



# **CRANIOFACIAL CENTERS STANDARDS**

**2014**

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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 (FCPA) 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 a sufficient number 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; 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 Florida Statute 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 2010, the Centers for Disease Control and Prevention (CDC) estimated that each year 2,651 babies in the United States are born with a cleft palate and 4,437 babies are born with a cleft lip with or without a cleft palate. 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 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 also 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 may 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 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**

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/ palate and/or craniofacial anomalies.

## **V. APPROVAL PROCESS FOR NEW CMS CRANIOFACIAL CENTERS**

- A. The CMS Craniofacial Center Approval Process is not a licensure process, but rather a quality assurance process to ensure that participating CMS craniofacial centers meet established minimum standards deemed necessary for the provision of quality services to children with special health care needs.
- B. Craniofacial centers will be designated on the basis of statewide needs, to address regions with a patient population that does not overlap or draw significantly from an existing center.
- C. 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 center's compliance with these Standards.
- D. The review team will report their findings and recommendations to the CMS Deputy Secretary.
- E. To assure timely approval of craniofacial center applications, the process must be completed within ninety (90) days of the completed application being received. An application is considered complete when the report of the on-site review of the center is received by the CMS Central Office.
- F. The CMS Deputy Secretary will make the final approval status determination.
- G. The Hospital Administrator and 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 center.

## **VI. CMS CRANIOFACIAL CENTER STANDARDS**

### **A. GENERAL**

- 1. To address the comprehensive needs of the patients and their families, the core members of a CMS Craniofacial Clinic team must include a program coordinator, pediatrician, surgeon (as defined in section VI.B.5.c. of this document), neurosurgeon, orthodontist, speech-language pathologist, audiologist, pediatric dentist, otolaryngologist, oral and maxillofacial surgeon, pediatric psychologist, nurse care coordinator, social worker, and a geneticist or genetic counselor.

The team must also include a feeding specialist and parent advocate. Although these two team members have been identified as providing crucial functionality to a craniofacial team, it is not necessary for one person to fulfill each separate job category. A team should ensure that all essential team functions are adequately being provided to the patients.

2. The CMS Craniofacial Centers have responsibility within the CMS system of care for providing interdisciplinary evaluations of children with complex craniofacial conditions and performing complex diagnostic and surgical procedures. In addition, children with cleft lip and/or palate from the local service area will be evaluated and treated at the center. The Center Team will coordinate the overall plan of care and assist with arranging the delivery of care at the local level whenever possible.
3. 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.
4. To ensure professional expertise and high quality care, there shall be at least 50 CMS and/or private patients with a craniofacial anomaly and/or a cleft lip/palate within the CMS service area per year to justify maintenance of an existing interdisciplinary center or to establish a new center. As part of the minimum of 50 children seen each year, 20 new patients should be evaluated per year, with 10 of those 20 meeting the definition of complex, as defined in Section III.
5. Each Craniofacial team must annually perform no fewer than 40 primary or secondary cleft lip and/or palate repairs, with at least one surgeon performing no fewer than 20 of the required 40. Each team must annually perform a minimum of 10 intracranial surgical procedures.
6. Representation from each core member specialty, as well as any other relevant providers will attend all scheduled Craniofacial Center Clinics, examine all patients, and document their findings and recommendations. The team will review the findings and recommendations with the parents.
7. A primary care physician should be identified for each child. The team should communicate with the primary care physician by submission of the Center's reports in a timely manner, and by FAX or phone for acute or immediate concerns. In addition, the patient's community specialists (e.g. orthodontics and timing of orthognathic surgery) should receive communication from the Program Coordinator to assure an organized treatment plan.
8. All team members will make efforts to inform other specialists in the community of the availability of the CMS Craniofacial Center Clinics for every child with a cleft lip, cleft palate, or craniofacial anomaly.
9. All team members are encouraged to participate in related continuing education annually to maintain competence and to be active in their respective professional organizations.

10. Participation in FCPA is encouraged.
11. It is recommended that teams develop and maintain programs that enhance mentorship and orientation opportunities for new team members.
12. Maintain comprehensive records on each patient, including histories, physical exam diagnoses, reports of evaluations, treatment plans, reports of treatment, and supporting documentation such as photographs, radiographs, dental models, and speech recordings.
13. In addition to all the requirements of the Craniofacial Teams outlined in these Standards, the Craniofacial Teams must also meet all requirements of the Cleft Lip/Cleft Palate Teams, as outlined in the *Cleft Palate Clinic Standards, 2013*.

