseases), hypothalamic disorders, and severe arthritis of the weight-bearing joints). TRICARE does not cover non-surgical treatment of obesity or morbid obesity for dietary control or weight reduction (i.e., nutritional or behavioral counseling or weight loss medication).

**2.4** One of the priorities of the Assistant Secretary of Defense for Health Affairs (ASD(HA)) is to establish a uniform weight management program for TRICARE Prime enrollees in the Military Health System (MHS). Therefore, on July 6, 2005 (Vol 70, No 38888), the **Federal Register** announced a demonstration project in which the DoD will provide TRICARE reimbursement for Prime enrollees (excluding active duty members and those enrolled in special programs) residing in Indiana, Illinois, Michigan, and Ohio to receive weight management intervention for the treatment of obesity.

**2.5** The Demonstration project is planned for three years. The Demonstration will continue based on outcome measures related to utilization rates, weight loss rates, and success of pharmacotherapy.

### **3.0 POLICY AND ELIGIBILITY**

**3.1** Effective October 1, 2005, the Demonstration is authorized for overweight (Body Mass Index (BMI > 25)) non-active duty TRICARE Prime enrollees, who are age 18 to 64, residing in Ohio, Michigan, Indiana, or Illinois.

**3.2** The Demonstration does not apply to active duty members or those TRICARE-eligible beneficiaries enrolled in special programs (i.e., Extended Care Health Option (ECHO)) available through TRICARE.

### **4.0 MANAGED CARE SUPPORT CONTRACTOR (MCSC) RESPONSIBILITY**

**4.1** The MCSC shall enroll eligible beneficiaries into the Demonstration through the Defense Online Enrollment System (DOES) based on applications received from the Demonstration contractor. The MCSC is not required to verify or validate enrollment information. Rather, the MCSC is simply the data entry portal for reporting the enrollment to the Defense Enrollment Eligibility Reporting System (DEERS). The MCSC shall accomplish the required data entry within five calendar days of receiving an approved enrollment application from the Demonstration contractor. Enrollments that cannot be effected because of ineligibility on DEERS or because of invalid or incomplete information shall be returned to the Demonstration contractor with an explanation of the problem within five calendar days of receipt of the application.

**4.2** The MCSC shall disenroll beneficiaries and make changes as necessary. The MCSC shall notify the Demonstration contractor of any changes in status from DEERS.

**4.3** The MCSC shall provide Pharmacy Data Transaction Service (PDS) with a weekly list of all enrollments completed during the week. The list will include: beneficiary's name, beneficiary's Social Security Number (SSN), sponsor's name, sponsor's SSN, beneficiary's address and date of enrollment into the Demonstration. The weekly list shall be e-mailed to **pds.ameddcs@amedd.army.mil**.

**4.4** DoD will cost-share all medical care required as a result of participation in the Demonstration. This includes physician visits for medical management and prescription pharmacotherapy through the TRICARE Mail Order Pharmacy (TMOP).

**4.5** The MCSC shall process claims and allow TRICARE benefits for otherwise covered health care services (i.e., physician visit, medication management visit, etc.) related to the treatment of obesity. Normal TRICARE Prime cost-sharing applies.

### **5.0 APPLICABILITY**

The provisions of this demonstration are limited to those TRICARE-eligible beneficiaries as stated above in [paragraph 3.1](#).

**6.0 ASD(HA) RESPONSIBILITIES**

ASD(HA) is the designated Executive Agent for the Demonstration project. They shall designate a project officer in the Office of the DASD (Clinical Services) for the Demonstration. The project officer shall provide clinical oversight and ongoing program management of the Demonstration.

**7.0 EFFECTIVE DATE**

This demonstration is effective for claims for services provided on or after October 1, 2005.

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## EXPIRED - Department Of Defense (DoD) Tobacco Cessation Demonstration

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### 1.0 PURPOSE

This demonstration will allow the Department of Defense (DoD) to determine the efficacy and acceptability of a telephone-based tobacco cessation quitline and pharmacotherapy in producing and maintaining tobacco cessation. The Tobacco Cessation Demonstration (hereby referred to as the Demonstration) will also provide information that will enable DoD to determine whether to authorize telephone-based tobacco cessation counseling alone or with pharmacotherapy as part of the TRICARE benefit.

### 2.0 BACKGROUND

**2.1** Tobacco use is the leading cause of preventable death in the United States. It is responsible for 440,000 deaths annually nationwide, including 14,000 in the DoD. The case for an expanded and comprehensive approach to DoD tobacco cessation is compelling. With estimated medical costs from tobacco use that exceed \$1.6 billion per year and the observation of an alarming increase in smoking prevalence among young active duty, the need for a global and effective DoD strategy has never been greater.

**2.2** Research indicates tobacco use has a negative impact on readiness during wartime (e.g., 20-50% reduction in night vision; rapid nicotine withdrawal affects cognitive functioning and visual acuity; significant decrement in tracking and longer reaction times). Tobacco use also:

- Puts individuals at greater risk for pneumonia, asthma, and lung disease;
- Results in more hospitalization and lost work in young active duty;
- Degrades performance on physical fitness tests; and
- Increases likelihood of sustaining musculoskeletal injuries.

**2.3** Substantial research confirms that pharmacotherapy, proactive telephone quitlines, and individual/group counseling are effective interventions. According to the Centers for Disease Control and Prevention (CDC), smokers are more likely to utilize telephone counseling than group and individual counseling. High intensity interventions are more effective than lower intensity ones. The Demonstration will provide the opportunity to test the effectiveness of potential benefit changes in the DoD population.

**2.4** One of the priorities of the Assistant Secretary of Defense for Health Affairs (ASD(HA)) is to establish a uniform tobacco cessation program for TRICARE Prime enrollees in the Military Health System (MHS). Therefore, on July 6, 2005 (Vol 70, No 38888), the **Federal Register** announced a demonstration project in which the DoD will provide TRICARE reimbursement for tobacco

cessation services for TRICARE beneficiaries who meet the eligibility requirements outlined in [paragraph 3.1](#). The scope of services available through this demonstration will include:

- The availability of a proactive toll-free telephone quitline;
- The availability of a web-based tobacco cessation information resource;
- Prescription pharmacotherapy and physician visits, with normal copays; and
- Unlimited numbers of quit attempts.

This demonstration project is being conducted under the expanded Health Maintenance Organization (HMO) Uniform Benefit of the [32 CFR 199.18\(b\)\(2\)](#).

**2.5** The Demonstration project is planned for three years. The Demonstration will continue based on outcome measures related to utilization rates, quit rates, and success of pharmacotherapy.

### **3.0 POLICY AND ELIGIBILITY**

**3.1** Effective October 1, 2005, the Demonstration is authorized for TRICARE eligible beneficiaries enrolled in Prime, 18-64 years of age, and who are non-Medicare entitled and reside in the identified zip code areas of the demonstration. The demonstration area includes an area greater than 40 miles from inpatient Military Treatment Facilities (MTFs) in Colorado, Minnesota, Missouri, and Kansas.

**3.2** The Demonstration does not apply to those TRICARE-eligible beneficiaries enrolled in special programs (e.g., Extended Care Health Option (ECHO)) available through TRICARE.

### **4.0 MANAGED CARE SUPPORT CONTRACTOR (MCSC) RESPONSIBILITY**

**4.1** The MCSC shall enroll eligible beneficiaries into the Demonstration through Defense Online Enrollment System (DOES) based on applications received from the Demonstration contractor. The MCSC is not required to verify or validate enrollment information. Rather, the MCSC is simply the data entry portal for reporting the enrollment to Defense Enrollment Eligibility Reporting System (DEERS). The MCSC shall accomplish the required data entry within seven calendar days of receiving an approved enrollment application from the demonstration contractor. Enrollments that cannot be effected because of ineligibility on DEERS or because of invalid or incomplete information shall be returned to the demonstration contractor with an explanation of the problem within seven calendar days of receipt of the application.

**4.2** The MCSC shall provide the Pharmacy Data Transaction Service (PDTs) with a weekly list of all enrollments completed during the week. The list will include: beneficiary's name, beneficiary's Social Security Number (SSN), sponsor's name, sponsor's SSN, beneficiary's address, and date of enrollment into the Demonstration. The weekly list shall be e-mailed to **[pdt.ameddcs@amedd.army.mil](mailto:pdt.ameddcs@amedd.army.mil)**.

**4.3** DoD will cost-share all medical care required as a result of participation in the Demonstration. This includes physician visits for medical management and prescription pharmacotherapy through the TRICARE Mail Order Pharmacy (TMOP).

**4.4** The MCSC shall process claims and allow TRICARE benefits for otherwise covered health care services (i.e., physician visits, medication management visits, prescription pharmaceuticals, etc.)

related to tobacco cessation. Normal TRICARE Prime copays for provider visits and prescription pharmacotherapy will apply under this Demonstration. No copays will be assessed for Quitline services or web-based tobacco cessation information.

**4.5** The MCSC shall disenroll demonstration participants upon notification of loss of eligibility by DEERS (due to a change in DEERS status or relocation outside of the demonstration area), upon notification of completion of treatment, or upon termination of the demonstration (whichever comes first).

**4.6** The MCSC shall notify the demonstration contractor of any DEERS status changes for demonstration participants which could affect eligibility for the demonstration.

## **5.0 APPLICABILITY**

The provisions of this demonstration are limited to those TRICARE-eligible beneficiaries and Active Duty Service Members (ADSMs) as stated in [paragraph 3.1](#).

## **6.0 ASD(HA) RESPONSIBILITIES**

ASD(HA) is the designated Executive Agent for the Demonstration project. They shall designate a project officer in the Office of the DASD (Clinical Services) for the Demonstration. The project officer shall provide clinical oversight and ongoing program management of the Demonstration.

## **7.0 EFFECTIVE DATE**

This Demonstration is effective for claims for services provided on or after October 1, 2005.

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## **EXPIRED** - Department Of Defense (DoD) Alcohol Abuse Prevention And Education Demonstration

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### **1.0 PURPOSE**

The purpose of this demonstration is to test the efficacy of web-based training in the avoidance of abusive behaviors related to alcohol consumption. This section is for information only.

### **2.0 BACKGROUND**

**2.1** Web-based alcohol prevention education courses are a new and innovative approach to education that active duty members can relate to and feel comfortable with. Such an approach combines proven science-based teaching with the latest web-based media technologies. Available courses offer potentially engaging and easy to follow audio-visual productions including streaming video, interactive assignments and case studies, self assessments, customized feedback about current drinking levels, as well as final examinations. These courses also offer the benefit of being available at any time for the user. Additionally, due to the very nature of the internet, such programs also have the potential to provide researchers with a wealth of data that can help determine the outcomes of the program.

**2.2** This project will enhance Service-level Alcohol Prevention Education Program by providing another option for alcohol prevention education. The case of an expanded and innovative Department of Defense (DoD) approach to alcohol prevention education is compelling. According to the 2002 DoD "Survey of Health Related Behaviors Among Military Personnel," trends in alcohol consumption between 1982 and 1998 were showing great promise. Over this period, heavy alcohol consumption had declined by 36%, members facing serious consequences from alcohol consumption declined by 54%, and productivity losses from alcohol consumption declined by 60%. However, between 1998 and 2002, alarming trends have begun to emerge erasing many of the gains made in the late 1980s and 1990s. Heavy alcohol consumption increased by 27%. Additionally, for the first time, binge drinking was measured in the 2002 survey, and DoD rates of 18-25 year old active duty binge drinkers (53%) exceed civilian binge drinkers in the same age group (44%).

