



# **CLEFT LIP/PALATE CLINICS STANDARDS**

**2008**

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## I. HISTORY

In 1982 the Florida Legislature provided funding for planning a statewide program for all children in the state with a cleft lip, cleft palate, or other craniofacial anomaly. The funding for this statewide program ensured the development of policies, procedures, treatment protocols, and a registry of children with cleft lip, cleft palate and craniofacial anomalies. This program development was in conjunction with the Florida Cleft Palate-Craniofacial Association (FCPCA) and an appointed Advisory Council to the Department of Health and Rehabilitative Services (HRS), Children's Medical Services (CMS).

Standards were established in 1987 for the continuation of existing programs and the creation of new programs. They included the criteria for the care and treatment of children with cleft lip, cleft palate, and craniofacial anomalies. Professionals who serve on the teams at CMS Cleft Lip/Palate Clinics and Craniofacial Centers and other stakeholders from across the state of Florida meet periodically to revise the Standards and keep them in alignment with the current standards of practice. The American Cleft Palate-Craniofacial Association (ACPA) publishes a consensus document entitled "Parameters for Evaluation and Treatment of Patients with Cleft Lip/Palate or Other Craniofacial Anomalies". The CMS Standards are based on the ACPA document and support the fundamental principles outlined in those national standards, including:

- A. Management of patients with craniofacial anomalies is best provided by an interdisciplinary team of specialists.
- B. Optimal care for patients with craniofacial anomalies is provided by teams that see sufficient numbers of patients each year to maintain clinical expertise in diagnosis and treatment.
- C. The optimal time for the first evaluation is within the first few weeks of life and, whenever possible, within the first few days. However, referral for team evaluation and management is appropriate for patients at any age.
- D. From the time of the first contact with the child and family, every effort must be made to assist the family in adjusting to the birth of a child with a craniofacial anomaly and to the consequent demands and stress placed upon the family.
- E. Parents/caregivers must be given information about recommended treatment procedures, options, risk factors, benefits, and costs to assist them in (a) making informed decisions on the child's behalf, and (b) preparing the child and themselves for all recommended procedures. The team should actively solicit family participation and collaboration in treatment planning. When the child is mature enough to do so, he or she should participate in treatment decisions.

- F. Treatment plans should be developed and implemented on the basis of team recommendations.
- G. Care should be coordinated by the team but should be provided at the local level whenever possible; however, complex diagnostic and surgical procedures should be restricted to major centers with the appropriate facilities and experienced care providers.
- H. It is the responsibility of each team to be sensitive to linguistic, cultural, ethnic, psychosocial, economic, and physical factors that affect the dynamic relationship between the team and the patient and family.
- I. It is the responsibility of each team to monitor both short-term and long-term outcomes. Thus, longitudinal follow-up of patients, including appropriate documentation and record-keeping, is essential.
- J. Evaluation of treatment outcomes must take into account the satisfaction and psychosocial well-being of the patient as well as effects on growth, function, and appearance.

In 1998 the Florida Legislature enacted F.S. 627.64193 mandating insurance companies writing policies in Florida to provide specific coverage for children with clefts. The coverage must include medical, dental, speech therapy, audiology, and nutrition services when the services are prescribed by the treating physician or surgeon, deemed medically necessary, and are consequent to treatment of the cleft lip or cleft palate. Staff at the CMS Cleft Lip/Palate clinics and Craniofacial centers assist commercial insurance companies in understanding their obligation under the law and assist families in ensuring that reimbursement is received for medically necessary services for their child with a cleft.

## **II. CMS SYSTEM OF CARE**

It is believed that interdisciplinary care provides the highest quality of care for infants and children with cleft lip, cleft palate, and craniofacial anomalies. Through Children's Medical Services a network of interdisciplinary cleft lip/palate clinics and craniofacial centers has been approved to serve all children in Florida with these conditions.

In the United States, cleft lip and /or palate affects approximately one in 750 newborns each year. At the time of the birth of an infant in Florida with a cleft lip, cleft palate or craniofacial anomaly, the parents receive individualized feeding instruction for their baby along with educational materials (brochures, videos, etc.) while in the hospital. In addition, they are informed of the services which are provided by CMS and how to access those services. If the hospital contacts the CMS area office, the CMS care coordinator will make every effort to visit the family while in the hospital.

Infants and children may be referred to a CMS cleft lip/palate clinic or craniofacial center by their parent, private practitioner or other provider(s). Children enrolled in the CMS program are provided the full benefit package of care coordination, clinics, and social work services through the clinics and centers. Private patients have access to this system of family-centered care to receive periodic evaluations and a treatment plan recommended by the interdisciplinary team. All care is coordinated with the child's primary care physician.