## B. PROFESSIONAL LICENSING, CERTIFICATION AND REQUIREMENTS

1. 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.
2. Physicians 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.
3. Other Healthcare Providers are fully licensed and/or certified in their specialty area.
4. Where required, as stated in VI.B.5.a-s, training and fellowships may be commensurate with experience.
5. Following are the requirements for each specialist and the services to be provided:
  - a. **Program Coordinator** – should have experience involving children with cleft lip/palate or other craniofacial anomalies. The coordinator often is the first contact for patients prior to their application to the CMS program. This individual is responsible for:
    - 1) Monitoring each patient's care plan to assure that all recommended services have been obtained or scheduled.
    - 2) Providing educational and emotional support to parents and children as well as ensuring the family's understanding of care need.
    - 3) Referring families to support services and resources, including books, pamphlets and bottles, through organizations such as the FCPA family network.

- 4) Promoting community awareness of available services for children with cleft lip/palate or craniofacial anomalies.
  - 5) Maintaining communication with area hospitals regarding newborns with cleft lip, cleft palate or craniofacial anomalies, providing hospital staff with information regarding services and resources such as free books, pamphlets and bottles available through CMS and other organizations, such as the FCPA.
  - 6) Involvement in registering patients in the statewide registry
- b. **Pediatrician** – must be board certified in Pediatrics with experience in child development, 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 understanding of the child's health needs.
  - 2) Work with the parents and the team to ensure that all children seen by the team receive routine well child care.
  - 3) Assure timely referral of all children to a CMS Craniofacial Center, when appropriate, for comprehensive evaluation and treatment recommendations.
  - 4) Communicate with the team of providers about acute and chronic health concerns relative to the patient's condition; this includes medical, developmental, psychological and emotional needs.
  - 5) Refer to appropriate specialists as needed.
  - 6) Assess each patient's treatment progress at each clinic visit.
  - 7) Monitor each patient's overall growth and development and treat as needed.
  - 8) Gather, document, and record data at each examination.
- c. **Surgeon** – must be fellowship trained in Craniofacial Surgery and board certified, or actively pursuing board certification in General Plastic Surgery, Otolaryngology, Facial Plastic Surgery, or Oral-Maxillofacial Surgery. The Surgeon should have a minimum of two years experience in pediatric surgical (re)habilitation of craniofacial deformities and have active hospital privileges to perform the surgical procedures involved in the management of those conditions. 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) Jointly coordinate all surgical specialties with the comprehensive treatment plan and in consultation with the interdisciplinary team to facilitate optimum outcome for each patient.
  - 4) Provide surgical management for major craniofacial deformities and for cleft lip, cleft palate, rhinoplasty, velopharyngeal insufficiency, and alveolar bone grafting.
- d. **Neurosurgeon** – must be board certified as a neurosurgeon with a minimum of two years experience in pediatric neurosurgery and have familiarity with craniofacial surgery.
- e. **Orthodontist** – must be board certified or actively pursuing board certification as an orthodontist, with a minimum of two years experience in treating children with cleft lip and palate. 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 and to monitor the progress of this treatment at scheduled clinics. The team orthodontist will evaluate findings and recommend orthodontic and/or pediatric or general dental care, which may include:
- 1) Orthopedic manipulation of palatal segments and nasal cartilage prior to lip closure.
  - 2) Orthopedic manipulation of palatal segments prior to alveolar bone graft.
  - 3) Retention support of palatal segments following lip closure.
  - 4) Feeding plates in large open palatal clefts.
  - 5) Correction of cross-bites as needed in the primary, mixed and permanent dentitions to encourage unimpeded natural, lateral and sagittal (forward) palatal/alveolar growth and the development of normal nasal respiration.
  - 6) Alignment of teeth in the mixed and/or permanent dentition to provide good functional and aesthetic relationships to accommodate facial growth potential and provide adequate lip support.

- 7) Creation of proper spacing where teeth are missing to allow appropriate prosthetic replacement or dental implantation.
  - 8) Guidance and advice to surgeons regarding the aesthetic contour of the lips and nasomaxillary complex.
  - 9) Pre-surgical support and radiographs (i.e., orthodontic treatment in preparation for orthognathic surgery and post-surgical tooth movement).
- f. **Speech-Language Pathologist** – must be licensed as such 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. The speech-language pathologist must also be American Speech and Hearing Association (ASHA) certified. 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/or 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/or videofluoroscopy.
  - 3) Based on perceptual and instrumental measures, including videofluoroscopy and/or nasendoscopy, the speech-language pathologist shall assist in making a recommendation for surgical, prosthetic, or behavioral treatment.
  - 4) Maintain serial records of all patient data.