**2.3** Research of the literature and studies conducted within the Military Health System (MHS) indicate the impact of heavy alcohol use. According to the DoD Task Force Report on Care for Victims of Sexual Assault, alcohol use contributes to 50% of alleged sexual assaults by service members. Based on a review of active duty suicide data, alcohol was a factor in approximately 29% of all DoD suicides. In review of active duty private motor vehicle fatalities, alcohol contributed to 20-25% of those fatalities (civilian rate 40%). The DoD administratively separates more than 700 members per year for alcohol-related reasons. Research indicates alcohol reduces productivity by at least 1,764 Full Time Equivalent (FTEs)/year (treatments, illness, hospitalization, and duty losses). All these issues directly impact force readiness.

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**EXPIRED** - Department Of Defense (DoD) Alcohol Abuse Prevention And Education Demonstration

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**2.4** One of the priorities of the Assistant Secretary of Defense for Health Affairs (ASD(HA)) is to establish a uniform inexpensive web-based alcohol prevention education program for active duty in the MHS.

**2.5** The Alcohol Prevention Education Program is planned for two years. The Demonstration will continue based on outcome measures related to utilization rates, alcohol abuse rates, and who will need a continuum of services.

**3.0 ELIGIBILITY**

Effective October 1, 2005, the Demonstration is authorized for all active duty members.

**4.0 OPERATION**

The Alcohol Abuse Prevention and Education Demonstration will be operated by a Demonstration contractor. No Managed Care Support Contractor (MCSC) involvement is required.

- END -

## **EXPIRED** - TRICARE Demonstration Project For The State Of Alaska - Critical Access Hospital (CAH) Payment Rates

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### **1.0 PURPOSE**

Under this demonstration project, TRICARE will reimburse Critical Access Hospitals (CAHs) in the state of Alaska in a similar manner as they are reimbursed under Medicare. This demonstration project will test adopting a Medicare-like CAH reimbursement methodology prior to nationwide implementation, in those states that have established State Flex Programs. It will also test CAH provider participation in TRICARE, beneficiary access to care, cost of health care services, military medical readiness, morale and welfare. This demonstration will be conducted under statutory authority provided in 10 United States Code (USC) 1092.

### **2.0 BACKGROUND**

**2.1** Hospitals are authorized TRICARE institutional providers under 10 USC 1079(j)(2) and (4). Under 10 USC 1079(j)(2), the amount to be paid to hospitals, Skilled Nursing Facilities (SNFs), and other institutional providers under TRICARE, "shall be determined under joint regulations... which provide that the amount of such payments shall be determined to the extent practicable in accordance with the same reimbursement rules as apply to payments to providers of services of the same type under [Medicare]:". Under [32 CFR 199.14\(a\)\(1\)\(ii\)\(D\)\(1\)](#) through [\(9\)](#) it specifically lists those hospitals that are exempt from the Diagnosis Related Groups (DRG)-based payment system. CAHs are not listed as excluded, thereby making them subject to the DRG-based payment system. CAHs are not listed as exempt, because at the time this regulatory provision was written, CAHs were not a recognized entity.

**2.2** Legislation enacted as part of the Balanced Budget Act (BBA) of 1997 authorized states to establish State Medicare Rural Hospital Flexibility Programs, under which certain facilities participating in Medicare could become CAHs. CAHs represent a separate provider type with their own Medicare conditions of participation as well as a separate payment method. Since that time, a number of hospitals, acute care and general, as well as Sole Community Hospitals (SCHs), have taken the necessary steps to be designated as CAHs. Since the statutory authority requires TRICARE to apply the same reimbursement rules as apply to payments to providers of services of the same type under Medicare to the extent practicable, TRICARE must proceed with publication of a proposed and final rule to exempt CAHs from the DRG-based payment system and adopt a method similar to Medicare principles for these hospitals when it becomes practicable to implement. The purpose of the demonstration is to test implementation immediately for CAHs in the state of Alaska.

**EXPIRED** - TRICARE Demonstration Project For The State Of Alaska - Critical Access Hospital (CAH)  
Payment Rates

**3.0 POLICY**

**3.1** Otherwise covered services and supplies provided by CAHs in the state of Alaska shall be reimbursed for inpatient and outpatient facility services at the lesser of the billed charge or on the basis of 101% of their allowable and reasonable costs. That is, an overall inpatient Cost-To-Charge Ratio (CCR) and overall outpatient CCR, obtained from data on the hospital's most recent Medicare cost report will be multiplied by the billed charge; the resulting amount will be increased by 1%. This amount shall be compared to the billed charge and the lesser of the two shall be paid to the provider.

**3.2** The following inpatient CCRs shall be effective for inpatient admission on or after July 1, 2007. The outpatient CCRs shall be effective for outpatient facility services with dates of service on or after July 1, 2007.

**FIGURE 18.7-1 CRITICAL ACCESS HOSPITALS (CAHs) IN ALASKA AND THEIR CCRS ON OR AFTER JULY 1, 2007**

NAME	INPATIENT CCR	OUTPATIENT CCR
Valdez Regional Health Authority (VRHA)	2.1029	1.3978
Providence Seward Medical & Care Center (PSMCC)	0.6799	0.7674
Sitka Community Hospital (SCH)	1.0100	0.8098
Petersburg Medical Center (PMC)	0.9762	0.8901
Wrangell Medical Center (WMC)	0.9445	0.7574
Providence Kodiak Island Medical Center (PKIMC)	0.6992	0.6079
Cordova Community Medical Center (CCMC)	1.0544	1.3456
Norton Sound Health Corporation (NSHC)	1.0438	1.1183
Ketchikan General Hospital (KGH)	0.5770	1.1669

**3.3** The following inpatient CCRs shall be effective for inpatient admission on or after July 1, 2008. The outpatient CCRs shall be effective for outpatient facility services with dates of service on or after July 1, 2008.

**FIGURE 18.7-2 CRITICAL ACCESS HOSPITALS (CAHs) IN ALASKA AND THEIR CCRS ON OR AFTER JULY 1, 2008**

NAME	INPATIENT CCR	OUTPATIENT CCR
Valdez Regional Health Authority (VRHA)	1.5739	1.2364
Providence Seward Medical & Care Center (PSMCC)	0.9906	0.6405
Sitka Community Hospital (SCH)	1.0852	0.8717
Petersburg Medical Center (PMC)	0.8958	0.8895
Wrangell Medical Center (WMC)	0.8391	0.7346
Providence Kodiak Island Medical Center (PKIMC)	0.6340	0.5586
Cordova Community Medical Center (CCMC)	0.6026	0.8697

**FIGURE 18.7-2 CRITICAL ACCESS HOSPITALS (CAHs) IN ALASKA AND THEIR CCRS ON OR AFTER JULY 1, 2008 (CONTINUED)**

NAME	INPATIENT CCR	OUTPATIENT CCR
Norton Sound Health Corporation (NSHC)	1.0967	0.8851
Ketchikan General Hospital (KGH)	0.6827	0.6711

**3.4** The TRICARE Management Activity (TMA) shall provide a list of CAHs in the state of Alaska to the MCSC and the inpatient and outpatient CCRs to be used for this demonstration. The CCRs shall be updated on an annual basis using the most recent CCRs for each hospital. TMA shall provide the updated inpatient and outpatient CCRs to the contractor and the updated inpatient and outpatient CCRs shall be effective as of July 1 of each respective year, with the first update occurring effective July 1, 2008.

**3.5** Payment for TRICARE covered outpatient services provided by physicians and other non-institutional individual professional providers in the state of Alaska shall be reimbursed in accordance with the Federal Register (FR) notice published on November 20, 2006 (71 FR 67112-67113). That is, TRICARE will adopt a rate that is 1.35 times the current TRICARE allowable rate. These rates are included in the CHAMPUS Maximum Allowable Charge (CMAC) file that is provided to each of the Managed Care Support Contractors (MCSCs).

**3.6** The TRICARE cost-shares, copayments, and deductibles applicable to hospitals shall also apply to the services provided by CAHs under this demonstration.

**3.7** The CAH portion of the state of Alaska demonstration excludes those Indian Health Service (IHS) facilities that are also CAHs. IHS facilities will continue to be reimbursed the DRG or the negotiated rate for inpatient care, the lower of the billed charge or negotiated rate for outpatient facility care, and the CMAC rates for Alaska for care rendered by individual professional providers.

#### **4.0 MCSC RESPONSIBILITY**

**4.1** The MCSC for the state of Alaska shall price and process inpatient and outpatient facility claims under this demonstration using the reimbursement methods described in [paragraph 3.0](#).

#### **4.2 Out-Of-Jurisdiction Claims**

**4.2.1** In the event the MCSC for the state of Alaska receives an out-of-jurisdiction claim, the MCSC shall price the claim using the methods described in [paragraph 3.0](#). Once the claim has been priced, the claim shall be forwarded to the appropriate contractor based on the jurisdiction provisions found in [Chapter 8, Section 2](#).

**4.2.2** In the event that a north or south MCSC or other TRICARE contractor receives a claim from one of the CAHs under this demonstration, the claim shall be sent to the MCSC for the state of Alaska to be priced using the provision of this demonstration. Once the claim has been priced by the state of Alaska MCSC, the claim shall be forwarded to the appropriate contractor based on the jurisdiction provisions found in [Chapter 8, Section 2](#). The claim shall be sent to the fax number: 1-715-843-8435, Attn: CAH Processing.

**TRICARE Operations Manual 6010.56-M, February 1, 2008**

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**EXPIRED** - TRICARE Demonstration Project For The State Of Alaska - Critical Access Hospital (CAH)  
Payment Rates

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**5.0 EFFECTIVE DATES**

**5.1** The portion of the state of Alaska demonstration that provides for 1.35 times the current TRICARE allowable rate took effect on February 1, 2007.

**5.2** The enhanced portion of the state of Alaska demonstration that provides for 101% of reasonable costs for inpatient and outpatient facility reimbursement to CAHs shall be effective for inpatient admissions on and after July 1, 2007, and for outpatient facility services with dates of service on or after July 1, 2007.

**5.3** The CAH portion of the demonstration will expire on November 30, 2009. Requirements of this section as related to the CAH portion of the demonstration cease at 12:00 midnight on November 30, 2009, except for claims for patients admitted prior to 12:00 midnight on November 30, 2009. The demonstration retains responsibility for these claims until the beneficiary is discharged from the CAH. For information on CAH reimbursement, see the TRICARE Reimbursement Manual (TRM), [Chapter 15, Section 1](#).

- END -

## **EXPIRED** - Operation Noble Eagle/Operation Enduring Freedom Reservist And National Guard (NG) Benefits Demonstration

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### **1.0 PURPOSE**

The purpose of this demonstration is to test if the Military Health System (MHS), with certain flexibility in operation, can ensure timely access to health care during a national crisis, maintain clinically appropriate continuity of health care to family members of activated reservists and guardsmen, appropriately limit the extraordinary out-of-pocket expenses for those family members, and remove potential barriers to health care access by families.

### **2.0 BACKGROUND**

**2.1** A number of reservists and members of the NG are being ordered to active duty in support of operations that result from the terrorist attacks on the World Trade Center (WTC) and the Pentagon on September 11, 2001. These individuals are being ordered to active duty under Executive Order 13223, 10 U.S.C. 12302, 10 U.S.C. 12301(d), or 32 U.S.C. 502(f). Such operations include for example, Operation Noble Eagle and Operation Enduring Freedom.