### **III. DESCRIPTION OF TERMS**

The terms "complex" and "less complex" have been used to describe the conditions managed by cleft lip/palate clinics and the craniofacial centers. These terms are defined as follows:

- A. Less Complex Conditions may be evaluated by either a CMS-approved Cleft Lip/Palate Clinic or Craniofacial Center and include the following:
  - 1. Limited anomalies of facial structures below the orbits.
  - 2. Unilateral or bilateral, incomplete or complete clefts of the lip and/or primary and/or secondary palatal structures which require surgical, medical, speech, audiological, and dental intervention and family care.
- B. Complex Conditions are to be evaluated at a CMS approved Craniofacial Center. Care should be coordinated by the center team but should be provided at the local level whenever possible with complex diagnostic and surgical procedures restricted to the centers. Complex conditions include the following:
  - 1. Craniofacial anomalies involving the face, orbit(s) and/or cranium.
  - 2. Major cleft and non-cleft craniofacial deformities which involve multiple malformations that compromise the patient for usual and customary procedures and that may require more comprehensive care than can be provided by a cleft team.
  - 3. Syndromal anomalies with cleft lip/palate/other craniofacial anomalies.
  - 4. Conditions related to craniomaxillofacial, craniomandibulofacial, and acquired craniofacial deformities, as well as facial clefts other than cleft lip.

### **IV. DIAGNOSTIC AND TREATMENT FACILITIES OR SERVICES**

- A. In-patient care for CMS patients with cleft lip, cleft palate, or cleft lip and palate shall be provided in CMS approved hospitals conforming to the standards contained in Chapter 64C, Florida Administrative Code (F.A.C.).

- B. In accordance with Chapter 391, F.S., CMS may designate a network of clinics/centers capable of providing a range of health care services to patients with cleft lip, cleft palate, or cleft lip and palate.

**V. APPROVAL OF NEW CMS CLEFT LIP/PALATE CLINICS**

- A. When considering the addition of a cleft lip/palate clinic a CMS area office will determine if :
1. there is a minimum of 50 children in the service area to warrant a clinic.
  2. there is support among the community providers to ensure core staffing, outlined in section VI, for clinics to be conducted at least six times a year.
- B. After one year of operation an interdisciplinary review team, appointed by the Deputy Secretary, will conduct an on-site review during a scheduled clinic to establish the clinic's compliance with these Standards.
- C. The review team will report their findings and recommendations to the CMS Deputy Secretary.
- D. The CMS Deputy Secretary will make the final approval status determination.
- E. The CMS area office Medical Director will be notified in writing of the findings and recommendations of the review team as well as the approval status of the clinic.

**VI. CMS STANDARDS**

**A. GENERAL**

1. The local CMS Area Office Medical Director, in consultation with the CMS Deputy Secretary, is responsible for establishing and maintaining interdisciplinary clinics in those CMS areas where there is a sufficient population of CMS and private children to be served.
2. A CMS Cleft Lip/Palate Clinic has primary responsibility for providing care management for children with cleft lip and/or palate residing in the local service area. They also provide follow-up, as indicated, for children in the service area who access services at one of the regional craniofacial centers.
3. CMS Craniofacial Centers are tertiary facilities staffed by an interdisciplinary team to evaluate children with complex craniofacial conditions which cannot be treated at the local level through a CMS Cleft Lip/Palate Clinic.
4. CMS Cleft Lip/Palate Clinics are staffed by an interdisciplinary team to serve children with cleft lip, cleft palate, or other limited anomalies of facial structures below the orbits.

5. Cleft Lip/Palate and Craniofacial team members are all CMS approved providers through CMS Central Office and must meet all CMS approval and re-approval criteria.
  - a) Physician must be board certified by their pediatric and specialty Board, or actively pursuing board certification. For specialties with a multi-phase board process, Phase 1 must have been successfully completed.
  - b) Other Healthcare Providers are fully licensed and/or certified in their specialty area
6. To ensure professional expertise and high quality care, there shall be at least 50 CMS or private patients with cleft lip/palate seen by the CMS Cleft Lip/Palate Clinic per year to justify maintaining an existing interdisciplinary clinic.
7. As part of the minimum of 50 children seen each year, 10 new patients with a cleft lip and/or cleft palate should be evaluated per year.
8. To ensure sufficient clinic time for all patients, a CMS Cleft Lip/Palate Clinic should be conducted at least six times a year.
9. The CMS Medical Director shall appoint a CMS approved pediatrician as the team leader and determine the team membership in accordance with the core team staffing standards contained in this document.
10. In addition to recruiting professionals from the community, the CMS Medical Director may also work collaboratively with the nearest CMS approved Craniofacial Center for assistance in ensuring the availability of all core team specialists on the Cleft Lip/Palate Clinic team.
11. A team staffing is to be conducted at the end of each clinic and attended by all team members to contribute their expertise in the development of a coordinated treatment plan as required by patient needs and in accordance with the treatment protocols outlined in Appendix A. Discussion of testing results and implications allows for coordination of follow-up care.
12. Maintain comprehensive records on each patient, including histories, diagnoses, reports of evaluations, treatment plans, reports of treatment, and supporting documentation such as photographs, radiographs, dental models, and speech recordings

