December 12, 2003

TO: CALIFORNIA CHILDREN SERVICES (CCS) ADMINISTRATORS, MEDICAL CONSULTANTS, CHIEF/SUPERVISING THERAPISTS, STATE CHILDREN’S MEDICAL SERVICES (CMS) BRANCH STAFF AND REGIONAL OFFICE STAFF

SUBJECT: REQUEST FOR PILOT PROJECT APPLICATION: MEDICAL THERAPY PROGRAM

Serial casting can be of great benefit to Medical Therapy Unit (MTU) clients, improving their physical function and avoiding or postponing surgical intervention. The serial casting procedure is not as available to in the medical community as it was in the past. For this reason applications for pilot projects are requested to determine the safety and appropriateness of performing the procedure in selected MTUs. If the pilot projects are completed successfully, the CMS branch will establish guidelines for the use of serial casting in the Medical Therapy Program, statewide.

Enclosed is an information package for a Serial Casting Pilot Project for the Children’s Medical Services (CMS) Branch. Qualified County CCS MTPs interested in participating in the Project are requested to submit an application demonstrating their competence to perform serial casting at specific MTUs.

The tentative time line for the application is included in Section 7.0, Application Evaluation Process. Specific items of immediate interest to prospective applicants include:

Questions and Answers

All questions regarding the application and this process must be submitted in writing or by e-mail to the CMS Branch by January 31, 2004. The CMS Branch will respond to questions in a likewise manner.
Letters of intent/Application Submission Date


The application process and approval of the serial casting pilot will be solely at the discretion of the CMS Branch. No more than five counties will be approved for the pilot study.

The CMS Branch may modify the enclosed document, the time line, schedule of events leading to the application deadline, or any requirements deemed necessary by the CMS Branch as part of the process of selecting county programs to implement the pilot projects. Such modifications will be issued as an addendum and be re-issued.

Any questions concerning the pilot project application will be directed to the Serial Casting Review Committee at the CMS Branch, care of:

James Boyd, M.D.
Children’s Medical Services Branch
1515 K Street, Suite 400
MS 8100
P.O. Box 942732
Sacramento, CA 94234-7320
(916) 686-1652
jboyd@dhs.ca.gov

Thank you for your interest in participation in this pilot project.

Original Signed by Maridee A. Gregory, M.D.

Maridee A. Gregory, M.D., Chief
Children’s Medical Services Branch

Attachment
1. REQUEST FOR PARTICIPATION IN SERIAL CASTING PILOT PROJECTS

1. INTRODUCTION

1.1. Statement of Intent:
A. Provision of a trial of serial casting as applied by the Medical Therapy Unit (MTU) staff, under the direction of the Medical Therapy Conference (MTC) physician with documentation of:
• safety
• effectiveness (muscle stretch and increased range of motion)
• complications
• cost
• liability
B. The procedure shall be limited to joints of the following body regions:
• elbow
• forearm
• wrist
• hand
• knee
• ankle
• foot
C. A qualified physical therapist shall provide serial casting of all of the above body regions. An occupational therapist shall assist when serial casting is applied to the upper extremity and may assist in lower extremity serial casting.

1.2. Background:
A. Serial Casting is a procedure which is effective in improving the positioning, range of motion, and subsequently the physical function in children with muscle and joint contracture. The procedure involves the placement of a circumferential cast to provide gradual stretch on the muscles and joints. The cast is changed at frequent intervals as the range of motion improves. When appropriate range has been achieved the cast is replaced by a bi-valved cast, splint, brace or stretching program to maintain the gains achieved. Surgical intervention can often be postponed or avoided. This procedure can be used in conjunction with botulinum toxin when severe hypertonicity makes cast tolerance difficult for the patient.
B. The California Children’s Services (CCS) Manual of Procedures, Chapter 4.8.5, limits the type of casting performed by MTU therapy staff to bi-valved casting only. Non-bi-valved or “serial casts” are not an approved casting method for MTU therapists.
C. In the past, CCS determined that serial casting:
• was easily available because there were adequate numbers of providers in the community that could provide the service.
• was not part of the formal curriculum of physical therapy schools.
• competency to perform the procedure could not be determined or monitored in an objective manner.
• would be a liability issue because, in an emergency, MTU staff could not provide 24 hour availability to remove the cast.