**2.2** In many cases, reservist families live far from Military Treatment Facilities (MTFs), and are not supported by TRICARE provider networks. Some doctors do not participate in TRICARE, and by law may bill beneficiaries for up to 15% above TRICARE allowable amounts. Family members of reservists could face undue financial hardships if they use such providers.

**2.3** In some cases family members of activated reservists and members of the NG are in the middle of a course of medical care (e.g., obstetrical care) which would be disrupted if the family member were suddenly required to continue their care at a military treatment facility.

**2.4** Most reservists and members of the NG are enrolled in a commercial health plan when they are called to active duty. Since in nearly every case they will have paid a deductible under their commercial health plan, they would be unfairly penalized if they had to meet a second deductible under TRICARE for care provided to their family members.

### **3.0 POLICY**

**3.1** Effective September 14, 2001, this demonstration is authorized for family members of reservists or members of the NG as described in [paragraph 2.1](#). These beneficiaries will be identified by Special Indicator (SI) Code "02" on the Defense Enrollment Eligibility Reporting System (DEERS).

**EXPIRED** - Operation Noble Eagle/Operation Enduring Freedom Reservist And National Guard (NG)  
Benefits Demonstration

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**3.2** The TRICARE Encounter Data (TED) record for each Noble Eagle/Enduring Freedom claim must reflect the Special Processing Code "NE".

**3.3** Claims are to be paid from financially underwritten funds. On claims for care from non-participating professional providers, contractors shall allow the lesser of the billed charges or the balance billing limit (115% of the allowable charge). If the charges on a claim from a non-participating professional provider are exempt from the balance billing limit, the contractor shall allow the billed charges. This applies to all claims from non-participating professional providers for services rendered to Standard beneficiaries. In double coverage situations, normal double coverage requirements shall apply.

**Note:** This special demonstration payment provision does not apply to Prime beneficiaries. Family members of reservists or members of the NG who are called to active duty in support of Operation Noble Eagle/Operation Enduring Freedom and who are enrolled in Prime will be protected when they receive services outside the network under the provisions of [Chapter 8, Section 5](#).

**3.4** In order to protect beneficiaries from incurring greater out-of-pocket costs under these special procedures, the beneficiary cost-share for these claims will be limited to what it would have been in the absence of the higher allowable amount under this demonstration. That is, the cost-share is 20% of the lesser of the CHAMPUS Maximum Allowable Charge (CMAC) or the billed charge. Any amounts that are allowed over the CMAC will be paid entirely by TRICARE.

**3.5** TED records submitted for these non-participating professional claims that are reimbursed at the lesser of the balance billing limit or the billed charge are to be identified with Pricing Rate Code "W" but only if the allowed amount is greater than the CMAC. If the billed charge equals or is less than the CMAC, Pricing Rate Code "W" is not to be used. On the other hand, when the claim is reimbursed as billed because the billed charge is greater than the CMAC but less than the balance billing limit or the charges are exempt from the balance billing limit, Pricing Rate Code "W" is to be used.

**3.6** All Non-Availability Statement (NAS) requirements are waived for beneficiaries identified by DEERS Special Indicator Code "02". TED records submitted for these beneficiaries are to use Care Authorization (CA)/NAS Exception Reason 9, "TRICARE Demonstration Project".

**3.7** The TRICARE Standard and Extra deductible is waived for all beneficiaries identified by DEERS Special Indicator Code "02".

#### **4.0 EVALUATION**

**4.1** The evaluation will assess the impact that the higher payment rates have on beneficiary access to care.

**4.2** The evaluation will assess the financial impact of the higher payment rates.

**4.3** The evaluation will assess the impact on the continuity of care for beneficiaries whose claims were paid at the higher rates and for whom the NAS requirements were waived.

**TRICARE Operations Manual 6010.56-M, February 1, 2008**

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**EXPIRED** - Operation Noble Eagle/Operation Enduring Freedom Reservist And National Guard (NG)  
Benefits Demonstration

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**4.4** The evaluation will assess the financial impact of waiving the deductibles for these beneficiaries.

**5.0 EFFECTIVE DATES**

This demonstration is effective for claims for services provided on or after September 14, 2001, and before November 1, 2009.

- END -



## **EXPIRED** - Web-Based TRICARE Assistance Program (TRIAP) Demonstration

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### **1.0 PURPOSE**

The purpose of this Demonstration is to test the use of web-based technologies to get information and Employee-Assistance Program (EAP)-like Behavioral Health (BH) services to our beneficiaries to determine if it increases the effectiveness and efficiency of identifying those who need medically necessary mental health care and in identifying their medical mental health needs earlier and in getting them referred or getting them access to the appropriate level of mental health care more effectively. We are also interested in learning if providing this level of care reduces a later need for mental health care. In addition, this will enable the Department of Defense (DoD) to determine whether:

- The availability to provide web-based EAP-like counseling is a valid mechanism to improve access in rural or underserved areas.
- There is acceptance and use of this delivery system by eligible beneficiaries.
- It is feasible to offer this service on a permanent basis.

### **2.0 AUTHORITY**

**2.1** Section 1092, Chapter 55, Title 10 of the United States Code (USC) allows the Secretary of Defense to conduct studies and demonstration projects. This section also specifies that the Secretary may enter into contracts with public or private organizations to conduct these studies and demonstrations.

**2.2** In the House Report 2638 DoD Appropriations Act for Fiscal Year (FY) 2009 Joint Explanatory Statement (p.405), Congress stated: "An area of particular interest is the provision of appropriate and accessible counseling of service members and their families who live in locations that are not close to Military Treatment Facilities (MTFs), other Military Health System (MHS) facilities or TRICARE providers. Web-based delivery of counseling has significant potential to offer counseling to personnel who otherwise might not be able to access it. Therefore, the Department is directed to establish and use a web-based Clinical Mental Health Services Program as a way to deliver critical clinical mental health services to service members and their families in rural areas." The ability to provide web-based TRICARE Assistance Program (TRIAP) services is a valid mechanism to augment the basic TRICARE mental health benefit to provide short-term counseling options.

### **3.0 BACKGROUND**

**3.1** The DoD currently provides a robust program of mental health care for our Active Duty Service Members (ADSMs) and their families. In addition, the Department offers Military One Source which provides multiple, currently 12, face-to-face BH non-medical counseling sessions for each issue faced by a beneficiary. For those needing medical treatment, BH care is provided in MTFs or through the TRICARE program.

**3.2** The Managed Care Support Contractors (MCSCs) currently provide an array of text and multi-media based educational materials targeting pre-deployment, deployment, and post-deployment adjustment concerns. They also have BH Provider Locator and Appointment Assistant Centers staffed with licensed counselors, or beneficiary service representatives and customer service representatives to provide first and second level support, triage, and make appropriate BH referrals and locate providers for beneficiaries. This demonstration project will expand access to on-line contact options including web-based e-mail and video-conferencing to those eligible as indicated in this section to provide TRIAP services which are not otherwise covered as TRICARE authorized medically necessary mental health services.

### **4.0 DEFINITIONS**

#### **4.1 Interactive Telecommunications System**

Interactive telecommunications systems are defined as multimedia communications equipment that includes, at a minimum, audio-video equipment permitting two-way, real time service or consultation involving the beneficiary and counselor as appropriate to the BH needs of the patient. Telephone services excluded by [32 CFR 199.4\(g\)\(52\)](#) do not meet the definition of interactive telecommunications services.

#### **4.2 TRIAP Counseling**

The DoD goal for professional, web-based assistance services is to provide ADSMs and their families, TRICARE Reserve Select (TRS) enrollees, and Transitional Assistance Management Program (TAMP) beneficiaries with an avenue for private, non-reportable discussion of personal life issues such as family difficulties and pressures, crisis intervention, anxiety, and self-esteem on a one-on-one basis in the context of a confidential relationship with a licensed professional.

#### **4.3 TRIAP Services**

Private, non-reportable discussions of personal life issues such as dealing with relationships, crisis intervention, stress management, family issues, parent-child communications, family separations, anxiety, and self-esteem on a one-on-one basis in the context of a confidential relationship with a licensed professional.

### **5.0 POLICY**

**5.1** TRIAP services will be provided to ADSMs and their spouses of any age, and their family members 18 years of age or older, and those beneficiaries enrolled in TRS and TAMP 18 years of age or older. A full range of private, confidential, counseling services via the web, including on-line video chat to address current and emerging needs are available.

**5.2** Generally, the TRIAP services will support ADSMs and their families, TRS enrollees, and TAMP beneficiaries as it:

- Makes expert short-term, TRIAP services available on demand.
- Helps cope with normal reactions to abnormal/adverse situations.
- Assesses and delivers short-term, solution-focused counseling for situations resulting from commonly occurring life circumstances such as deployment stress, relationships, personal loss, and parent-child communications.
- Provides an avenue for private, non-reportable discussion of personal life issues such as family difficulties and pressures, crisis intervention, anxiety, self-esteem, loneliness, and critical life decisions on a one-on-one basis in the context of a confidential relationship.

## **6.0 MINIMUM REQUIREMENTS FOR DELIVERY OF TRIAP SERVICES**

**6.1** If the beneficiary requests assistance services during the initial contact, the contractor shall determine the appropriate level of care required and direct the beneficiary accordingly. If appropriate and the beneficiary possesses the required hardware and software, video assistance services is an option that can be offered. However, the beneficiary must also be offered the alternative of face-to-face care if it is available. If video assistance services are not possible or not appropriate for the beneficiary's needs, referrals for care outside this demonstration to the MTF or network providers can be made (with appropriate authorization). Additionally, referrals can be made to Military One Source for telephonic or face-to-face counseling. If the provider determines that additional TRIAP services are necessary, the first follow-up session will be scheduled within three days of the initial intervention.

**6.2** The contractor shall establish protocols and procedures for assessment, referral, and recordkeeping of beneficiaries in need of assistance services.

**6.3** All employees, contractors, and subcontractors who will have access to beneficiary information will be advised of the confidential nature of the information, that the records are subject to the requirements of the Privacy Act of 1974, and to the extent applicable the Health Insurance Portability and Accountability Act of 1996 (HIPAA), and that unauthorized disclosures of beneficiary information may result in the imposition of possible criminal penalties.

**6.4** Contractor shall establish and maintain a recordkeeping system that is designed to protect the ADSM or family members' and others privacy and confidentiality, as appropriate and required for specific services. Although this TRIAP service is private and confidential, the contractor must keep utilization records which document that confidential and private services have been provided to service members, their families, and others eligible for the demonstration. The counselor must explain to the service member, family member, or other that the personal identification information will be held in strictest confidence by the contractor. The contractor shall post the details of each contact on the recordkeeping system within three business days of the contact.

**6.5** The contractor shall capture selective beneficiary contact and demographic information, to include ensuring that beneficiaries meet eligibility criteria, while ensuring beneficiary

confidentiality, in a database and provide monthly reports detailing assistance services that includes at a minimum, the information necessary to provide monthly reports.

**6.6** The contractor shall maintain procedures for responding to emergency, urgent, and non-urgent calls. These procedures shall include an immediate response for emergency situations, access to mental health counseling outside of this demonstration within one business day for urgent calls, and access to web-based TRIAP services within three business days for non-urgent calls if the services cannot be provided immediately.

**6.7** The contractor shall maintain a counseling model and process flow for triage purposes to determine if TRIAP services are appropriate.