- 5) Communicate with the speech-language pathologist who is working with a child in the local community and monitor the child's progress of this treatment at scheduled clinic visits.
- g. **Audiologist** – must be licensed as such and have a minimum of two years experience in the evaluation, diagnosis and treatment of audiological problems associated with cleft lip, cleft palate, craniofacial anomalies, and VPI in infants and children. The audiologist will provide assessment of hearing sensitivity, which includes:
- 1) 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 and/or bone 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) Audiological recommendations for follow-up based on auditory testing that are threshold seeking rather than pass/fail. Recommendations may include otological treatment, auditory training, hearing-aid evaluation/fitting (amplification and FM system), or special tests, such as auditory brainstem testing or otoacoustic emissions.
  - 3) Recommendation of appropriate monitoring of pressure-equalizing tube patency and middle-ear function.
  - 4) Maintain serial audiograms on all patients.
- h. **Pediatric Dentist** – must be board certified or actively pursuing board certification as a pediatric dentist, with a minimum of two years documented experience in pediatric dentistry to oversee and coordinate all aspects of oral health care for the patient. The dentist's responsibilities include:
- 1) Orthopedic manipulation of palatal segments and nasal cartilage prior to lip closure.
  - 2) Providing oral health care throughout the patient's developmental years starting at birth.
  - 3) Providing information about prevention of caries and standards of dental care.
  - 4) Assuring patients have a local pediatric dental home if the team dentist is not the treating dentist.

- k. **Otolaryngologist** – must be board certified in Otolaryngology or actively pursuing board certification and have experience managing otitis media and eustachian tube dysfunction in children with cleft palate. The otolaryngologist's responsibilities include:
- 1) Assessing each child's long term otologic care needs.
  - 2) Recommending tympanostomy tubes and monitoring outcomes and complications.
  - 3) Evaluating children referred with conductive and sensorineural hearing impairments.
- l. **Oral and Maxillofacial Surgeon** – must be board certified, or actively pursuing board certification, by the American Board of Oral and Maxillofacial Surgery, and have 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. It is preferred that the oral and maxillofacial surgeon have fellowship training in cleft lip and palate, pediatric maxillofacial and craniomaxillofacial surgery. The oral and maxillofacial surgeon's responsibilities include:
- 1) Working with treatment team in maximizing results of orthognathic surgical procedures in coordination with orthodontic care.
  - 2) Performing bone grafting.
  - 3) Evaluating maxillary and mandibular spatial relationships.
  - 4) Performing dental implants.
- m. **Pediatric Psychologist or Child Clinical Psychologist** – must be licensed as such and have a minimum of two years experience in the assessment of behavioral and emotional issues related to facial disfigurement and other disabilities. The psychologist's responsibilities include:
- 1) Assessment of the psychological and social environment, as well as the impact of the condition on patients and families.
  - 2) Provision of or referral for psychosocial services to patients and their families.
  - 3) Development and maintenance of liaisons with appropriate resources and community agencies to meet goals of the care plan.

- n. **Nurse Care Coordinator** – must be a registered nurse, licensed in the State of Florida and have experience in the care and management of children with cleft lip, cleft palate and other craniofacial anomalies. The nurse care coordinator’s responsibilities include:
- 1) Ensuring that patient records are prepared for the team staffing.
  - 2) Providing current updates on each patient’s treatment status to the team specialists as needed.
  - 3) Oversight of the patient flow through the team’s evaluation to ensure each patient has been seen by the appropriate specialists.
  - 4) Assisting team members with patient examination/evaluation, as necessary.
  - 5) Serving as liaison between the team and the family and as the patient’s advocate, as necessary.
  - 6) Ensuring the family receives instruction regarding appropriate feeding techniques, care of appliances, pre- and postoperative care concerns, etc., as indicated.
  - 7) Be available to the family as new issues in the patient’s care arise.
  - 8) Ensuring that the patient is referred to Children’s Medical Services and assists with enrollment and re-enrollment as needed.
  - 9) Ensuring that appropriate referrals are made for genetic counseling, nutrition counseling, early intervention, and speech therapy by working with Early Steps, the school system, and other agencies, as indicated.
  - 10) Ensuring post-clinic follow through on treatment recommendations.
  - 11) Ensuring that post-clinic counseling is provided to all patients and families.
  - 12) Ensuring that the patient and family receive educational brochures appropriate for the patient’s stage of development and treatment and information regarding resources available through organizations such as the Florida Cleft Palate Craniofacial Association (FCPA).
  - 13) Ensuring that parent support group information is provided to the family as indicated, including information on the Florida Cleft and Craniofacial Network (FCCN) website: [www.cleftnetwork.com](http://www.cleftnetwork.com).