D. Currently, many county CCS programs experience difficulty obtaining providers to perform serial casting. Additionally, some materials currently used for serial casting can be removed safely and simply by the family at home. In addition, the State of California, Department of Consumer Affairs, Physical Therapy Examining Committee has determined that serial casting is within the scope of practice of physical therapists. However, the therapist must have appropriate training and competency in the procedure. It is standard practice at medical rehabilitation centers that serial casting is available and usually performed by a physical therapist under the direction of a physician.

1.3. Program Overview: Medical Therapy Units are located in Public Schools. Medically necessary therapy services are provided by licensed occupational therapists and physical therapists who are supervised by senior therapists. The therapy is prescribed and monitored by licensed physicians who have appropriate training and experience with CCS Medical Therapy Program (MTP) eligible conditions. The purpose is to assist the family and child to achieve the child’s optimal physical function. Services provided at the MTU are at no cost to the family and do not require financial eligibility. However, there are limited hours of operation (without 24/7 follow-up for evaluation and management of complications). Medical services that are needed outside of the MTU require financial coverage (Medi-Cal, Healthy Families, CCS, Private Insurance, Private Pay).

2. APPLICATION REQUIREMENTS
2.1.1. Applicant Eligibility:
2.1.2. The applicant county must be an independent county.
2.1.3. The County application must designate the MTU sites that will be in the pilot project.
2.1.4. Each MTU site participating in the serial casting pilot project must be a certified outpatient rehabilitation center (OPRC).
2.1.5. Each participating MTU must have the appropriate staffing with adequate level of experience. (defined in section 4, below)
2.1.6. The County Administrative Office must agree to provide the appropriate supplies and equipment necessary to apply and remove serial casts.
2.1.7. The county must have arrangements for the management of any required urgent care on a 24 hour, 7 day per week basis (24/7) in the local area. Urgent care must be available for children who have CCS financial eligibility and for those children who do not.
2.1.8. The MTC MD and Orthopedic staff must be in agreement with the Serial Casting Pilot and one of them is willing to prescribe the procedure and provide monitoring and follow-up.

2.1.9. There must be a statement that the serial casting procedures performed at the MTU are within the current liability insurance of the prescribing physician, and the therapists performing the procedure. This applies to contract therapists and county therapy staff.

2.1.10. The County CCS Administrator, County Medical Consultant/Director and the Chief or Supervising therapists of the County must sign off on the pilot project application.

2.2. Each MTU participating must have adequate staffing hours available to provide the prescribed therapy in addition to serial casting.

3. SCOPE OF WORK

3.1. General: The Medical Therapy Unit shall provide serial casting by qualified therapists, under physician prescription, with appropriate parent/caregiver training and 24/7 method of evaluation and management of complications.

3.2. Policies/Procedures/Protocols: the MTU must have protocols or procedure statements which identify the:

- clinical indications for use of the serial casting procedures
- goals of serial casting
- methods of serial casting
- materials for serial casting
- specific procedure location within the MTU
- family/caregiver education
- informed consent form (see glossary and insurance carrier requirements)
- documentation of therapist competency by the chief/supervising therapist
- supervision of the procedure
- monitoring of outcome by chief therapist and prescribing physician
- urgent/emergency care plan that is in effect 24/7
- project log documenting patient, procedure, therapists, outcome, and untoward effects

3.3. Therapist Competency: The MTU shall have a method of determining that therapists performing serial casting have skill and proficiency that includes, but is not limited to all of the following:

- Therapists who perform the procedure shall have at least one year of supervised work experience with neurologically impaired children.
- The therapist must have a certificate of completion from a formal serial casting training program and evidence of the factual knowledge of the procedure, indications, management of possible complications, and personal demonstration of the
procedure. An exception may be granted for therapists who have done 10 or more procedures within the last 3 years if they can provide a letter from a qualified physician stating that the therapist has current experience and has achieved good results with serial casting.

- The therapist must have performed at least one procedure under the direct observation of a person who is qualified to perform the procedure and who is designated by the chief/supervising therapist.

3.4. Continued Competency: The therapist shall maintain competency by performing or assisting with at least 3 procedures at the MTU every year, or have a letter signed by a MTC physician and another qualified therapist stating that the therapist has done at least one procedure with good results and has demonstrated competency.