- B. PERSONNEL REQUIREMENTS AND SERVICES TO BE PROVIDED
1. CMS Cleft Lip/Palate Clinic team members must be approved CMS providers with specialty training in working with these patients. Physicians and other health care providers are approved as CMS providers by the Deputy Secretary for CMS.
  2. All members shall be licensed, if licensure is required for the discipline. New team members should have had experience in treating children with cleft lip/palate or craniofacial anomalies prior to joining a team.
  3. All team members will attend all scheduled Cleft Lip/Palate Clinics, examine patients, and document their findings and recommendations. After the examination, each team member will briefly review the findings and anticipated recommendations with the parents.
  4. A primary care physician should be identified for each child, and should become an extended member of the team through routine receipt of team dictations.
  5. All team members will make efforts to inform other specialists in the community of the availability of the CMS Cleft Lip/Palate Clinic for every child with a cleft lip, cleft palate, or craniofacial anomaly.
  6. All team members are encouraged to participate in related continuing education annually to maintain competence and to be active in their respective professional organizations.
  7. To address the comprehensive needs of the patients and their families, the **core members** of a CMS Cleft Lip/Palate Clinic team must include a pediatrician, cleft surgeon, orthodontist, speech-language pathologist, audiologist, dentist, otolaryngologist, nurse care coordinator, social worker, feeding specialist, and parent advocate (when available).
  8. Following are the requirements for each specialist and the services to be provided:
    - a. **Pediatrician** - board certified with a background in developmental pediatrics, who will direct and coordinate the interdisciplinary team. In addition, the pediatrician will:
      - 1) Serve as the patient/family advocate and liaison between the team and the family ensuring parental questions regarding health issues are addressed, assisting parents in understanding the child's health needs, and following the implementation of the team treatment plan.

- 2) Work with the CMS nurse to assure that all children seen by the team receive routine pediatric well-baby care through the family's choice of a primary care provider (i.e., private pediatrician, CHD, community health center physician, etc.).
  - 3) Assure timely referral of all children enrolled in CMS to an approved craniofacial center, when appropriate, for comprehensive evaluation and treatment recommendations.
  - 4) Provide anticipatory guidance to parents of newborns with clefts or craniofacial anomalies regarding initial recommendations of the team and special concerns for care of their infant in the first few months of life.
  - 5) Communicate with the primary care provider about acute and chronic health concerns relative to the patient's condition which includes medical, developmental, psychological and emotional needs. Referral to appropriate specialists will be made in cooperation with the primary care provider
  - 6) Assess each patient's treatment progress at each clinic visit.
  - 7) Evaluate the patient's overall growth and development needs and treat in coordination with the child's primary care provider.
  - 8) Provide on-going support, family counseling and coordination of care, as indicated.
  - 9) Gather and document findings at each examination.
- b. **Cleft Surgeon** - board-certified, or actively pursuing board certification in General Plastic Surgery, Otolaryngology with fellowship training in pediatric or facial plastic surgery, or Oral-Maxillofacial Surgery. The Cleft Surgeon should have a minimum of two years experience in pediatric surgical (re)habilitation of cleft lip and palate and have active hospital privileges for pediatric surgical (re)habilitation of cleft lip and palate. In all cases, surgical techniques should be individualized according to the needs and condition of the patient. Surgical procedures should be coordinated to minimize the number of anesthetic exposures and hospitalizations. The major factor in the quality of surgical outcome is the skill, training, and experience of the operating surgeon. Reduction of morbidity and mortality from craniofacial operations requires establishment of a dedicated surgical team, frequent performance of operative procedures, and adequate support facilities. The surgeon will:

- 1) Examine and evaluate each patient and provide a clinical assessment of structures and functions involving the cleft(s) and/or anomalies, and document findings in the patient's record.
  - 2) Schedule recommended sequence of surgeries to best correct the condition, utilizing current treatment techniques.
  - 3) Recommend referral of patients requiring complex craniofacial surgery to one of the approved craniofacial centers
  - 4) Jointly coordinate all surgical specialties with the comprehensive treatment plan and in consultation with the interdisciplinary team to facilitate optimum outcome for each patient.
  - 5) Provide surgical management for primary surgical closure of the lip and palate as well as management of secondary surgical procedures involving the lip, nose, palate, and jaws.
  - 6) Perform secondary palatal and pharyngeal surgery for velopharyngeal inadequacy only after evaluation of the velopharyngeal mechanism and review by the team.
  - 7) Document and record findings and recommendations at each patient intervention and ensure a copy is included in the CMS patient record.
  - 8) Maintain adequate surgical skills in repairing cleft lip and palate by performing no fewer than ten (10) primary or secondary cleft lip and/or palate repairs per year on patients who have been evaluated by the cleft palate clinic team.
- c. **Orthodontist** - board-certified, or actively pursuing board certification, with a minimum of two years experience in treating children with cleft lip and palate. The orthodontist must have available adequate facilities to deliver treatment and collect needed diagnostic data as overall care progresses. If it is necessary to refer orthodontic treatment to an orthodontist who is not a team member, then it is the team orthodontist's responsibility to communicate with the treating orthodontist as needed and to monitor the progress of this treatment at scheduled clinics. The orthodontist will evaluate findings and recommend orthodontic and dental care, which may include:
- 1) Provide orthopedic manipulation of palatal segments prior to lip closure.
  - 2) Provide orthopedic manipulation of palatal segments prior to alveolar bone graft.