- 14) Ensuring that care plan goals are met by coordinating arrangements for care with the CMS nurse care coordinator, assisting families with arrangements for care, and supporting the child's medical home.
- 15) Making sure home/ school/ hospital visits are scheduled as necessary to ensure compliance, provide emotional support, and provide appropriate parent training, as available.
- 16) Ensuring coordination of community agency services and resources by serving as a liaison between the Team and community providers as appropriate to meet family needs.
- 17) Monitoring the treatment plan and the child's progress against established clinical guidelines. The nurse care coordinator will also 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.

The above Nurse Care Coordinator responsibilities may be delegated as appropriate.

- o. **Social Worker** – must be a licensed clinical social worker, preferably with a Masters in Social Work (MSW) and have 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's responsibilities include:
  - 1) Assessing patient and family resources, needs, and understanding of the child's medical and developmental needs.
  - 2) Providing information about family support.
  - 3) Notifying team if education needs are identified.
  - 4) Encouraging/supporting family and child in asking questions.
  - 5) Making, or arranging for, home visits, as available.
  - 6) Referring patient and family to support services and resources.
  - 7) Supporting the family in obtaining pediatric dental care for their child.
  - 8) Supporting the family in understanding that their child's orthodontist is required to obtain authorization from insurance before beginning treatment.

- p. **Geneticist/Genetic Counselor** – must be 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.
- q. **Feeding Specialist** – must be 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 or other craniofacial conditions. The feeding specialist's responsibilities include assisting and educating medical personnel and families regarding feeding issues and techniques for babies with cleft lip/palate.
- r. **Parent Advocate and Educator** – should have a minimum of two years experience involving children with cleft lip/palate and other craniofacial anomalies. The parent advocate and educator will be enrolled as a CMS volunteer and complete the necessary confidentiality requirements. The parent advocate and educator's responsibilities include:
  - 1) Meeting with patients and parents to provide support and resources from a parent's perspective.
  - 2) Assisting professional staff in clinic activities to promote family-centered care.
- s. **Additional specialists** – may be required for consultation and treatment to provide proper care for patients with cleft lip/palate and craniofacial disorders. These specialists may be a part of the core team composition for a given patient or patients. Additional board certified, actively pursuing board certification or licensed specialists include, but are not limited to:
  - 1) **Ophthalmologist** – must be board certified in Ophthalmology with a minimum of two years experience in pediatric issues associated with specific craniofacial malformations.
  - 2) **Pediatric Psychiatrist** – who is licensed in the State of Florida and board certified in Psychiatry 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 psychiatrist's responsibilities include:
    - a. Assessment of the psychological and social environment, as well as the impact of the condition on patients and families and provide written psychological evaluations.
    - b. Provision of or referral for psychosocial and psychiatric 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.
- 3) **Radiologist** – board certified by the American Board of Radiology or actively pursuing board certification, with a minimum of two years experience in imaging children with craniofacial disorders.
  - 4) **Prosthodontist** – licensed, with a minimum of two years experience in pediatric intra-oral prostheses such as speech bulbs, palatal lifts and fistulae obturators.
  - 5) **Pediatric Anesthesiologist** – board certified in Anesthesiology and board certified in the Subspecialty of Pediatric Anesthesiology, 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 in Pediatrics and board certified in the Subspecialty of Pediatric Pulmonology 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 experience in preparing children for procedures and treatments related to the care of children with clefts and/or craniofacial anomalies.
  - 9) **General Dentist** – with a minimum of two years experience in care of children and adolescents with cleft and craniofacial needs.

#### C. OFFICE AND CLINIC FACILITIES

1. Craniofacial centers shall encompass an institution or closely affiliated group of facilities providing care for complex craniofacial problems.
2. The craniofacial center clinic area must include a conference room for presenting and discussing cases.