3.5. Therapist Training: The MTU shall have a policy description of acceptable training options that shall include at least one of the following methods:

- Training may be obtained from a course which is acceptable to the chief/supervising therapist and that meets the above competency requirements OR

- Training internal to the CCS program may be conducted by county physical therapy staff when each of the individual trainers meets all of the competency requirements listed above and the primary trainer shall have experience preparing educational materials and have a specific educational plan for teaching serial casting.

3.6. Space and Equipment: Adequate space and equipment must be available for the serial casting procedure in addition to all other therapy that is prescribed.

3.7. Outpatient Rehabilitation Center Certification (OPRC) and Current Survey: State Therapy Consultant must verify the OPRC certification status and MediCal provider number for the unit.

3.8. Quality Assurance/Tracking and Monitoring: Serial casting procedures and outcomes shall be reviewed by the county CCS program utilization review team a minimum of once per year.

3.9. Data Management: Quarterly data shall be submitted to the CMS Regional Office that includes, but is not limited to:

- Name of chief/supervising therapist responsible for the pilot project
- Names of therapists currently approved to provide serial casting
- Basis upon which therapists have obtained approval (training and experience)
- Medical record numbers of the children receiving serial casting
- Dates of casting
- Therapists assisting in casting
- Outcome of casting
3.10 Complications that require hospitalization shall be reported immediately to the CMS Regional Office.

4. STAFFING REQUIREMENTS

4.1. General: Therapists supervising and participating in the pilot project must be county employees.

4.2. Administrator/Director: The chief/supervising therapist, or a qualified MTU therapist designated by the chief/supervising therapist, shall monitor the pilot project, determine the appropriate training options, identify those therapists who have sufficient skill and competency as defined above, assure that the procedures are being performed by qualified therapists, monitor untoward effects, and assure that the pilot project documentation is completed and submitted in a timely fashion.

4.3. MTC Physician: The MTC orthopedist or physiatrist shall review all requests for serial casting of children with MTP eligible conditions, including those received from private prescribing physicians. If the MTC physician is in agreement that the procedure is appropriate to meet the child’s goals, a statement of agreement and prescription is dictated as part to the MTC or chart review in the case of a private physician request. The prescribing physician shall evaluate the child at the onset and completion of the serial casting to determine need and document the outcome.

4.4. Chief/Supervising Therapist: See Administrator/Director.

4.5. Physical Therapist: There shall be at least one qualified physical therapist available to perform serial casting of the upper and lower extremities (elbow, forearm, wrist, hand, knee, ankle and foot) for each MTU participating.

4.6. Occupational Therapist: There shall be at least one qualified occupational therapist available to assist the physical therapist in serial casting of the upper extremity (elbow, forearm, wrist and hand) for each MTU participating. An occupational therapist may also assist in serial casting of the lower extremity.

4.7. Parent: There must be a parent or legal guardian who has received instructions and accepts responsibility for follow up care.

4.8. County Administrator: The County Administrator shall be responsible for providing supplies necessary for application and removal of serial casts and must be in agreement with the county participation in the pilot project.

4.9. County Medical Director/Consultant: The County Medical Director/Consultant must be in agreement with the MTU(s) participation in the pilot project.
5. APPLICATION GUIDELINES

5.1. Approach: Interested Counties must submit a letter of intent and an application to James Boyd, MD at the following address:
Children’s Medical Services Branch
MS 8100
P.O. Box 942732
Sacramento, CA, 94234-7320

5.2. The written application must address all of the following elements:
- assessment of need for MTU to provide serial casting
- policy and procedure for all areas of scope of work
- informed consent form (see glossary and insurance carrier requirements)
- medical supervision
- therapist training and competency
- monitoring method
- record keeping
- safety and precautions
- materials for the procedure
- educational materials for the family which include a written emergency plan
- management of medical complications 24/7 for children with CCS financial eligibility and for those who are not financially eligible.
- Serial casting pilot project evaluation procedures

5.3. Timetable:
- Solicitation letter release: December 12, 2003
- Letter of intent due: January 31, 2004
- Applications due: May 3, 2004
- CCS decision announcement date July 5, 2004
- Readiness review date September 6, 2004. At the time of the readiness review the implementation date for pilot projects, submission of data and report due dates, pilot projects end will be determined.