- 3) Provide retention support of palatal segments following lip closure.
  - 4) Provide feeding plates in large open palatal clefts.
  - 5) Correct cross-bites as needed in the primary, mixed and permanent dentitions to encourage unimpeded natural, lateral, and sagittal (forward) palatal/alveolar growth and development of normal nasal respiration.
  - 6) Align teeth in the mixed and permanent dentition to provide good functional and aesthetic relationships to accommodate facial growth potential and provide adequate lip support.
  - 7) Create proper spacing where teeth are missing to allow appropriate prosthetic replacement or dental implantation.
  - 8) Offer guidance and advice to surgeons regarding the aesthetic contour of the lips and nasomaxillary complex.
  - 9) Provide pre-surgical support and radiographs (i.e., orthodontic treatment in preparation for orthognathic surgery and post-surgical tooth movement).
- d. **Speech-language pathologist** - licensed with a minimum of two years experience and training in the evaluation, diagnosis, and treatment of speech, language, voice, resonance, articulation, and feeding problems associated with cleft lip, cleft palate and velo-pharyngeal insufficiency (VPI) in infants and children. Evaluation of speech and language development provides information that is needed by the team in planning of treatment, particularly surgical and dental management. Further, information about the patient's speech, language, voice, and resonance are important in the assessment of the outcome of treatment. Speech-language evaluations must occur often enough to assure adequate documentation of each child's progress and to develop appropriate recommendations for intervention. The speech/language pathologist will:
- 1) Provide a quantitative screening of speech (articulation, voice, resonance and intelligibility) and language, which shall include:
    - a) Review of case history.
    - b) Evaluation of home communication environment based on interview(s) with parents/care givers or through home visiting, as appropriate.

- c) Evaluation of velopharyngeal function for speech and assessment of nasal air emission, hypernasality and hyponasality during speech.
  - d) Assessment of vocal quality as a measure of laryngeal function.
  - e) Assessment of articulation on an age-appropriate screening articulation test and in a speech sample.
  - f) Assessment of receptive and expressive language development.
- 2) Perform or refer patients for a full evaluation of VPI using nasendoscopy and videofluoroscopy.
  - 3) Based on perceptual and instrumental measures, including videofluoroscopy and nasendoscopy, the speech pathologist shall recommend surgical, prosthetic, or behavioral treatment.
  - 4) Maintain records on each patient, including reports of evaluations, treatment plans, reports of treatment, and supporting documentation such as speech recordings.
  - 5) When a child is working with a speech therapist in the community, it is the team speech therapist's responsibility to communicate with the treating therapist and to monitor the progress of this treatment at scheduled clinics.
- e. **Audiologist** - licensed with a minimum of two years experience in the evaluation, diagnosis and treatment of audiological problems associated with cleft lip, cleft palate and velopharyngeal insufficiency (VPI) in infants and children. Hearing loss can have a significantly adverse influence on speech and language development, educational and psychological status, and eventually on social and vocational status. For these reasons, children with cleft lip/palate require ongoing audiological surveillance. The audiologist will:
- 1) Provide audiological assessment in the team setting consisting of auditory testing across the speech sound spectrum and tympanometry to evaluate the middle ear system. Testing is to be done in a sound suite utilizing air conduction audiometry, otoacoustic emissions tympanometer, and visual reinforcement audiometry (VRA), if appropriate. Testing must occur prior to clinic to permit sufficient time for the report to be available to the team on the day of clinic.
  - 2) Provide audiological recommendations for follow-up based on auditory testing that is threshold seeking rather than pass/fail. Recommendations may include otological treatment, auditory training,

hearing-aid evaluation/fitting, or special tests, such as auditory brainstem testing or otoacoustic emissions.

- 3) Recommend appropriate monitoring of pressure-equalizing tube patency and middle-ear function.
  - 4) Maintain serial audiograms on all patients
- f. **Pediatric Dentist** or **General Dentist** – board certified or actively pursuing board certification and licensed, with a minimum of two years documented pediatric experience, to oversee and coordinate all aspects of dental care for the patient. The dentist will:
- 1) Provide orthopedic manipulation of palatal segments and nasal cartilage prior to lip closure.
  - 2) Provide pediatric intra-oral prostheses such as speech bulbs, palatal lifts and fistulae obturators.
  - 3) Palatal expansion for alveolar bone graft (ABG) and basically all of the early childhood appliances that the Orthodontist has listed before ABG.
  - 4) Provide dental care throughout the patient's developmental years starting at one year of age.
  - 5) Provide information about prevention of caries and standards of dental care.
  - 6) Assure patients have a local treating dentist if the team dentist is not the treating dentist.
  - 7) Nasoalveolar molding device when appropriate and if trained to do so.
- g. **Otolaryngologist** - board certified, or actively pursuing board certification, with a minimum of two years experience in managing otitis media and eustachian tube dysfunction in children with cleft palate. The otolaryngologist will:
- 1) Assess each child's short and long term otologic care needs.
  - 2) Recommend tympanostomy tubes as needed and monitor outcomes.
  - 3) Evaluate children referred with conductive and sensorineural hearing impairments for recommendations and treatment options.