**VII. MONITORING AND QUALITY ASSURANCE**

- A. Each CMS craniofacial center 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 every 12 months by each center.
- 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 numbers that brings the center's numbers 10% below the current CMS volume standards; or
  - 3. Significant change in the craniofacial center team composition.

**VIII. RECORDS**

- A. Patient records will include an on-going summary of procedures/tests/surgeries related to the craniofacial or cleft condition that the child has had performed.
- 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 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 center 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:

#### **PRENATALLY**

Parents may learn from prenatal ultrasound studies that their infant has a cleft lip, cleft palate, or other craniofacial difference. It is customary for the obstetrician to refer the prospective parents to the Craniofacial Center for information before the baby is born.

1. All parents with prenatal diagnoses of clefts or craniofacial conditions should receive support and counseling regarding initial and later treatment needs, feeding techniques that may be needed, and resources that can assist them.
2. Usually at least two of the following members of the center team talk with the family: nurse coordinator, plastic surgeon, or pediatrician. It is beneficial, for these members to also evaluate the infant after birth and provide on-going support to the parents.
3. Family should be given written brochures about the team, about the potential care needs, and be given contacts for the FCCN and the ACPA.
4. When families request talking with all team members, they may come to a team clinic. Alternatively, individual appointments can be arranged. When families want to talk with a family of a child with a similar facial difference, this can be arranged by one of the team members.

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

All newborns with a cleft lip, cleft palate, or other craniofacial differences should be referred to a cleft palate or craniofacial center. Early evaluation should be performed. Team members present shall be determined on an individual basis based on the child's condition. Standard basic information should be recorded and diagnostic records obtained, including details of the type of congenital abnormality.

1. All parents of newborns should receive support and counseling regarding initial and later treatment needs as indicated by the cleft palate team recommendations. The family should be given appropriate feeding supplies and written materials related to the anomaly and have contact with a team member prior to hospital discharge. Families should be given a name and number for a contact person on the team.
2. 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.

3. CMS contact should be made with the family prior to hospital discharge whenever possible.
4. All newborns should receive a hearing evaluation prior to hospital discharge at the birth facility or within 1 month of discharge.
5. Parents should be given phone numbers and web-site addresses of the Florida Cleft and Craniofacial Network (FCCN): [www.cleftnetwork.com](http://www.cleftnetwork.com), the Regional Coordinator, and other organizations specific to the newborn's diagnosis.
6. Cleft Palate Clinic evaluation findings and recommendations for treatment should be communicated to the referring professional with notations as to whether future cleft palate team evaluations are necessary.

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

1. The team coordinator or nurse should contact the family within two weeks of hospital discharge to follow up on feeding, questions, assessment of nutritional intake and weight gain and overall status.
2. A feeding/swallowing evaluation by a team member should be performed and appropriate referrals for further evaluation, such as a swallow study and/or appliances needed for feeding should be made, 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. Repair of cleft lip should be initiated. 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 as soon as possible, followed by genetic counseling for the family.
8. Otologic and audiologic examination should occur 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. As medically indicated, 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. There should be a continuation of 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 pre-language stimulation training for parents and patients.
6. Another team evaluation is required at 18 months of age. The status of oral facial development, palate, and velopharyngeal function should be recorded. 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 Early Steps may be needed if developmental concerns are identified.
8. Patients with submucous clefts should be monitored closely and their palates repaired only if there is evidence of feeding, otologic, or speech problems.
9. Genetics representative will review past diagnoses, explore for new information, clarify information with family if needed, and refer for additional evaluations if indicated.

### **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. The status of any occlusion and velopharyngeal function should be recorded.
6. Referral to Early Steps may be needed if developmental concerns are identified.
7. Genetics representative will review past diagnoses, explore for new information, clarify information with family if needed, and refer for additional evaluations if indicated.

### **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 and instruction in oral hygiene accompanied by other preventive recommendations. Routine dental visits in a dental office of the family's choice can occur with the team's coordination.
5. Prosthetic obturation and orthodontic manipulation are to be provided if recommended by the orthodontist.
6. There should be complete team evaluations 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. If recommended by the team, there should be a referral to educational settings such as Early Steps Program or Florida Diagnostic Learning Resource System (FDLRS).