5.4. Letter of Intent
A. Requirement for Letter of Intent
   1. A county which intends to submit an application for serial casting shall submit a Letter of Intent.
B. Process for Submitting Letter of Intent
   1. All letters of intent shall be on the prospective county's letterhead and shall state:
      a. The legal name, address, telephone and fax numbers, and a liaison or contact person of the prospective county.
      b. The name and address of the CCS County and MTUs
c. The name and title of a single person to whom all communication regarding the Serial Casting Pilot Project should be addressed.

2. Letters of intent shall be submitted in writing, labeled and addressed to:
   - James Boyd, M.D.
   - Children’s Medical Services Branch
   - MS 8100
   - P.O. Box 942732
   - Sacramento, CA, 94234-7320

3. Letters of intent shall be received on or before the final submission date for letters of intent.

5.5. Serial Casting Pilot Project Addenda
The DHS reserves the right to amend the Serial Casting Pilot Project.

6. SUBMISSION REQUIREMENTS

6.1 GENERAL SUBMISSION REQUIREMENTS

A. Each applicant county shall submit a master set and five copies of the application.

B. The master set shall bear the original signature of the Agency Official and be packaged separately and labeled "Master Set". All applications must be submitted to:
   - James Boyd, M.D.
   - Children’s Medical Services Branch
   - MS 8100
   - P.O. Box 942732
   - Sacramento, CA, 94234-7320

Applicants are cautioned to allow sufficient delivery time as the CMS Branch does not receive mail directly from the U. S. Postal Services, but from the DHS mailroom. It may take at least five (5) working days after mail is delivered to the DHS mailroom before the mail arrives in the CMS Branch.

All applications shall be received no later than 2 p.m., May 3, 2004. Any application received after the specified time and date will be rejected by the State. It is the sole responsibility of the Applicant to ensure that CMS receives the applications prior to the required time and date. No exceptions shall be made.

C. All applications and other submissions shall be submitted in 12 point font, on three hole punched, 8-1/2 x 11", white bond paper, with one inch margins, no less than standard single spacing, with pages numbered sequentially and be bound in three-ring binders.

D. The outside of each package shall be marked to identify the contents along with the name of the Applicant and the statement:
   "CHILDREN’S MEDICAL SERVICES, CCS MTP/MTU SERIAL CASTING PILOT PROJECT"
A complete set of the Applications should be contained in as few packages as possible. If there is more than one package the packages shall be clearly labeled and indicate on the outside of each the total number of packages transmitted to the Branch.

6.2 AUTHORITY TO VERIFY APPLICANT’S INFORMATION
All applicants agree that in submitting an application they authorize the State to verify any and all claimed information.

6.3 ALTERATION/MODIFICATION TO APPLICATION
Applications shall be complete when submitted. No changes, modifications, corrections or additions to the applications shall be made by the Applicant once they are filed with the Department. However, an application may be withdrawn in its entirety and resubmitted if still within the limitations of Section 5.3.

6.4 FORMAT AND CONTENT OF APPLICATION
The Applicant shall respond to each of the requirements described in this Serial Casting Pilot Project Application. Responses shall be clear, complete, and in sufficient detail to enable the reviewer to evaluate the application. The application shall include the following sections, have numbered pages, and be assembled and arranged in the following order:

A. Application Checklist
   Complete the Application Checklist which contains a summary of all items, documents and other information required in the submission of the application. CMS shall use the checklist to verify inclusion of all submission requirements. Table of Contents immediately after the Applicant Information Sheet, place the Table of Contents with the appropriate page numbers. Number the pages in the Table of Contents to match the application. When evaluating the application, reviewers shall follow the Table of Contents when looking for specific areas to evaluate.

B. Application Content
   Contents shall include explanation of how the agency will perform all of the required elements of serial casting (delineated above in SECTION 3.0 – SCOPE OF WORK).