- h. **Oral and Maxillofacial Surgeon** - board certified by the American Board of Oral and Maxillofacial Surgery, or actively pursuing board certification, with a minimum of two years experience in pediatric surgical correction of maxillary and mandibular skeletal deformities associated with cleft lip/palate and other craniofacial malformations. The oral-maxillofacial surgeon will:
- 1) Perform orthognathic surgical procedures in coordination with orthodontic care to optimize and correct maxillary and mandibular spatial relationships.
  - 2) Perform bone grafting.
  - 3) Evaluate maxillary and mandibular spatial relationships.
  - 4) Perform dental implants.
  - 5) Maintain adequate surgical skills in working with cleft lip and palate patients by performing no fewer than ten (10) of the surgical procedures above per year.
- i. **Nurse Care Coordinator** – registered and licensed with experience in the care and management of children with cleft lip, cleft palate and other craniofacial anomalies. Complete interdisciplinary management for individuals with cleft lip/palate requires a high level of ongoing coordination of services. Nursing assessment, interventions, and ongoing follow-up evaluations are integral to the long-term care needs of the child and family. The nurse will:
- 1) Prepare patient records for the team staffing.
  - 2) Provide current updates on each patient's treatment status to the team specialists as needed.
  - 3) Assist in coordinating patient flow through the team's evaluation to ensure each patient has been seen by the appropriate specialists.
  - 4) Assist team members with patient examination/evaluation, as necessary.
  - 5) Serve as liaison between the team and the family and as the patient's advocate, as necessary.
  - 6) Ensure the patient and family receive instruction regarding appropriate feeding techniques, care of appliances, pre- and postoperative care concerns, etc., as indicated.

- 7) Ensure that appropriate referrals are made for genetic counseling, nutrition counseling, speech therapy through the Early Steps Program, the school system, and other agencies, as indicated.
  - 8) Provide post-clinic follow through on treatment recommendations.
  - 9) Provide the patient and family with educational brochures appropriate for the patient's stage of development and treatment and information regarding resources available through organizations such as the FCPCA.
  - 10) Provide parent support group information to the family as indicated, including information on the Florida Family Network.
  - 11) Assure care plan goals are met by assisting families with arrangements for care and supporting the child's medical home.
  - 12) Conduct or arrange for home/ school/ hospital visits as necessary to ensure compliance, provide emotional support, and provide appropriate parent training.
  - 13) Ensure coordination of community agency services and resources by serving as a liaison between the Team and community providers as appropriate to meet family needs.
  - 14) Work with the regional craniofacial coordinator to facilitate initiation of patients into the State registry through the FCPCA.
  - 15) Monitor the treatment plan and the child's progress against established clinical guidelines. Work with the team to provide educational and health care information to the caregiver and patient in order to achieve maximum compliance with treatment guidelines.
- j. **CMS Social Worker** - or other clinical social worker (MSW preferred) with experience in health care to provide psychosocial services to the patient and family and to assist the team in case management and coordination of needed services. The social worker will:
- 1) Assess patient and family resources, needs, and understanding of the child's medical and developmental needs.
  - 2) Provide information about family support.
  - 3) Notify team if education needs are identified.

- 4) Encourage/support family and child in asking questions.
  - 5) Make home visits.
  - 6) Refer patient and family to support services and resources.
- k. **Feeding Specialist** - who is a licensed nutritionist, speech/language pathologist, occupational therapist or other individual knowledgeable in the identification and assessment of feeding disorders associated with cleft lip and palate. The feeding specialist will assist and educate medical personnel and families regarding feeding issues and techniques for babies with cleft lip/palate.
- l. **Parent advocate and educator**- with a minimum of two years experience involving children with cleft lip/palate and other craniofacial anomalies. The parent advocate and educator will complete the necessary confidentiality requirements. The parent advocate and educator will:
- 1) Meet with patients and parents to provide support and resources from parent perspective.
  - 2) Assist professional staff in clinic activities to promote family-centered care.
- m. **Additional specialists** - for consultation and treatment may be required to provide proper care for patients with cleft lip/palate. These specialists may be a part of the core team composition for a given patient or patients. Additional board-certified, actively pursuing board certification and/or licensed specialists include, but are not limited to:
- 1) **Pediatric psychologist** - who is licensed in the State of Florida and board certified or actively pursuing board certification, with training and a minimum of two years experience in the assessment and treatment of developmental, behavioral, and emotional issues related to facial disfigurement and other disabilities. The psychologist's responsibilities include:
    - a) Assessment of the psychological and social environment, as well as the impact of the condition on patients and families.
    - b) Provision of or referral for psychosocial services to patients and their families.
    - c) Development and maintenance of liaisons with appropriate resources and community agencies to meet goals of the care plan.

- 2) **Radiologist** - board certified or actively pursuing board certification, with a minimum of two years experience in imaging children with craniofacial disorders.
- 3) **Prosthodontist** - licensed with a minimum of two years experience in pediatric intra-oral prostheses such as speech bulbs, palatal lifts and fistulae obturators.
- 4) **Geneticist** - board certified or actively pursuing board certification, with a minimum of two years experience in inherited craniofacial malformations including cleft lip/palate and other syndromes.
- 5) **Pediatric Anesthesiologist** - board certified or actively pursuing board certification, with a minimum of two years experience in pediatric airway obstructive problems associated with malformations (e.g. Pierre Robin Sequence).
- 6) **Nutritionist** - licensed with a minimum of two years experience in the management of infants and children who are chronically ill and those with clefts and/or craniofacial anomalies.
- 7) **Pediatric Pulmonologist** - board certified or actively pursuing board certification, to review upper airway function, especially when a child has Pierre Robin sequence.
- 8) **Child life specialist** with a minimum of two years experienced in preparing children for procedures and treatments related to the care of children with clefts and/or craniofacial anomalies.