## **7.0 GENERAL**

**7.1** There are no referral and authorization requirements for web-based TRIAP services. TRICARE beneficiaries who are eligible for the Demonstration may access this care using Personal Computers (PCs). Current referral rules apply to medically necessary TRICARE authorized mental health care.

**7.2** Web-based TRIAP services are available 24 hours a day, seven days a week.

**7.3** Web-based interaction such as e-mails, online video chat, or video Instant Message (IM) for TRIAP services is not limited to a certain number of interactions. E-mail may be used to make appointments for assistance services, if needed.

## **8.0 FUNDING**

This demonstration will be reimbursed using administrative funds. There are no claims to be filed.

## **9.0 AUTHORIZED PROVIDERS**

**9.1** Web-based TRIAP services may be provided by mental health clinicians who are licensed and authorized to provide these web-based services. State laws must be complied with. In addition to TRICARE-authorized providers, counselors providing web-based TRIAP services could include independently licensed masters prepared clinicians, including, but not limited to, licensed psychotherapists, marriage and family counselors, and licensed professional counselors.

**9.2** The contractor will ensure that those providing counseling have knowledge of military family programs and knowledge of the unique cultural aspects of the military lifestyle.

## **10.0 ELIGIBILITY**

**10.1** This demonstration is available to ADSMs, ADSM's spouses of any age, their family members 18 years of age or older, those enrolled in TRS, and TAMP beneficiaries. All must reside in the Continental United States (CONUS).

**10.2** In the event that a beneficiary Outside the Continental United States (OCONUS) accesses TRIAP services, TRIAP personnel should encourage the beneficiary to utilize other outlets for similar

counseling that have the ability for more immediate follow-up or intervention if necessary. This includes MTFs, combat stress control units, and supervisors/commanders. Military One Source services are available in both CONUS and OCONUS and are a viable referral option. If the TRIAP counselor believes that the ADSM is at-risk of any of the circumstances in which a DoD issuance requires health care providers to notify an ADSM's commander, the counselor shall obtain as much information as possible regarding the individual; i.e., Branch of Service, unit, a contact/call-back number, their location (as precisely as possible), closest MTF (if known) and command information. The TRIAP counselor shall then contact the ADSM's commander (or the commander's designee for receiving protected health information) and inform the commander or designee about the at-risk individual, in order to ensure he or she receives appropriate counseling/care. The circumstances triggering this requirement include, but are not limited to, serious risk of causing harm to oneself or others. The currently applicable DoD issuances are DoD 6025.18-R, C7.11.1 and Directive-Type Memorandum (DTM) 09-006, "Revising Command Notification Requirements to Dispel Stigma in Providing Mental Health Care to Military Personnel," July 2, 2009. The requirements of this DTM will be incorporated in DoD 6025.18-R or its successor issuance. In the event the counselor cannot obtain enough information to contact the ADSM's commander, the counselor shall then contact the appropriate Service Operations Center (Army Operations Center, Air Force Watch, Navy Watch Center, Coast Guard Operations Center, or Marine Corps Operations Center) for assistance. The Service Operations Center contact numbers are unclassified but sensitive and will be provided by the Contracting Officer's Representative (COR).

**10.3** In the event reservists who lose TRICARE eligibility or are not enrolled in TRS access TRIAP services, TRIAP personnel should encourage the reservist to utilize other outlets for counseling such as community resources or the Department of Veterans Affairs (DVA) if eligible.

## **11.0 MCSC RESPONSIBILITY**

**11.1** An assessment made by a licensed professional at the BH Care Provider Locator and Appointment Assistance or Customer Service Staff to determine if web-based professional TRIAP services are appropriate for the beneficiary. If it is, the BH contact center will determine if the beneficiary has the necessary software and hardware (the most currently available technology that meets the requirements of this Demonstration) to support web-based care. If that is the case, the BH Care Provider Locator and Appointment Assistance or Customer Service Staff will instruct the beneficiary on accessing web-based counseling.

**11.2** Referral to an appropriate level of care if the beneficiary does not have the necessary hardware or software, or requires care beyond the scope of this Demonstration. This level of care may include a MTF, or a TRICARE network or authorized provider.

**11.3** Provide a virtual resource library of electronic documents related to BH/mental health concerns, to include, but not limited to, suicide prevention, post-traumatic stress disorder, and depression.

**11.4** Provide a secure, web-based e-mail, online video chat and IM capability.

**11.5** When a call is received from an ADSM, the TRIAP counselor shall ask if the caller is on the Personnel Reliability Program (PRP). The purpose of the PRP is to ensure that each person who performs duties involving nuclear weapons meets the reliability standards of the PRP. Each person assigned to PRP duties is responsible for their reliability and is required to report any behavior or

circumstance about themselves or others in the PRP that may be expected to result in degradation in job performance or personal reliability or an unsafe or insecure condition involving nuclear weapons and/or Nuclear Command and Control (NC2) material. If the member responds that he/she is on the PRP, the TRIAP counselor shall read the following statement reminding the member of his or her obligation to self-report any information that could be Potentially Disqualifying Information (PDI) before providing any counseling services.

“As a Personnel Reliability Program (PRP) certified or administrative qualified individual, you are personally responsible for advising your Certifying Official or supervisor of any factors that could have an adverse impact on your performance, reliability, or safety while you are performing PRP duties. This includes factors that impact your physical and mental wellness, your dependability, your personal financial circumstances, or other legal concerns. When you receive any type of medical/dental treatment or evaluation, to include mental health or family related counseling, you are personally responsible for reporting the treatment or evaluation to your Certifying Official and for providing appropriate documentation concerning the treatment or evaluation to the competent medical authority (CMA) at your military treatment facility responsible for consulting with the certifying official on this matter. Failure to make these notifications or to provide the appropriate documentation may cast doubt on your reliability and may violate the provisions of DoD Regulation 5210.42. If you have any questions regarding these requirements you should consult with your Certifying Official for more information.”

**11.6** The TRIAP counselor shall document that the statement was read or that it could not be read for any reason including the person hanging up.

**11.7** By the 10th of each month, the contractor shall capture and report all service member, family member, TRS enrollee contracts by military service and installation, to include Guard and Reserve member affiliation as described in the Contract Data Requirements List (CDRL) DD Form 1423.

## **12.0 TRICARE MANAGEMENT ACTIVITY (TMA) RESPONSIBILITY**

An independent evaluation of the demonstration will be conducted. It will be performed retrospectively and use a combination of administrative and survey measures of BH care access to provide analyses and comment on the effectiveness of the demonstration in meeting this goal of improving beneficiary access to BH call centers by incorporating web-based technology.

## **13.0 EFFECTIVE DATES**

This demonstration project will be effective for services on or after August 1, 2009. The demonstration project will continue until March 31, 2012.

## **14.0 EXCLUSIONS**

Medical treatment including medication management and psychoanalysis.

- END -

## General

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### 1.0 GENERAL

The TRICARE Dual Eligible Fiscal Intermediary Contract (TDEFIC) encompasses the processing of all TRICARE claims for services rendered within the 50 United States and the District of Columbia, as well as Puerto Rico, Guam, the U.S. Virgin Islands, American Samoa, and the Northern Mariana Islands, to individuals who have dual eligibility under both TRICARE and Medicare.

### 2.0 DUAL ELIGIBLES

There are six general categories of beneficiaries who have dual eligibility under both TRICARE and Medicare and whose claims will be processed under TDEFIC:

**2.1** TRICARE beneficiaries, who are 65 or older and who are entitled to premium-free Medicare Part A and who have Medicare Part B;

**2.2** TRICARE beneficiaries who are 65 or older and who are not entitled to premium-free Medicare Part A on their own record or the record of their current, former, or deceased spouse but have Medicare Part B;

**2.3** Active Duty Family Members (ADFM) who are 65 or older and who are entitled to premium-free Medicare Part A only;

**2.4** TRICARE beneficiaries who are entitled to premium-free Medicare Part A because of a disability or End Stage Renal Disease (ESRD) and who **have** Medicare Part B;

**2.5** ADFMs who have a disability or ESRD and are entitled to premium-free Medicare Part A only (While those with Medicare based on disability get a special enrollment period and therefore are not subject to the Part B premium surcharge, the special enrollment period does not apply to those with ESRD. ESRD patients who do not keep Medicare Part B when first eligible may have to pay a surcharge of 10% for each 12 month period that they could have enrolled in Part B but did not.); and

**2.6** TRICARE **beneficiaries**, who are entitled to premium-free Medicare Part A because of a disability, where Social Security Disability Insurance (SSDI) is awarded on appeal. These beneficiaries **will have a Medicare Part B effective date of October 1, 2009 or later and a six-month minimum gap between their Medicare Part A and Medicare Part B effective dates and will** remain TRICARE eligible for the period where only Part A was effective. If a beneficiary declines Part B coverage, he/she will be ineligible for TRICARE from the original Part B **effective date** until Part B coverage is **established**.

**3.0 APPLICABILITY OF TRICARE REQUIREMENTS**

Unless specifically waived or superseded by the provisions of this chapter, all normal TRICARE requirements set forth in the TRICARE Operations Manual (TOM), TRICARE Policy Manual (TPM), TRICARE Reimbursement Manual (TRM), and TRICARE Systems Manual (TSM) apply to claims processed under TDEFIC.

- END -

## Claims Processing For Dual Eligibles

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### 1.0 GENERAL

Claims under the TRICARE Dual Eligible Fiscal Intermediary Contract (TDEFIC) will be adjudicated under the rules set forth below. In general, TRICARE pays secondary to Medicare and any other coverage.

### 2.0 DETERMINING PAYMENTS DUE AFTER COORDINATION WITH MEDICARE

**2.1** Special double coverage procedures are to be used for all claims for beneficiaries who are eligible for Medicare, including active duty dependents who are age 65 and over as well as those beneficiaries under age 65 who are eligible for Medicare for any reason. For specific instructions, refer to the TRICARE Reimbursement Manual (TRM), [Chapter 4, Section 4](#).

### 3.0 EXCEPTIONS TO TIMELY CLAIMS FILING

#### 3.1 Medicare

The contractor may grant exceptions to the claims filing deadline if Medicare accepted the claim as timely. If submitted by the beneficiary, the claim must be submitted within 90 calendar days from the date of Medicare's adjudication to be considered for a waiver.

#### 3.2 Other Health Insurance (OHI)

Reference [Chapter 8, Section 3, paragraph 2.4](#).

### 4.0 CLAIMS DEVELOPMENT REQUIREMENTS

#### 4.1 Medicare Providers

**4.1.1** The contractor shall accept the Medicare certification of individual professional providers who have a like class of individual professional providers under TRICARE without further authorization. An exception to this general rule occurs if there is information indicating Medicare, TRICARE or other federal health care program integrity violations by the physician or other health care practitioner. In such cases the Managed Care Support Contractor (MCSC) shall seek guidance from TRICARE Management Activity (TMA) Program Integrity (PI) prior to accepting the Medicare certification as valid for TRICARE purposes. Individual professional providers without a like class (e.g., chiropractors) under TRICARE shall be denied.

**4.1.2** TRICARE claims which TRICARE processes after Medicare, do not need to be developed to the individual provider level for home health or group practice claims.

**4.1.3** Electronic “cross over” claims received from Medicare after Medicare completes its claims processing do not need a beneficiary or provider signature. For paper claims, when TRICARE is second pay to Medicare and a Medicare EOB is attached, the contractor does not need to develop for provider or beneficiary signature. Signature on file requirements of [Chapter 8, Section 4](#) apply.