8. Nasendoscopy and videofluoroscopy are provided as recommended by the speech pathologist, if developmental level allows.
9. Genetics representative will review past diagnoses, explore for new information, clarify information with family if needed, and refer for additional evaluations if indicated.

#### **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.
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 and instructions in oral hygiene accompanied by other preventive recommendations. Routine dental visits in a dental office of the family's choice can occur with the team's coordination to ensure ongoing routine dental care.
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.
8. Genetics representative will review past diagnoses, explore for new information, clarify information with family if needed, and refer for additional evaluations if indicated.

#### **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, continues.
3. Orthodontic evaluation and treatment planning are provided.

4. If a child presents with a consistent velopharyngeal insufficiency for speech, a speech/language assessment is conducted, including videofluoroscopy and nasendoscopy.
5. Audiologic and otologic monitoring and treatment are continued as recommended by the audiologist and otolaryngologist.
6. Team visits and evaluations should 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 should occur as necessary.
8. Genetics representative will review past diagnoses, explore for new information, clarify information with family if needed, and refer for additional evaluations, if indicated.

#### **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 can be made 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. Team visits and evaluations 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. Genetics representative will review past diagnoses, explore for new information, clarify information with family if needed, and refer for additional evaluations if indicated.

### **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. 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 alveolus is reconstructed, if feasible.
5. Screening for learning problems is provided.
6. Genetics representative will review past diagnoses, explore for new information, clarify information with family if needed, and refer for additional evaluations, if indicated.

### **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.
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 aesthetic 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. Dental care may include orthodontic treatment with additional study casts at ages 10 and 15, orthognathic surgery and prosthetic and restorative dental care.
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.

5. Genetics representative will clarify information with patient and family and refer for additional evaluations and counseling if indicated. Personal genetic counseling should be offered.
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.

**CHILDREN'S MEDICAL SERVICES  
CRANIOFACIAL CENTER  
DATA REPORT**

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

Number of new patients with a complex diagnosis this reporting period: \_\_\_\_\_

Number of new patients this reporting period: \_\_\_\_\_

Number of returning patients this reporting period: \_\_\_\_\_

Number of total patients this reporting period: \_\_\_\_\_

**Surgical Data**

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

Name of Surgeon	_____	_____	_____	_____
Cleft lip – Primary repair	_____	_____	_____	_____
Cleft lip – Secondary Repair	_____	_____	_____	_____
Cleft palate –Primary Repair	_____	_____	_____	_____
Cleft palate –Secondary Repair	_____	_____	_____	_____
Alveolar bone grafts	_____	_____	_____	_____
Pharyngeal flaps	_____	_____	_____	_____
Rhinoplasties	_____	_____	_____	_____
Osteotomies	_____	_____	_____	_____
Distraction Osteogenesis	_____	_____	_____	_____
Orthognathic Surgery	_____	_____	_____	_____
Intracranial Surgical Procedures	_____	_____	_____	_____
Other – please specify:	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
<b>TOTAL PROCEDURES</b>	_____	_____	_____	_____

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**CHILDREN'S MEDICAL SERVICES  
CRANIOFACIAL CENTER DATA REPORT  
Diagnostic Data (CMS and Private Patients)**

<b># of Cleft Lip Patients:</b>	<b># of Cleft Palate Patients:</b>	<b># of Cleft Lip and Palate</b>
<b>Patients:</b>		
Unilateral _____	Incomplete _____	Unilateral _____
Bilateral _____	Complete _____	Bilateral _____

**Craniofacial anomalies involving the face, orbit(s), and/or cranium:**

Specify anomaly	Total #	# new this reporting period
_____	_____	_____
_____	_____	_____
_____	_____	_____

**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:**

Specify anomaly	Total #	# new this reporting period
_____	_____	_____
_____	_____	_____
_____	_____	_____

**Syndromal anomalies with cleft lip/palate/other craniofacial anomalies:**

Specify anomaly	Total #	# new this reporting period
_____	_____	_____
_____	_____	_____

**Conditions related to craniomaxillofacial, craniomandibulofacial, and acquired craniofacial deformities, as well as craniofacial clefts of the face, other than cleft lip:**

Specify anomaly	Total #	# new this reporting period
_____	_____	_____
_____	_____	_____

**Other:**

Specify anomaly	Total #	# new this reporting period
_____	_____	_____
_____	_____	_____

<b>TOTAL PATIENTS</b>	<b>TOTAL NEW PATIENTS</b>
_____	_____

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

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