#### C. OFFICE AND CLINIC FACILITIES

1. Must meet the CMS Basic Pediatric Clinic Standards.
2. The team members will have hospital privileges at an approved CMS chronic care hospital.
3. A sound booth to ensure adequate hearing testing at the time of the clinic visit is needed in the clinic area or adjacent facility.

### VII. MONITORING AND QUALITY ASSURANCE

- A. Each CMS-approved cleft lip/palate clinic will be evaluated on-site using these standards at least once every three years by an interdisciplinary team of professionals. The Deputy Secretary for CMS will approve the review team.
- B. Interim data will be submitted to the CMS Central Office annually by each clinic.

- C. Impromptu reviews may be scheduled on an as-needed basis for the following:
1. Complaints regarding quality care issues;
  2. A decline in volume that brings the clinic's number of children 10% below the current CMS volume standard, resulting in less than 45 children being followed or less than 9 new clients per year ;
  3. Significant change in the clinic team composition.

## **VIII. RECORDS**

- A. Patient records will include an on-going summary of procedures/tests/surgeries related to the cleft condition.
- B. Current test results will be available in the patient record at the time the child is seen in clinic.
- C. Documentation of numbers of CMS and private children scheduled/seen at each clinic will be maintained.
- D. A copy of the team evaluation and recommendations at each clinic will be provided to the child's primary care physician and offered to the family.
- E. The clinic staff will maintain data as detailed in Appendix B.

## APPENDIX A

### TREATMENT PROTOCOLS

The following reflects optimal service recommendations for patients identified at birth. For patients entering the system at other stages of age/treatment, assessment of specific condition(s) and treatment status shall be made initially, with adjustments and/or modifications by the team based on each specific patient's needs. Such decisions shall be recorded with patient-specific rationale (in detail) as follows:

#### **SHORTLY AFTER BIRTH (Prior to hospital discharge)**

1. All newborns should be referred to a team (cleft palate or craniofacial center as appropriate). Professional referrals should be made and families should be given a name and number for a contact person on the team.
2. All parents of newborns should receive special feeding supplies, counseling, support and written materials related to the anomaly and have contact with a team member prior to hospital discharge.
3. Parents should be counseled prior to hospital discharge by the pediatrician and other team members as appropriate for the condition(s) to include coaching in feeding techniques and in pre-language stimulation.
4. CMS contact should be made with the family prior to hospital discharge whenever possible.
5. All newborns should receive a hearing evaluation prior to hospital discharge at the birth facility or within 1 month of discharge .
6. Parents should be given the "hotline" phone numbers and web-site addresses of the Florida Family Network Hotline, the Regional Coordinator, and other organizations specific to the newborn's diagnosis.
7. Cleft Palate Clinic evaluation findings and recommendations for treatment should be communicated to the appropriate referring party with notations as to whether future cleft palate team evaluations are necessary.
8. Early evaluation should be performed by all team members, standard basic information recorded and approved diagnostic objective records obtained, including details of the type of congenital abnormality, with further counseling of the family regarding initial and later treatment needs as indicated by the cleft palate team recommendations.

### **FIRST YEAR (Birth – 12 Months)**

1. Weekly assessment of nutritional intake and weight gain during the first month of life. The team coordinator or nurse should contact the family within two weeks of hospital discharge to follow up on feeding, questions, weight gain and overall status.
2. Feeding/swallowing evaluation by trained team member and appropriate referrals for further evaluation, such as a thorough swallow study and/or appliances needed for feeding, if indicated by the team.
3. An oral examination by a pediatric or general dentist should be completed to evaluate factors that may influence surgical management.
4. The use of pre-surgical maxillary orthopedic appliances should be coordinated with initial lip closure procedures in selected cases.
5. Initiate repair of cleft lip. The nasal deformity is an integral part of the cleft lip. Depending on the severity, primary nasoplasty may be done at the time of the primary lip repair.
6. Permanent baseline records should be collected when appropriate, including but not limited to, appropriate photographs, cast impressions of the maxillary arch, consultant evaluation reports, neonatal and primary physician reports, and craniofacial center evaluation.
7. Genetic/dysmorphology screening should be provided followed by genetic counseling for the family.
8. Otologic and audiologic examination with treatment as indicated.
9. Information on speech and language development provided to parents.
10. Full team evaluations should be completed within 3 months of birth unless other diagnoses necessitate delay. The patient should be scheduled for follow-up team visits for evaluation at 6 months and 12 months of age as determined by the team. This evaluation should include a pediatric screening for growth and development, detection and treatment as appropriate of acute or previously undetected conditions and overall review of patient's condition prior to major procedures.
11. Referral to Early Steps may be needed if developmental concerns are identified.