#### **4.2 Civilian Services Rendered To Military Treatment Facility (MTF) Inpatients**

Civilian claims for TRICARE dual eligible beneficiaries shall be processed by Medicare first without consideration of the Supplemental Health Care Program (SHCP).

#### **4.3 Preauthorization Requirements**

Special authorization/preauthorization services outlined in the TRICARE Policy Manual (TPM), [Chapter 1, Section 7.1](#) require preauthorization, and if necessary, review of waivers of the day limits for dual eligible beneficiaries when TRICARE is the primary payer. As secondary payer, TRICARE will rely on and not replicate Medicare’s determination of medical necessity and appropriateness in all circumstances where Medicare is primary payer (see the TRM, [Chapter 4, Section 4](#)). In the event that TRICARE is primary payer for these services and preauthorization was not obtained, the contractor shall obtain the necessary information and perform a retrospective review.

**4.3.1** The TDEFIC contractor shall develop a communication/education plan for Skilled Nursing Facilities (SNFs) and TRICARE dual eligible beneficiaries related to the SNF preauthorization requirement and the general SNF benefit. In addition to the initial education, this plan shall accommodate periodic SNF education (not to exceed two per year) that the contractor will conduct at the request of the TMA. The plan shall be coordinated with TMA.

**4.3.2** The TDEFIC contractor preauthorization standards for SNFs shall be as follows: 90% of all requests for preauthorization/authorization will be completed within five working days following receipt of the request and all required information, and 100% of such requests will be completed within eight working days following receipt of the request and all requested information. As such, SNF preauthorizations should be tracked separately from the required preauthorizations noted in [Chapter 7, Section 2](#). A SNF preauthorization shall not be extended for more than 30 days per instance.

#### **4.4 Referral Requirements**

The TDEFIC contractor is not responsible for obtaining or verifying that a Prime-enrolled dual eligible has a referral for care not provided by their Primary Care Manager (PCM). Dual eligibles who are enrolled in Prime are not subject to Point of Service (POS) cost-sharing.

#### **5.0 UTILIZATION MANAGEMENT**

Any utilization management provisions applied under the TRICARE Managed Care Support Services (MCSS) contracts, except for those specifically required by the TPM, TRM, or TRICARE Operations Manual (TOM), shall not apply under TDEFIC. Region-specific requirements shall not apply.

## **6.0 END OF PROCESSING**

### **6.1 Beneficiary Cost-Shares**

End Of Processing. Beneficiary cost-shares shall be based on the following when TRICARE is the primary payer. If the services were received by a TRICARE Prime enrollee (as indicated on DEERS), the contractor shall apply the Prime copayments. For a TRICARE Standard beneficiary, if a provider is known to be a network provider (e.g., Veteran Affairs Medical Center (VAMC)), the Extra cost-shares shall be applied. In all other cases, the TRICARE Standard cost-shares shall be applied.

### **6.2 Application Of Catastrophic Cap**

Only the actual beneficiary out-of-pocket liability remaining after TRICARE payments will be counted for purposes of the annual catastrophic loss protection.

### **6.3 Appeals And Grievances**

#### **6.3.1 Initial Determinations**

Services and supplies denied payment by Medicare will not be considered for coverage by TRICARE if the Medicare denial of payment is appealable under the Medicare appeal process. If, however, a Medicare appeal results in some payment by Medicare, the services and supplies covered by Medicare will be considered for coverage by TRICARE. Services and supplies denied payment by Medicare will be considered for coverage by TRICARE, if the Medicare denial of payment is not appealable under the Medicare appeal process. The appeal procedures set forth in [Chapter 12](#) are applicable to initial denial determinations by TRICARE under TDEFIC.

#### **6.3.2 Grievance System**

The contractor shall develop and implement a grievance system, separate and apart from the appeal process. The grievance system shall allow full opportunity for aggrieved parties to seek and obtain an explanation for and/or correction of any perceived failure of contractor or subcontractor personnel to furnish the level or quality of service to which the beneficiary may believe he/she is entitled. Any TRICARE beneficiary, sponsor, parent, guardian, or other representative who is aggrieved by any failure or perceived failure of the contractor or subcontractor to meet the obligations for timely, quality service may file a grievance. All grievances must be submitted in writing. If the written complaint reveals a TRICARE appealable issue, the correspondence shall be forwarded to the contractor's appeals unit for a reconsideration review. If the complaint reveals a Medicare appealable issue or regards care for which Medicare was the primary payer and the issue does not involve any actions by a TRICARE contractor, the complaint shall be forwarded to Medicare for resolution. The beneficiary shall be notified that the complaint was forwarded to Medicare and the address and phone number of where the complaint was forwarded.

## **7.0 TED SUBMISSION**

For every claim processed to completion, the TDEFIC contractor shall submit a TRICARE Encounter Data (TED) record to TMA in accordance with the requirements of the TRICARE Systems Manual (TSM).

**8.0 TRICARE PROCESSING STANDARDS**

All TRICARE Processing Standards in [Chapter 1, Section 3](#) apply except for [Chapter 1, Section 3, paragraph 1.2](#), and the following wording replaces the [Chapter 1, Section 3, paragraph 1.7.1](#), Claim Payment Errors, requirements: "The absolute value of the payment errors shall not exceed 1.5% of the total billed charges."

- END -

members/survivors at the time of EFT/RCC election that an insufficient funds fee of up to \$20 U.S. will be assessed, if sufficient funds are not available.

**5.3.2** The contractor shall be responsible for initiating EFTs and automatic credit/debit card payments with the member's/survivor's financial institution upon request, or when required, by the TRS member/survivor.

**5.3.3** The contractor shall direct bill the TRS member/survivor when a problem occurs in initially setting up the EFT or when there are insufficient funds to process a monthly EFT. The contractor may apply a fee of up to \$20 U.S. for insufficient funds. The contractor shall include notice of the fee of up to \$20 U.S. when billing the member/survivor. If the contractor is unable to obtain the requested premium payment from the TRS member's/survivor's account for any reason after an EFT is established, the TRS member will be responsible for paying the overdue premiums and any insufficient funds fee by means of direct billing.

**5.3.4** Premium payments shall be made payable to the contractor servicing the member's or survivor's coverage as specified in [paragraph 5.1](#).

#### **5.4 Annual Premium Adjustment**

**5.4.1** Contractors shall include advance notification of annual premium adjustments on the October, November and December monthly bills (the October notification may not include the actual premium rates for the new year). The notification shall include the new amount for member only and member and family coverage. For those members/survivors not receiving a monthly bill, the contractor shall issue a notice advising the member/survivor of the adjusted premium amount at the same time the payment is collected in October, November, and December bills are mailed and shall initiate all actions required to allow the continuation of the EFT transaction or credit/debit card payment with the adjusted premium amount.

**5.4.2** For premium adjustments that go into effect at any time other than January the first, the government will provide instructions about notification of members/survivors.

#### **5.5 Premium Adjustments from Changes Associated with QLEs**

**5.5.1** When a QLE is processed that changes the premium, the effective date of the premium change shall be the date of the QLE.

**5.5.2** If the change from a QLE results in an increase in the premium, the contractor shall adjust the next bill or electronic payment, to include any underpaid amount (prorated to the day as specified in [paragraph 5.3](#)), to the effective date of the change.

**5.5.3** If the change from a QLE results in a decrease in the premium, the contractor shall retain any overpaid amount and apply it to subsequent bills or electronic payments until all of the overpayment is exhausted.

#### **5.6 Suspensions/Terminations and Premium Adjustments**

The contractor shall initiate the process to refund any premium amounts applied for coverage after the date of [suspension/termination](#) as specified in [paragraph 4.4](#).

## 5.7 Online Transactions

In addition to requirements specified in [paragraph 5.0](#) and its subordinate paragraphs, the contractor may provide online capability for TRS members/survivors to conduct business related to premium collection and other applicable administrative services through secure access to the contractor's web site.

## 6.0 CLAIMS PROCESSING

**6.1** The contractor shall process TRS claims under established TRICARE Standard and TRICARE Extra ADFM cost-sharing rules and guidance. Normal TRICARE Other Health Insurance (OHI) processing rules apply to TRS.

**6.2** The contractor shall pend all claims for health care provided to a newborn/new child of a TRS member until the member completes the process specified in [paragraph 4.2.3.1](#). If the contractor becomes aware that a TRS member has an unregistered newborn/new child, the contractor shall notify the TRS member of the requirement to enroll the newborn/new child in DEERS and submit a request form for the newborn/new child NLT 60 days after birth/custody. When the member completes the process specified in [paragraph 4.2.3.1](#), the contractor shall process any claims associated with the newborn/new child's health care. If the member fails to complete the process as specified in [paragraph 4.2.3.1](#), the contractor shall deny any claims associated with the newborn/new child's health care.

**6.3** Premium payments made for TRS shall not be applied to the fiscal year deductible or catastrophic cap limit.

**6.4** Non-Availability Statement (NAS) requirements shall apply to TRS members, family members, and survivors in the same manner as for ADFMs under TRICARE Standard/Extra.

**6.5** Medicare is the primary payer for TRICARE beneficiaries who **are eligible for** Medicare. Claims under the TRICARE Dual Eligible Fiscal Intermediary Contract (TDEFIC) will be adjudicated under the rules set forth in **the TRICARE Reimbursement Manual (TRM), Chapter 4, Section 4**. The Managed Care Support Contractors (MCSCs) shall follow procedures established in [Chapter 8, Section 2, regarding claims jurisdiction for dual eligibles](#).

**6.6** If the contractor receives a PNT notifying them of a retroactive TRS disenrollment the contractor shall initiate recoupment of claims paid, if appropriate, as specified in [Chapter 10](#).

**6.7** If at any time the contractor discovers that the Selected Reserve member may be eligible for or enrolled in the FEHBP, the contractor shall report the discovery to the appropriate TRICARE RD, or their designee, or TAO Director NLT one business day after discovery. As applicable, the contractor shall follow [paragraph 4.4.1](#) and its subordinate paragraphs for loss of TRS eligibility. If any other actions are to be taken by the contractor as a result of this discovery, the TRICARE RD, or their designee, or TAO Director will send instructions to the contractor.

## 7.0 BENEFICIARY EDUCATION AND SUPPORT DIVISION (BE&SD)

In addition to BE&SD functions specified throughout this chapter, the contractor shall perform BE&SD functions to the same extent as they do for TRICARE Standard and TRICARE Extra.

form for the newborn/new child NLT 60 days after birth/custody. When the member completes the process specified in [paragraph 4.2.3.1](#), the contractor shall process any claims associated with the child's health care. If the member fails to complete the process as specified in [paragraph 4.2.3.1](#), the contractor shall deny any claims associated with the child's health care.

**6.3** Premium payments made for TRR shall not be applied to the fiscal year deductible or catastrophic cap limit.

**6.4** Non-Availability Statement (NAS) requirements shall apply to TRR members, family members, and survivors in the same manner as for retirees under TRICARE Standard/Extra.

**6.5** If a Retired Reserve member purchases TRR during the same calendar year that the member had a TRICARE Reserve Select plan in effect, the catastrophic cap, deductibles and cost shares shall not be recalculated.

**6.6** Medicare is the primary payer for TRICARE beneficiaries who **are entitled to** Medicare. Claims under the TRICARE Dual Eligible Fiscal Intermediary Contract (TDEFIC) will be adjudicated under the rules set forth in the **TRICARE Reimbursement Manual (TRM), Chapter 4, Section 4**. The MCSCs shall follow procedures established in **Chapter 8, Section 2** regarding **claims jurisdiction for** dual-eligibles.