7. APPLICATION EVALUATION PROCESS
7.1 EVALUATION OF THE SERIAL CASTING PILOT PROJECT APPLICATION
   A. Each application received by 2 p.m. on May 3, 2004, shall be subject to a review and scoring mechanism to determine its complete responsiveness to the pilot project application. Applications found to be incomplete or unresponsive at any stage for any reason will be removed from further consideration.
   B. CMS may waive any immaterial defect/deviation in any application. CMS reserves the right, at its sole discretion, to determine and define immaterial defects/deviations and will in no way modify the pilot
project application requirements or excuse an applicant from full compliance with the pilot project application requirements.

C. CMS reserves the right to reject all applications without remedy to any applicant, if this action is deemed to be in CMS’ best interest.

D. Items which may cause an application package to be deemed non-responsive include, but are not limited to:
   1. Failure of an applicant to properly complete and sign all required forms, documents, and attachments as instructed in the pilot project application or on the attachments themselves.
   2. Failure of an applicant to meet the pilot project application format or submission requirements including the labeling, packaging and/or timely and proper delivery of applications.
   3. Presentation of incorrect, inaccurate, or misleading information in an applicant's response.
   4. Determination by CMS that an applicant is unwilling or unable to fully comply with all contract terms and conditions.

7.2 APPLICATION EVALUATION PROCESS

Each application will be competitively reviewed and scored. CMS shall use a four (4) step process in the evaluation and scoring of the application. Each application shall be reviewed and scored based on the adequacy and thoroughness of the response to the pilot project application requirements. A team of professionals with educational, administrative, and clinical expertise shall evaluate the applications.

A. Step One
   The first step will be a review of the Application Certification Checklist. To pass this review, each of the items identified on the Checklist must be included in the application package. This is a pass/fail review. If all items are not included, the application will be deemed non-responsive and ineligible for further consideration.

B. Step Two
   Each of the MTUs listed on the application shall have received certification as a CCS Outpatient Rehabilitation Center and shall continue to meet the standards set forth in the California Code of Regulations Title 22 sec 51213 and 51314. If this requirement is not met the application will be deemed ineligible for further consideration.

C. Step Three
   Step three shall be an evaluation of the technical components of the submission requirements of the pilot project application. The applications passing steps one and two shall enter step three for evaluation and scoring. Scoring shall be based on a pass/fail basis for each element of the application. Each element must receive a passing score.

☐ Signatures of the County CCS Administrator, County Medical Director/Consultant, and Chief/Supervising Therapist
Assessment of need for MTU to provide serial casting
Policy and Procedure related to serial casting
Informed consent form
Medical supervision
Therapist training and competency
Monitoring method
Record keeping
Safety and precautions
Materials for the procedure
Educational materials for the family which include a written emergency plan
Management of medical complications 24/7
Serial casting evaluation procedures
Liability insurance coverage
Serial Casting Evaluation procedures

C. Step Four
The approval of pilot projects shall be limited to no more than 5 counties. The counties shall be selected to represent significant regions of the State of California so that the information derived from the pilot project will be applicable throughout the State. The award of a pilot project and full implementation by the County CCS program and MTUs shall be solely at the discretion of CMS.

8. READINESS REVIEW
8.1 GENERAL
Each county accepted for the Serial Casting Pilot shall participate in a readiness review prior to the start of the operations period of the contract. The purpose of this readiness review is to ensure that the MTU(s) and county is capable of and operationally prepared to meet all of the elements and requirements specified in the pilot project application.

9. GLOSSARY
As used in this pilot project application, unless otherwise expressly provided or the context otherwise requires, the following definitions of terms will be used:

**Applicant**
A county which submits an application in response to the pilot project application.
**Assist (specific to serial casting)**
Help with a procedure (serial casting) by hands on effort that aligns the extremity and/or applies casting material. Additional effort may be required to comfort the child and maintain cooperation.

**Bi-valved Cast**
A solid material such as plaster or fiberglass which is applied to the circumference of any portion of an extremity and then immediately split longitudinally on each side for the purpose of muscle stretching and/or improvement of range of motion. A bi-valved cast is usually held together by straps, which can be adjusted.

**CCS Outpatient Rehabilitation Center**
A center that has been approved by CCS and continues to meet the standards set forth in California Code of Regulations Title 22 sec 51213 and 51314

**Complication (specific to serial casting)**
Any unexpected or adverse effect of the procedure of serial casting or any problem that is in any way related to the process of serial casting

**Direction of a physician**
Evaluation and formal prescription (on a prescription form or in the signed medical dictation), specifying the procedure, goals, and precautions. The evaluation must be both prior to the procedure in order to assess the need and after the procedure to assess the results.