## **SECOND YEAR (12-18 Months)**

1. Palatal closure should be completed by the age of 18 months, to be followed by assessment of resultant velopharyngeal adequacy for speech by perceptual studies, testing distortion of speech within the first year following surgery.
2. Referral to dentist is necessary to initiate dental care
3. Family counseling should be provided, as appropriate, relative to the patient's plan of treatment.
4. Audiologic and otologic monitoring for middle ear function and freedom from disease continues.
5. Speech/language/voice/resonance and swallow testing and stimulation training for parents and patients.
6. Another team evaluation is required at 18 months of age. Record status of oral facial development, palate, and velopharyngeal function. This evaluation should include a pediatric screening for normal growth and development, detection and treatment as appropriate of acute or previously undetected condition and overall review of patient's condition prior to major procedures.
7. Pediatric screening should include review of growth and development, detection and treatment as appropriate of acute or previously undetected conditions, overall review of patient's condition prior to major procedures.
8. Referral to Early Steps may be needed if developmental concerns are identified.
9. Patients with submucous clefts should be monitored closely and their palates repaired only if there is evidence of feeding, otologic, or speech problems.

## **SECOND YEAR (18 – 24 Months)**

1. Speech/language/voice/resonance/oral feeding and swallowing acquisition should be monitored regularly; minimum intervention is six-month evaluations; speech and language therapy provided, as recommended by the speech pathologist.
2. Audiologic monitoring with otologic intervention should be provided, as recommended by the audiologist.
3. Pre- and post-treatment casts should be made, as required by the dental specialists and/or surgeon.
4. A team evaluation is required at 24 months of age. This evaluation should include a pediatric screening for normal growth and development, detection and treatment as

appropriate of acute or previously undetected conditions and overall review of patient's condition prior to major procedures.

5. Record status of occlusion and velopharyngeal function.
6. Referral to Early Steps may be needed if developmental concerns are identified.

### **THIRD YEAR (24 – 36 Months)**

1. Speech/language/voice/resonance and swallowing acquisition should be evaluated with a recommendation by the speech pathologist for therapy and further language stimulation training.
2. Audiologic and otologic exam and treatment continue as recommended by the audiologist and otolaryngologist.
3. Pre- and post-treatment casts are made as required by the dental specialists and/or surgeon.
4. As the primary teeth erupt, each team evaluation should include a dental examination, oral hygiene and other preventive recommendations, and coordination of continuing routine dental visits in a dental office of the family's choice and restorative dentistry.
5. Prosthetic obturation and orthodontic manipulation are provided if recommended by the orthodontist.
6. Complete team evaluation of all involved functions at six to twelve-month intervals. This evaluation should include a pediatric screening for normal growth and development, detection and treatment as appropriate of acute or previously undetected conditions and overall review of patient's condition prior to major procedures.
7. Referral to educational setting such as Early Steps Program or Florida Diagnostic Learning Resource System (FDLRS) as recommended by the team.
8. Nasendoscopy and videofluoroscopy are provided as recommended by the speech pathologist, if developmental level allows.

#### **FOURTH YEAR (36 – 48 Months)**

1. Patients who are identified as having had closure of the palate but continue to demonstrate persistent velopharyngeal insufficiency should be referred for special services (as described on page 16 of this document) to identify the optimal treatment procedure including surgical, prosthetic and/or speech therapy.
2. Speech and language evaluation is completed, with a recommendation for therapy and further language stimulation training as needed.
3. Each team evaluation should include a dental examination, oral hygiene and other preventive recommendations, and ensuring ongoing routine dental visits in a dental office of the family's choice. Dental providers should be recommended for preventive dental procedures, such as sealants and restorative dentistry as necessary.
4. Pre- and post-treatment casts are made as required by the dental specialists and/or surgeon.
5. Team evaluation continues at six to twelve month intervals. This evaluation should include a pediatric screening for normal growth and development, detection and treatment as appropriate of acute or previously undetected conditions and overall review of patient's condition prior to major procedures.
6. Nasendoscopy and videofluoroscopy are provided as recommended by the speech pathologist.
7. Otologic and audiologic monitoring recommended by the otolaryngologist and audiologist.

#### **FIFTH YEAR (48 – 60 Months)**

1. Family counseling, education and training continue.
2. Pediatric dentistry evaluation, treatment, and fluoride treatment as recommended by the dental specialists.
3. Orthodontic evaluation and treatment planning are provided.
4. Speech/language assessment is conducted, including videofluoroscopy and nasendoscopy, if child presents with consistent velopharyngeal insufficiency for speech.
5. Audiologic and otologic monitoring and treatment are continued as recommended by the audiologist and otolaryngologist.
6. Team visit and evaluation continue at six to twelve month intervals. This evaluation should include a pediatric screening for normal growth and development, detection and

treatment as appropriate of acute or previously undetected conditions and overall review of patient's condition prior to major procedures.