**6.7** If the contractor receives a PNT notifying them of a retroactive TRR disenrollment the contractor shall initiate recoupment of claims paid if appropriate as specified in [Chapter 10](#).

**6.8** If at anytime the contractor discovers that the Retired Reserve member may be eligible for or enrolled in the FEHBP, the contractor shall report the discovery to the appropriate TRICARE RD or their designee or TAO Director NLT one business day after discovery. As applicable, the contractor shall follow [paragraph 4.4.1](#) and its subordinate paragraphs for loss of TRR eligibility. If any other actions are to be taken by the contractor as a result of this discovery, the TRICARE RD or their designee or TAO Director will send instructions to the contractor.

## **7.0 BENEFICIARY EDUCATION AND SUPPORT DIVISION (BE&SD)**

In addition to BE&SD functions specified throughout this chapter, the contractor shall perform BE&SD functions to the same extent as they do for TRICARE Standard and TRICARE Extra.

### **7.1 Customer Education**

**7.1.1** Materials (i.e., public notices, flyers, informational brochures, web site etc.) will be developed and distributed centrally by Department of Defense (DoD), TRICARE Management Activity (TMA), Office of BE&SD. The contractor shall distribute all informational materials associated with the TRR program to the same extent and through the same means as TRICARE Standard materials are distributed. Copies of the TRR handbook and other information materials may be obtained through the usual TMA BE&SD process.

**7.1.2** Upon start of coverage under TRR each contractor shall mail one copy of the TRR handbook to each TRR member/survivor with TRR member-only coverage and one copy to the household of each TRR member/survivor with TRR member-and-family coverage. The member/

survivor's servicing contractor shall send additional handbooks upon request, such as when covered family members live in different locations (split locations).

## **7.2 Customer Service**

The contractor shall provide all customer service support in a manner equivalent to that provided TRICARE Standard beneficiaries. When the contractor receives an inquiry involving TRR eligibility or qualifications, the contractor shall refer the individual to the appropriate RC.

## **8.0 ANALYSIS AND REPORTING**

TRR workload shall be included, but not separately identified, in all reports.

## **9.0 PAYMENTS FOR CONTRACTOR SERVICES RENDERED**

### **9.1 Claims Reporting**

The contractor shall report TRR program claims according to [Chapter 3](#). The contractor shall process payments on a non-financially underwritten basis for the health care costs incurred for each TRR claim processed to completion according to the provisions of [Chapter 3](#).

### **9.2 Fiduciary Responsibilities**

**9.2.1** The contractor shall act as a fiduciary for all funds acquired from TRR premium collections, which are government property. The contractor shall develop strict funds control processes for its collection, retention and transfer of premium funds to the government. All premium collections received by the contractor shall be maintained in accordance with these procedures.

**9.2.2** Either a separate non-interest bearing account shall be established for the collection and disbursement of TRR premiums or the account used for TRICARE Reserve Select (TRS) premium collections shall be used for TRR premiums as well. The contractor shall deposit premium collections to the established account within one business day of receipt.

**9.2.3** The contractor shall wire-transfer the premium collections, net of refund payments, monthly to a specified government account as directed by the TMA Contract Resource Management (CRM) Finance and Accounting Office (F&AO). The government will provide the contractor with information for this government account. The contractor shall notify the TMA CRM F&AO, by e-mail, within one business day of the deposit, specifying the date and amount of the deposit as well as its purpose (i.e. TRR premiums). Premiums for TRS and TRR may be sent as a single wire as long as CRM is notified of the amounts of each type of premium. Collections for delinquency cases that have been transferred to TMA Office of General Counsel-Appeals, Hearings & Claims collection Division (OGC-AC) shall be wire-transferred separately. The contractor shall notify TMA CRM F&AO and TMA OGC-AC by e-mail within one business day of the day of deposit, specifying the sponsor name, sponsor Social Security Number (SSN) (last four digits), payment amount, payment date, date case was transferred to TMA OGC-AC and the date and amount of the deposit.

from one region to another allowed each year. The gaining contractor shall perform the premium collections for future payments.

**5.1.3** All unsolicited PNTs for young adult dependents will be evaluated to determine if residential address changes require a notification to the young adult dependent (see [paragraph 5.1.2](#)).

## **5.2 Premium Collection Processes**

**5.2.1** The contractor shall credit the young adult dependent for premium payments received. Premium payments are due for receipt by the contractor NLT the last calendar day of the current month for the following month of coverage. In the case of a start date of coverage at anytime other than the first of a month (see [paragraph 4.1.2](#) or as directed by the waiver approval authority), the first **payment collected by the contractor** shall **include the** prorated **amount** on a daily basis **necessary** to synchronize **the paid-through date** to the **last day** of the month. The daily prorated amount **is** equal to 1/30th of the appropriate premium (rounded to the penny) regardless of how many days are actually in the month.

**5.2.2** The contractor shall collect monthly premium payments from TYA purchasers as appropriate and shall report the **premium amount paid** for those payments, including for any overpayments that are not refunded to the purchaser, to DEERS. (See the TSM, [Chapter 3](#).) In the event that there are insufficient funds to process a premium payment, the contractor may assess the account holder a fee of up to 20 U.S. dollars (\$20.00). The contractor shall provide commercial payment methods for TYA premiums that best meet the needs of beneficiaries while conforming to [paragraphs 5.2.3](#) through [5.2.8](#).

**5.2.3** Monthly premiums must be paid through an automated, recurring electronic payment through an EFTs or a RCC from a designated financial institution. These are the only acceptable payment methods for the recurring monthly premiums. An EFT/RCC payment shall be processed **within** the first **five** business days of the month of coverage.

**5.2.4** Purchasers must pay at least the first **initial payment as specified in [paragraph 4.1](#)** at the time the TYA application is submitted to allow time for the EFT/RCC to be established. The contractor shall accept payment of the first installment by personal check, cashier's check, traveler's check, money order, or credit card (e.g., Visa/MasterCard).

**5.2.5** The contractor shall initiate recurring monthly EFTs/RCCs and is responsible for obtaining and verifying the information necessary to do so.

**5.2.6** The contractor shall initiate action to modify EFT/RCC payment amounts to support premium changes.

**5.2.7** The contractor shall direct bill the young adult dependent only when a problem occurs in setting up or maintaining the EFT or RCC. Bills may be sent to the residential or mailing address designated by the young adult dependent.

**5.2.8** When an administrative issue arises that stops or prevents an automated monthly payment from being received by the contractor (e.g., incorrect or transposed number provided by the beneficiary, credit card expired, bank account closed, etc.), the contractor shall grant the TYA

purchaser 30 days after the paid-through date to provide information for a new automated monthly payment method. The contractor may accept payment in accordance with [paragraph 5.2.4](#) during this 30 day period in order to preserve the beneficiary's TYA enrollment status.

### 5.3 Annual Premium Adjustment

Contractors shall notify current purchasers in writing of any annual premium adjustments NLT 30 days after the contractors receive notification of the updated premiums. The notification shall include the new amount for TYA coverage and will include the following statement:

"Young adult dependents eligible for medical coverage from their eligible employer-sponsored health plan as defined in section 5000A(f)(2) of the Internal Revenue Code of 1986 or who are married do not qualify for TYA coverage. A request to terminate TYA coverage must be submitted to preclude recoupment actions and to request a refund of any overpaid premiums, as applicable."

## 6.0 CLAIMS PROCESSING

**6.1** The contractor shall process TYA claims using established TRICARE cost-sharing rules and guidance based on the sponsor's status and the TYA plan purchased. Normal claims jurisdiction rules apply (see [Chapter 8, Section 2](#)). Normal TRICARE Other Health Insurance (OHI) processing rules apply to TYA except for claims from eligible employer-sponsored health plans. See [paragraph 6.6](#).

**6.2** Non-Availability Statement (NAS) requirements shall apply to young adult dependents in the same manner as under the corresponding TRICARE plan.

**6.3** If a young adult dependent purchases TYA coverage during the same fiscal year that he or she had another TRICARE health plan in effect, the individual cost-shares, contributions to the individual and family deductibles, and contributions to the family catastrophic cap from the other TRICARE health plan still apply in that fiscal year and shall not be recalculated. If retroactive TYA coverage is purchased and replaces previously purchased CHCBP coverage, cost-shares, contributions to deductibles, or contributions to the catastrophic cap amounts previously paid under CHCBP shall be carried over to a TYA plan. Otherwise, any cost-shares, contributions to deductibles, or contributions to the catastrophic cap amounts previously paid under CHCBP shall not be carried over to a TYA plan.

**6.4** Medicare is the primary payer for TRICARE beneficiaries who are eligible for Medicare. Claims under the TRICARE Dual Eligible Fiscal Intermediary Contract (TDEFIC) will be adjudicated under the rules set forth in [the TRICARE Reimbursement Manual \(TRM\), Chapter 4, Section 4](#). The contractors shall follow procedures established in [Chapter 8, Section 2](#) regarding [claims jurisdiction for dual eligibles](#). Payment of Medicare Part B premiums do not provide a basis to waive TYA premiums.

**6.5** If the contractor receives a PNT notifying them of a retroactive TYA disenrollment the contractor shall initiate recoupment of claims paid if appropriate as specified in [Chapter 10](#).

**6.6** If at any time the contractor discovers that the young adult dependent may be eligible or is enrolled in an eligible employer-sponsored health plan from their employer, the contractor shall report the discovery to the appropriate waiver approval authority NLT one business day after discovery. Claims may be pended or held until a final decision is reached. As applicable, the contractor shall follow [paragraph 4.3](#) and its subordinate paragraphs for loss of TYA eligibility.

## **7.0 BENEFICIARY EDUCATION AND SUPPORT DIVISION (BE&SD)**

In addition to BE&SD functions specified throughout this chapter, the contractor shall perform BE&SD functions to the same extent as they do for other TRICARE plans.

### **7.1 Customer Education**

**7.1.1** Materials (i.e., public notices, flyers, informational brochures, web site, etc.) will be developed and distributed centrally by Department of Defense (DoD), TRICARE Management Activity (TMA), Office of BE&SD. The contractor shall distribute all informational materials associated with the TYA program to the same extent and through the same means as other TRICARE materials are distributed. Copies of TYA informational materials may be obtained through the usual TMA BE&SD process.

**7.1.2** Upon start of coverage under TYA, the DMDC-generated enrollment letter will include information on how purchasers can obtain TYA and other TRICARE plan materials over the internet or how to request fulfillment materials from the contractor. The servicing contractor shall send fulfillment materials only upon request.

### **7.2 Customer Service**

The contractor shall provide all customer service support to young adult dependents in a manner equivalent to that provided to other TRICARE beneficiaries.

## **8.0 ANALYSIS AND REPORTING**

TYA workload shall be included, but not separately identified, in all reports.

## **9.0 PAYMENTS FOR CONTRACTOR SERVICES RENDERED**

### **9.1 Claims Reporting**

The contractor shall report TYA program claims according to [Chapter 3](#). The contractor shall process payments on a non-financially underwritten basis for the health care costs incurred for each TYA claim processed to completion according to the provisions of [Chapter 3](#).

### **9.2 Fiduciary Responsibilities**

**9.2.1** The contractor shall act as a fiduciary for all funds acquired from TYA premium collections, which are government property. The contractor shall develop strict funds control processes for its collection, retention and transfer of premium funds to the government. All premium collections received by the contractor shall be maintained in accordance with these procedures.