**Goals**
Specific outcome to be achieved by the procedure or intervention

**Indications**
Appropriate reasons for considering and performing a procedure such as serial casting.

**Informed Consent for a Child**
The agreement of the parent or legal guardian to have their child undergo a proposed procedure after receiving and understanding an explanation of (a) the nature of the procedure, (b) the risks/complications, (c) the benefits, and (d) the alternatives. This is generally documented in writing with a witness. See additional requirements from insurance carrier. Also, there is useful material on American Academy of Pediatrics Website: http://www.aap.org/policy/00662.html.

**Letter of Intent**
A letter sent to CMS by a potential applicant expressing interest in submitting an application and identifying the MTU, county, address, and liaison person(s).

**Monitoring**
Re-evaluation of an individual child or overall pilot project to identify progress, complications, satisfaction, and identification of areas for improvement
Pilot Project
A time limited study of the procedural aspects, benefits, and complications of a procedure such as serial casting. A pilot project must include project standards, procedure descriptions, qualifications of persons performing the procedure, supervision, indications, incidental findings, outcomes, quality assurance, and assessment of complications.

Prescription
A written or dictated order from a physician for a specific procedure. In the case of serial casting the prescription must include name, date, CCS number, DOB, type of casting material, region of body to be casted, goal of muscle length and/or range of motion, and precautions if there are any unusual considerations. There must be a current medical evaluation on record which supports the decision to provide serial casting.

Procedure
A specific physical intervention for medical or therapeutic purpose such as serial casting.

Qualified, Trained, Competent
A person who is able to provide or supervise a procedure based upon specific training and experience. The person has specific skills and experience as designated by CCS policy and the specific criteria delineated in the pilot project application document.

Quality Assurance
A formal set of activities designed to assure the quality of clinical and non-clinical services provided. Quality assurance includes quality assessment and corrective actions taken to remedy any deficiencies identified through the assessment process.

Serial Casting
The repeated application of a solid material such as plaster or fiberglass to the circumference of any portion of an extremity for the purpose of muscle stretching and/or improvement of range of motion. A serial cast is not a bi-valved cast and is usually replaced in 2-7 days to until a specific muscle length or range of motion goal has been met.

Scope of Work
Work activities, actions to be performed, deliverables to be supplied, methods and approaches to be used and expected objectives and outcomes to be achieved under a contractual agreement.

State Administrative Manual (SAM)
A manual containing administrative policies and procedures for state agencies to use during the conduct of regular business affairs.

Supervision
Direct and indirect observation of activity, technique and skills. This includes feedback and coaching to improve performance and the acquisition of new techniques.
**Urgent/Emergency Care 24/7**
Evaluation and management of problems that cannot be handled at the MTU due to the time of day or seriousness. This care must be available 24 hours a day, 7 days a week, and 365 days per year.
CHECKLIST FOR APPLICANTS
SERIAL CASTING PILOT PROJECT

Applicant Name:

Address:

Date:

Liaison Person:

Phone Number:

County Name:

MTUs participating:

Supervising Therapist(s):

Enclosed Elements of the Application:

☑ Signatures of the County CCS Administrator, County Medical Director/Consultant, and Chief/Supervising Therapist
☑ Statement that the serial casting procedures are covered by liability insurance
☑ Assessment of need for MTU to provide serial casting
☑ Policy and Procedures related to serial casting
☑ Informed consent form
☑ Medical supervision
☑ Therapist training and competency
☑ Monitoring method
☑ Record keeping
☑ Safety and precautions
☑ Materials for the procedure
☑ Educational materials for the family which include a written emergency plan
☑ Management of medical complications 24/7 for children with CCS financial eligibility ad for those who are not financially eligible
☑ Serial Casting Evaluation procedures
Timetable:

- Solicitation letter release: December 12, 2003
- Letter of intent due: January 31, 2004
- Applications due: May 3, 2004
- CCS decision announcement date July 5, 2004

Readiness review date September 6, 2004. At the time of the readiness