7. Pre- and post-treatment casts as required by the dental specialists and/or surgeon.

### **SIXTH YEAR (60 – 72 Months)**

1. Speech and language assessment is provided, including videofluoroscopy and nasendoscopy if child presents with consistent evidence of velopharyngeal insufficiency.
2. Lateral cephalogram is done with teeth in occlusion as appropriate for pre/post surgical and facial growth evaluation.
3. Each team evaluation should include a dental examination, oral hygiene and other preventive recommendations, arrangements for routine dental visits in a dental office of the family's choice. Dental providers should be recommended for preventive dental procedures, such as sealants, varnish, and restorative dentistry as necessary. Dental radiographs should be taken as necessary to evaluate and assist in preparation for alveolar bone grafting.
4. Maxillary and mandibular study cast(s) may be taken when all primary teeth have fully erupted. This may be enhanced by appropriate facial and intraoral photographic records.
5. Audiologic and otologic monitoring and treatment are continued as recommended by the audiologist and otolaryngologist.
6. Attention is given to documentation and maintenance of all examinations in retrievable form, preferably electronic, for each patient for appropriate and indefinite storage after patient is discharged or is lost to follow-up.
7. Team visit and evaluation continue at six to twelve month intervals. This evaluation should include a pediatric screening for normal growth and development, detection and treatment as appropriate of acute or previously undetected conditions and overall review of patient's condition prior to major procedures.

### **EARLY SCHOOL AGE (6 - 10 years)**

1. Initial treatment has been completed (basic surgical, dental, pediatric, speech and hearing problems modified or eliminated).
2. Each team evaluation should include a dental examination, oral hygiene and other preventive recommendations, arrangements for routine dental visits in a CMS approved dental office of the family's choice. Dental providers should be recommended for preventive dental procedures, such as sealants and restorative dentistry as necessary.

Dental radiographs should be taken as necessary to evaluate and assist in preparation for alveolar bone grafting.

3. When indicated orthodontic therapy is provided in preparation for reconstruction of anterior maxillary alveolar defect.
4. Anterior maxillary alveolar is reconstructed if feasible.
5. Screening for learning problems is provided.

### **EARLY ADOLESCENCE TO ADULTHOOD (11 - 21 Years)**

1. Treatment services may include lip revisions, rhinoplasties, alveoloplasties, bone grafts, otologic care, audiologic routine assessments, speech evaluations and therapy as indicated by the team; dental care, including orthodontic treatment with additional study casts at ages 10 and 15, orthognathic surgery and prosthetic and restorative dental care.
2. Dentistry - Each team evaluation should include a dental examination, oral hygiene and other preventive recommendations, arrangements for routine dental visits in a CMS approved dental office of the family's choice. Dental providers should be recommended for preventive dental procedures, such as sealants, restorative dentistry as necessary and esthetic dental considerations. Dental radiographs should be taken as recommended by the dental specialists to evaluate the need and timing for alveolar bone grafting. Assistance should be provided for the management of malocclusions, replacement of congenitally missing teeth and periodontal health.
3. Screening for adjustment problems and individual counseling is to be provided, as recommended by the social worker, psychologist, or psychiatrist.
4. Orthodontist should initiate comprehensive orthodontic diagnosis and treatment planning.

## CHILDREN'S MEDICAL SERVICES CLEFT LIP/PALATE CLINIC DATA REPORT

Data for 12 month period  
from \_\_\_\_\_ to \_\_\_\_\_

Number of clinics conducted during this reporting period: \_\_\_\_\_

Number of new referrals during this reporting period: \_\_\_\_\_

Average number of patients **scheduled** per clinic: CMS \_\_\_\_\_ Private (PVT) \_\_\_\_\_

No. of patients <b>seen</b> in clinic during this period:	<u>Newborns</u>	<u>Other New Pts</u>	<u>Return Pts</u>
	CMS _____	CMS _____	CMS _____
	PVT _____	PVT _____	PVT _____

### Diagnostic Data (CMS and Private Patients)

	Total No.	No. New this Reporting Period
<b>Cleft Lip and Palate Patients:</b>		
Unilateral _____	_____	_____
Bilateral _____	_____	_____
<b>Cleft Lip Patients:</b>		
Unilateral _____	_____	_____
Bilateral _____	_____	_____
<b>Cleft Palate Patients:</b>		
Incomplete _____	_____	_____
Complete _____	_____	_____
<b>Other</b>		
Specify condition		
_____	_____	_____
_____	_____	_____
_____	_____	_____
	<b>TOTAL PATIENTS</b>	<b>TOTAL NEW PATIENTS</b>
	_____	_____

No. of Studied Performed: X-Ray speech studies \_\_\_\_\_ Nasendoscopies \_\_\_\_\_

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**CHILDREN'S MEDICAL SERVICES  
CLEFT LIP/PALATE CLINIC  
DATA REPORT**

**Surgical Data**

Procedures performed during this reporting period, **per surgeon**:

Name of Surgeon	_____	_____	_____	_____
Cleft lip – Primary repair	_____	_____	_____	_____
Cleft lip – Revisions	_____	_____	_____	_____
Cleft palate – Primary Repair	_____	_____	_____	_____
Cleft palate – Revisions	_____	_____	_____	_____
Specify procedure:				
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
Other:				
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
Alveolar bone grafts	_____	_____	_____	_____
Pharyngeal flaps	_____	_____	_____	_____
Rhinoplasties	_____	_____	_____	_____
Other – please specify				
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
TOTAL PROCEDURES	_____	_____	_____	_____

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