**9.2.2** Premiums shall be deposited into a non-interest bearing account to collect and disburse TYA premiums. The contractor shall deposit TYA premium collections to the established account within one business day of receipt. A separate bank account is not required; however, individual line item reporting for the TYA program is required.

**9.2.3** The contractor shall wire-transfer the premium collections, net of refund payments, monthly to a specified government account as directed by the TMA Contract Resource Management (CRM) Finance And Accounting Office (F&AO). The government will provide the contractor with information for this government account. The contractor shall notify the TMA CRM F&AO, by e-mail, within one business day of the deposit, specifying the date and amount of the deposit as well as its purpose (i.e., TYA premiums).

**9.2.4** The contractor shall maintain a system for tracking and reporting premium billings, collections, and starts of coverage. The system is subject to government review and approval.

**9.2.5** The contractor shall electronically submit monthly reports of premium activity supporting the wire transfer of dollars as described in the Contract Data Requirements List (CDRL) DD Form 1423.

## **10.0 CHCBP TO TYA PROCEDURES**

Young adult dependents who qualify for TYA coverage and were previously or are currently enrolled in the CHCBP may elect to purchase TYA.

### **10.1 Enrollment Procedures**

Enrollment actions must be coordinated between the CHCBP contractor and the TYA enrolling contractor. The CHCBP contractor will provide contact information to the enrolling contractors to coordinate CHCBP to TYA enrollments.

#### **10.1.1 CHCBP Coverage Was Terminated More Than 30 Days Before Receipt of TYA Application and Young Adult Dependent Is Not Eligible for Continuation or Retroactive TYA Coverage**

The enrolling contractor will validate in DEERS that the CHCBP enrollment was terminated more than 30 days from the date of the TYA application. The TYA enrolling contractor will process the TYA application according to [paragraph 4.1.2](#).

#### **10.1.2 Currently Enrolled in CHCBP or TYA Application Received Within 30 Days of Termination of CHCBP Coverage**

Upon receipt of a properly completed TYA application for someone currently enrolled in or within 30 days of termination of CHCBP coverage, the enrolling contractor will request the CHCBP contractor to disenroll the young adult dependent from CHCBP with an effective date one day prior to the requested start date. The CHCBP contractor will terminate the CHCBP coverage based on the TYA effective date or the CHCBP paid-through date, whichever is earlier. The CHCBP contractor will recalculate the amount of premiums required for the remaining CHCBP coverage, and refund any overpayment of CHCBP premiums. The refund shall include an explanation that the refund amount represents a refund of CHCBP premiums as a result of the TYA enrollment and how

## Continued Health Care Benefit Program (CHCBP), Eligibility And Coverage

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### 1.0 CONTINUED HEALTH CARE BENEFIT PROGRAM (CHCBP)

**1.1** The CHCBP is a health care program that allows certain groups of former Military Health System (MHS) beneficiaries to continue receiving health care coverage when they lose eligibility for military health care under the TRICARE programs. This temporary health program is supported by premium revenue collected from the participants in the program. The CHCBP contractor (herein referred to as the “contractor” unless otherwise specified) shall provide all services necessary to support the CHCBP as outlined in [32 CFR 199.20](#). Other references describing the CHCBP that are to be used by the contractor in fulfilling its responsibilities are applicable sections of the TRICARE Policy Manual (TPM), TRICARE Operations Manual (TOM), TRICARE Reimbursement Manual (TRM), TRICARE Systems Manual (TSM), and the **Federal Register** dated September 30, 1994 (pg. 49817ff), February 11, 1997 (pg. 6225ff), February 24, 1997 (pg. 8312), and September 16, 2011 (pg. 57637ff). The contractor shall perform these functions for CHCBP beneficiaries on a worldwide basis, irrespective of the geographic area in which the beneficiary resides or the area in which health care services are received.

**1.2** The legislative basis for the program is Section 4408 of the National Defense Authorization Act (NDAA) of 1993 (Public Law 102-484) which added Section 1078a to Chapter 55 of 10 United States Code (USC). Beneficiaries **who may be eligible to purchase the continued health program after eligibility for coverage ends under a health benefits plan under 10 USC Chapter 55 or 10 USC § 1145(a)** are described in 10 USC § 1078a. **For those covered under premium-based TRICARE health benefits plans such as TRICARE Reserve Select (TRS), TRICARE Retired Reserve (TRR), TRICARE Young Adult (TYA), etc., such coverage must have been purchased and in place the day before the loss of eligibility.**

**1.3** CHCBP is not part of the TRICARE Program; therefore, the contractor shall adhere to the following requirements for those areas in which the CHCBP instructions and processing requirements are different than TRICARE.

### 2.0 VALIDATE ELIGIBILITY FOR CHCBP

**2.1** Upon receipt of a Department of Defense (DoD) (DD) Form 2837, CHCBP Application, from a prospective beneficiary, the contractor shall validate eligibility on the Defense Enrollment and Eligibility Reporting System (DEERS) and request information necessary to validate eligibility. The

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supporting documentation that the contractor shall request from the applicant differs depending on the category of individual who is applying for enrollment as shown below:

**2.1.1** Individual Uniformed Service sponsor (herein referred to as "sponsor") and his/her family: a copy of the DD Form 214, Certificate of Release or Discharge from Active Duty, or a copy of the sponsor's active duty orders.

**2.1.2** Unremarried former spouse and stepchildren of the sponsor: a copy of the final divorce decree.

**2.1.3** Child who loses TRICARE coverage due to marriage: a copy of marriage certificate.

**2.1.4** Child who loses TRICARE coverage on his/her 21st birthday (age 23 if enrolled in a full-time course of study at an approved institution of higher learning and dependent on the uniformed service sponsor for more than half of their financial support): a copy of the front and back of the Uniformed Services identification (ID) card.

**2.1.5** Child who loses TRICARE coverage due to college graduation: a copy of college transcript.

**2.1.6** Child **over the age of 21 and before the age of 23** who loses TRICARE coverage when **no longer** enrolled in a full-time course of study at an approved institution of higher learning or **no longer** dependent on the uniformed service sponsor for more than half of their financial support: a letter from the institution of higher learning stating the student's status or a written statement from the dependent that he/she is no longer dependent on the uniformed services sponsor for more than half of their financial support.

**2.1.7** Child that was previously placed in sponsor's legal custody and then loses TRICARE coverage: a copy of the court order.

**Note:** Children who lose TRICARE coverage under [paragraphs 2.1.4 through 2.1.7](#) may qualify to purchase TYA coverage until reaching the age of 26 (see [Chapter 25](#)). If qualified to purchase TYA coverage, the child cannot purchase CHCBP as an individual. **Also, if the child does not qualify to purchase TYA because he or she qualifies for employer sponsored coverage, he or she is ineligible to purchase CHCBP.**

**2.1.8** Child who loses eligibility for TYA coverage. However, if the TYA coverage was terminated due to eligibility for employer-sponsored health care coverage based on their own employment or failure to pay TYA premiums, then the child is not eligible to purchase CHCBP coverage (see [Chapter 25](#)).

**2.1.9** For any other situations in which an individual loses TRICARE coverage and may potentially be eligible for CHCBP, the contractor shall request information needed to verify eligibility.

## **2.2 Family Members Not Identified on DEERS**

**2.2.1** When a contractor receives a CHCBP claim which includes a family member not identified on DEERS as enrolled, but the sponsor indicates CHCBP family coverage, the contractor is to take the following action: If the claim includes a copy of an appropriately marked CHCBP coverage card

for the beneficiary, the claim is to be processed. If the claim is for a beneficiary who is less than 60 days old, the claim is to be processed, even if no copy of an CHCBP coverage card is attached as long as at least one member of the sponsor's family is currently enrolled in CHCBP. In all other cases, the claim is to be denied.

**2.2.2** In order to be enrolled in the CHCBP, the beneficiary will be disenrolled from any TRICARE programs in which enrolled. This will require no action on the beneficiary's part.

### **2.3 Disputes Regarding Enrollment**

**2.3.1** Confirmation of a person's eligibility as a CHCBP beneficiary is the responsibility of the CHCBP contractor. Disputed questions of fact concerning a beneficiary's eligibility will not be considered an appealable issue, but must be resolved with the appropriate Uniformed Service.

**2.3.2** If the contractor determines the applicant does not appear eligible due to an ineligible response from DEERS (i.e., no history segments or record of previous DoD entitlement) or failure of the applicant to provide the documentation requested to verify eligibility the contractor shall deny the application in writing within 10 business days of the reason for the denial.

## **3.0 APPLICATION PERIOD AND PREMIUMS**

### **3.1 CHCBP Application Period**

There is a 60-day application period for CHCBP, beginning the day following the end date of the beneficiary's eligibility for TRICARE coverage. The contractor shall deny any applications received after the 60-day period. The contractor shall apply the following business rules when determining the start of the 60-day application period.

Former beneficiaries that were previously not eligible to purchase CHCBP until the NDAA for Fiscal Year (FY) 2008 have until November 12, 2013 to apply for retroactive coverage with an effective date of no earlier than October 16, 2011. Retroactive premiums must be paid to cover the period following the end date of the beneficiary's eligibility for TRICARE coverage.

#### **3.1.1 Members and Former Members, Their Families, and Other Individuals Losing TRICARE Coverage**

The government routinely notifies beneficiaries prior to their loss of TRICARE coverage (active duty members are notified of the CHCBP during outprocessing; other beneficiaries who lose TRICARE coverage are notified by the Defense Manpower Data Center (DMDC) in writing of the availability of the CHCBP). However, if an eligible beneficiary advises the contractor that he/she was not notified of this program and submits documentation to support their position, the contractor shall forward the documentation to the TRICARE Regional Office (TRO) - South Director or designee, who shall provide direction on the start-date of the 60-day application period.

#### **3.1.2 Unremarried Former Spouses**

There is no formal mechanism established to promptly identify unremarried former spouses that may qualify for this program, therefore the contractor shall process all applications from unremarried former spouses upon receipt.

### 3.2 Coverage Categories

CHCBP offers two coverage categories. Individual coverage is available to the member or former member, an unremarried former spouse, an adult child, a surviving spouse, or other qualified individuals. Family coverage is only available to the member or former member and his/her dependents. Dependents cannot be covered under family coverage unless the member or former member is also covered by family coverage.

### 3.3 CHCBP Application

DD Form 2837, CHCBP Application, shall be accepted as the application form for CHCBP coverage. No later than six months prior to the start work date of the contract, the contractor shall provide the Contracting Officer's Representative (COR) with the contractor's mailing address and toll-free telephone number. Should DD Form 2837 be revised or renumbered in the future, the contractor shall use the latest version.

### 3.4 Dates of Coverage & Premiums

**3.4.1** Coverage will begin the day following the beneficiary's loss of TRICARE coverage and will end the last day of premium coverage.

**3.4.2** Due to the documentation requirements for purchasing coverage, most coverage will be retroactive; however, there may be some coverage that will be prospective. Prospective coverage must be accompanied by a premium payment for one quarter. Retroactive coverage must be accompanied by full premium payment retroactive to the effective date of coverage through the end coverage date in the quarter in which the individual is applying.

**3.4.3** Premiums are as stated in [paragraph 3.5](#) of these instructions.

Examples of the premiums required for retroactive and prospective coverage:

	<b>Military Benefits End</b>	<b>Application Received</b>	<b>Quarters of Premium Due</b>	<b>CHCBP Coverage Begins</b>
Example 1:	10/01/2010	11/15/2010	1 quarter	10/02/2010
Example 2:	09/15/2010	02/10/2011	2 quarters	09/16/2010
Example 3:	11/05/2010	10/01/2010	1 quarter	11/06/2010
Example 4:	03/01/2011	11/01/2010	1 quarter	03/02/2011

### 3.5 Premium Rates

**3.5.1** The amount of the CHCBP premiums shall be established by the government and may be adjusted each fiscal year. Adjusted premium amounts will be provided in writing to the contractor by the Contracting Officer (CO).

**3.5.2** The contractor shall begin charging the adjusted quarterly premiums on the date directed by the CO.

**3.5.3** Upon receipt of adjusted rates from the government, the contractor shall issue a written notice to the beneficiary of the changes in premium amounts, to include the effective date of the

change. This notification should be done at least 30 days prior to the effective date directed by the CO.

**3.5.4** When qualifying events occur that change the sponsor from individual to family coverage or vice versa, coverage and premiums shall be changed effective with the date of the qualifying event. The contractor, within 10 business days of receiving such information, shall issue a written notice to the beneficiary of the changes in the coverage category and premium amount, including the effective date of the changes.

### **3.6 Form of Payment**

**3.6.1** Checks, money orders, or credit cards are allowable forms of payment for CHCBP beneficiaries to use in paying their premiums. The contractor may propose additional payment mechanisms, to include electronic processes for premium payments. Proposed electronic processes shall maintain the integrity and security of the application processes which includes important documentation required to validate eligibility for CHCBP.

**3.6.2** As a minimum, the contractor shall accept VISA and MasterCard® for credit card payments, and may, but is not required to, accept additional nationally recognized major credit cards as a form of premium payment.

**3.6.3** The contractor shall not accept premiums submitted by, or on behalf, of a health care provider for any beneficiary other than (a) the provider him/herself and (b) a member of the provider's immediate family. Should a provider submitted payment be received, the contractor shall return the payment to the provider with a written notice advising the provider that submission of premium payments by health care providers is prohibited. A copy of the letter should also be sent to the beneficiary. The contractor shall submit documentation to the TRICARE Management Activity (TMA) Program Integrity Office to include the following: a copy of contractor's notification to the provider, copy of front and back of premium (money order or check), originals of all documentation submitted by the provider (to include mailing envelope), documentation of all conversations and communications the contractor had with the provider on the subject of paying premiums, and any other information that the contractor has in its files or records concerning the provider that might be of assistance in Government follow-up action on this issue.

### **3.7 Insufficient Funds**

In the case of insufficient funds, the contractor shall, within three business days, issue a written notice to the applicant (for initial applications) or beneficiary (in the case of renewal premiums), advising the applicant or beneficiary of the insufficient funds, the amount of the premium due, and the date by which a valid premium must be received by the contractor. For initial application requests, the notice shall also advise the beneficiary that if premium payment is not received in full by the due date (the last day of the 60-day application period), the applicant will not be covered in CHCBP. For renewals, the notice shall advise the beneficiary that if the contractor does not receive valid payment in full within 30 days of the date of the contractor's letter, that coverage will be terminated. That notice shall also provide the effective date of termination if payment is not received. If the premium payment has not been received by the contractor within the specified time frame, the contractor shall terminate the CHCBP coverage and issue a written notice to the beneficiary confirming the termination of coverage.

### **3.8 Refunds**

Premiums shall be refunded if the applicant is no longer eligible for CHCBP coverage, i.e., beneficiary regains TRICARE eligibility; ex-spouse remarries; death of beneficiary; prospective member who has prepaid premium but fails to provide required eligibility documentation; and sponsor change in coverage from family to individual. Voluntary termination because the beneficiary obtained Other Health Insurance (OHI) does not constitute grounds for a refund of unused premiums. When refunds are appropriate, the contractor shall prorate the refund from the date of loss of eligibility for program benefits through the last coverage date for which the premium was paid.

### **3.9 Limits of CHCBP Coverage**

The length of a beneficiary's CHCBP coverage varies according to the category of individual. Coverage lengths and categories are listed in the TPM, [Chapter 10, Section 4.1, Figure 10.4.1-1](#), CHCBP Eligibility Table.

### **3.10 Processing Applications**

**3.10.1** Once the contractor has verified eligibility and approved the application request, the contractor shall enter the CHCBP enrollment into DEERS through the applicable on-line interface. As DEERS does not allow individuals to be added to a sponsor's record after the sponsor's TRICARE coverage ends, there will be a small number of CHCBP beneficiaries that the contractor cannot complete the CHCBP enrollment in DEERS. The majority will be newborns whose birth occurred after the sponsor's TRICARE coverage ends, but there will occasionally be other beneficiaries as well. The contractor should not rely on DEERS as being the sole determinant of whether or not an individual is eligible for CHCBP coverage as these individuals would not be reflected on DEERS (see [paragraph 2.0](#)). The contractor's systems shall accommodate these unique cases in which the beneficiary is covered under CHCBP but not reflected on DEERS to ensure these beneficiaries are provided with all required CHCBP benefits and accurate processes, i.e., claims processing, issuing authorizations, accessing services, etc.

**3.10.2** DEERS will not allow a CHCBP enrollment to be entered if the sponsor and/or dependents are still showing as eligible for TRICARE coverage. In these cases, the contractor shall pend the application and advise the applicant in writing for the sponsor to contact the nearest Uniformed Services ID card issuing office to rectify the situation. The contractor shall complete the processing of the application when DEERS has been updated to reflect that the sponsor and/or dependents are no longer eligible for services under TRICARE.

**3.10.3** Once the application has been fully processed, the contractor shall issue the beneficiaries a CHCBP coverage ID card within 10 business days. The card provides the beneficiaries with (a) confirmation that the individual is covered and the effective dates; and (b) documentation that the beneficiary can use to access health care services. The card shall contain sufficient information to facilitate access to health care. Coverage dates on the card shall be limited to those dates for which a valid quarterly premium has been received by the contractor. Cards shall be issued each quarter for all subsequent quarterly payments received by the contractor. The card shall reflect that coverage is for the CHCBP and at a minimum provides the contractor's name, address, toll-free telephone number, and claims center mailing address.

**3.10.4** Once an application has been fully processed, the contractor shall issue a letter to the applicant confirming CHCBP coverage (including the dates of coverage) within 10 business days. The letter shall advise the beneficiary of the requirements that must be met for continued coverage in the program, including information regarding future contractor billings and premium payments that the beneficiary will be required to make. The contractor shall also issue either a CHCBP coverage policy or such other sufficient written information regarding the CHCBP for beneficiaries' reference should they have any questions regarding benefits and program requirements.

### **3.11 Coverage and Renewals**

**3.11.1** The contractor shall mail initial premium renewal notices to beneficiaries no later than 30 days before the expiration of the coverage. The beneficiary's coverage in CHCBP is based on the documentation that the applicant submits to verify eligibility, therefore, the contractor shall not routinely query DEERS for renewal coverages and quarterly billings. Absent information or evidence to the contrary, the contractor shall assume that the individual continues to meet the requirements for CHCBP. Renewal notices shall clearly specify the premium amount due, the date by which the premium must be received, and the mailing address to which the premium payment must be sent. Renewal notices shall specify that failure to submit the premium due will result in denial of continued coverage and termination from the program.

**3.11.2** The contractor shall provide a 30 calendar day grace period following the premium due date in which the beneficiary may submit his/her premium and continue benefits with no break in coverage. If the premium is not received following the initial renewal notice to the beneficiary requesting premium for the next quarter, the contractor shall issue a second renewal notice to the beneficiary within 10 business days of the start of the grace period. The second renewal notice shall indicate that this is the second and final billing notice and that if payment is not received by the due date specified in the notice, that CHCBP coverage will be terminated as of that date. The notice shall also advise the beneficiary that if coverage is terminated due to nonpayment of premium, that he/she will be permanently locked-out of CHCBP.

**3.11.3** If the premium is not received by the end of the grace period, the contractor shall terminate the beneficiary's coverage in CHCBP and mail a letter to the beneficiary confirming the termination within 10 business days, to include the effective date and basis for the termination. The contractor shall enter all CHCBP terminations into DEERS.

**3.11.4** Beneficiaries who desire to voluntarily withdraw from the CHCBP prior to the end of their paid up period shall send a written request to the contractor. Beneficiaries who voluntarily disenroll from the CHCBP are not permitted to re-enroll until they gain and then once again lose TRICARE coverage. Refund of unused premiums is only allowed for items covered in [paragraph 3.8](#).

**3.11.5** Following a beneficiary's termination from the CHCBP, except for those who have re-established TRICARE coverage, the contractor shall issue a Certificate of Creditable Coverage (CoCC) to the beneficiary within 10 business days from the termination date and upon request up to 24 months after the termination date. No later than four months prior to the start work date of the contract, the government will furnish the contractor with a sample of the format for the CoCCs.

**3.11.6** In preparing and mailing all written notices and correspondence to applicants and beneficiaries, the contractor shall use the most current address on file or available.

### **3.12 CHCBP Coverage Data and Report**

The contractor shall maintain systems and databases to collect, track and process applications and to report monthly coverage information to the government as well as any ad hoc reports that may be requested regarding CHCBP coverage. The contractor shall have the capability to retroactively retrieve pertinent coverage information on any individual who has been accepted or denied coverage in the program, to include the basis for such denials.

### **4.0 PROGRAM MATERIALS**

All informational materials, booklets, brochures, and other public material are subject to review and approval by the TMA Beneficiary Education and Support Division (BE&SD) prior to finalizing the material, and all must contain the contractor's name, mailing address, toll-free telephone number and web site.

### **5.0 INQUIRIES AND CUSTOMER SERVICE FUNCTIONS**

The contractor shall respond to CHCBP inquiries from any geographic area, to include locations outside the 50 United States and the District of Columbia. The contractor shall provide timely, accurate and thorough responses to the inquiries it receives from any source, e.g., prospective applicants, beneficiaries, providers, other contractors, government officials, etc. in accordance with [Chapter 1, Section 3, paragraph 3.0](#).

### **6.0 FIDUCIARY RESPONSIBILITIES**

**6.1** The contractor shall act as a fiduciary for all funds acquired from CHCBP premium collections, which are government property. The contractor shall develop strict funds control processes for its collection, retention and transfer of CHCBP premiums to the government. The contractor shall follow the requirements in [Chapter 3](#).

**6.2** The contractor shall maintain a system for tracking and reporting premiums and beneficiaries/policy holders. The system is subject to government review and approval.

**6.3** By the 10th calendar day of the month following the activity, the contractor shall submit the following reports: CHCBP Workload Report, CHCBP Monthly Enrollee Premiums Report, CHCBP Adjusted Premiums Report, CHCBP Enrollment Data Report, and CHCBP Premiums Summary Report as described in the DD Form 1423, Contract Data Requirements List (CDRL), and submit per [Chapter 14, Section 2](#).

### **7.0 DEERS**

Refer to the DEERS instructions in the TSM for additional DEERS requirements related to CHCBP.

### **8.0 REPORTING RESPONSIBILITIES**

In addition to the written monthly reports, the CHCBP contractor may be required to produce CHCBP ad hoc reports as requested by the government. The data elements or information for such reports would be limited to that information that the CHCBP contractor has collected or should

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reasonably have collected in the performance of CHCBP work. Some manipulation and formatting of the data and information may be required to meet the requirements of the ad hoc reports. The government estimates that the CHCBP contractor would not receive more than three such requests per contract year and that the level of effort for the CHCBP contractor to produce the ad hoc reports is not expected to be significant.

- END -



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