



Benefit Design for Children under the Affordable Care Act

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Introduction and Executive Summary

There are two principal sections of the Patient Protection and Affordable Care Act (Affordable Care Act or ACA) that specify that certain health care benefits be provided to both adults and children:

(1) Section 1001, adding a new section 2713 to the Public Health Service (PHS) Act, provides that all insurance plans must cover preventive services and immunizations recommended by specified health agencies without and cost-sharing—that is, without any deductibles or co-pays.

(2) Section 1201, adding a new section 2707 to the PHS Act, requires that new health insurance plans for individuals and small groups, including those to be offered on the new state exchanges must cover specified “essential health benefits,” to be defined in detail this fall by the Secretary of Health and Human Services. Currently a draft is being developed with public input by the Institute of Medicine of the National Academy of Sciences.

At this point, defining these insurance benefits has been (in the case of category 1) or is being done (category 2) at the federal level. There will be state-level decisions to be made in the future, based on the federal framework. Groups in New Mexico should closely follow the development of the rules in category 2 because these will define what constitute essential benefits for insurance plans on the exchange. Ultimately, after adoption by the Secretary, if groups in New Mexico are not satisfied with the scope of the required benefits, the exchange could require additional benefits, but the state would have to pay for their costs.

Discussion

1. Preventive Services and Immunizations

Section 1001, section 2713 of the PHS Act, states that insurance plans offering coverage for infants, children, and adolescents, “shall, at a minimum, provide coverage for and shall not impose any cost sharing requirements for ... evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources and Services Administration (HRSA).” The Division of Maternal and Child Health, part of HRSA, selected the American Academy of Pediatrics to develop the latest version of the “comprehensive guidelines” to which reference is made in the ACA. The guidelines were published in 2008 and

are called: *Bright Futures: Guidelines for Health Supervision of Infants, Children, Adolescents*, 3rd edition.¹

Bright Future is a detailed comprehensive set of guidelines for health care professionals who deal with children and their families. Here is a description of the contents:

Part 1 features 10 chapters on key themes that recur in each stage of child development. Part 2 provides health supervision guidance and anticipatory guidance for the 31 recommended health supervision visits from infancy through late adolescence. Each visit:

- Starts with a context that captures the child at that age;
- Contains handy lists and tables that summarize interval history questions, parent-child and developmental observation, physical exam, medical screening, and immunizations;
- Lists five priorities that help you focus your discussions with parents and children on the most important issues for that visit; and
- Provides anticipatory guidance for each priority sample questions and discussion points help you talk to children and families.

The *Bright Futures* website (<http://brightfutures.aap.org/>) contains the details of the guidelines and lists materials that are available for study and training. The *Bright Futures* guidelines have been specified by CMS as fulfilling the Early Periodic Screening, Diagnosis and Treatment (EPSDT) services required for children enrolled in Medicaid by 42 USC Section 1896a(a)(43). EPSDT services are outlined in 42 USC Section 1905(r).² The CMS State Medicaid Manual, Section 5312.2, indicates that *Bright Futures* guidelines are appropriate for EPSDT.³

The requirement to follow the *Bright Futures* guidelines went into effect last September 23. The ACA does not require further state action with respect to these guidelines. All health insurance plans in the country—public and private—must offer the benefits specified in the guidelines with no cost sharing by the enrollees or their families. It will be up to the New Mexico Department of Insurance and the Medical Assistance Division of the state’s Human Services Department to ensure that private health care plans and Medicaid plans, respectively, offer these benefits to children and their families.

2. “Essential Benefits” Required of Health Plans in the Exchange

The ACA will allow individuals and businesses to purchase health insurance directly through state exchanges—competitive marketplaces where buyers can compare coverage of various health insurance plans offered by insurance companies. Individuals and families with incomes between 138 and 400 percent of the Federal Poverty Level will be eligible for tax credits to subsidize their purchase of an insurance plan. It has been estimated that about two-thirds of the individuals who will purchase health insurance through the exchanges will be eligible for a federal subsidy.⁴

The ACA requires that plans offered on the exchanges be “qualified health plans” (QHPs) that may vary in coverage levels but which must all meet certain standards in categories of care and certain limits on patient cost sharing. These qualified plans must all offer certain “essential health benefits” broadly described in the ACA, section 1302(b). The Secretary of HHS must develop detailed definitions of these benefits based on the scope of benefits offered by a typical employer plan, and is planning to issue definitions in the fall of 2011.

There are ten general categories of “essential health benefits” specified in section 1302(b) of the ACA: ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services including oral and vision care.

The U.S. Secretary of Labor has recently reported on her survey of the scope of benefits offered by typical employer plans across the country, which must form the basis of the definition of the “essential health benefits.”⁵

The Secretary of HHS, Kathryn Sibelius, asked the Institute of Medicine, part of the National Academy of Sciences, to conduct a detailed study and make recommendations on the criteria and methods for determining and updating the essential health benefits package. The IOM appointed a committee.⁶ Here is the committee’s summary of its responsibilities:

The committee will identify the criteria and policy foundations for determination of the essential health benefits offered by QHPs taking into account benefits as described in sections 1302(b)(1) and 1302(b)(2)(A), and the committee will assess the methods used by insurers currently to determine medical necessity and will provide guidance on the “required elements for consideration” taking into account those outlined in section 1302(b)(4)(A-G), including ensuring appropriate balance among the categories of care covered by the essential health benefits, accounting for the health care needs of diverse segments of the population, and preventing discrimination against age, disability, or expected length of life. The committee will also take into account language in 1302 on periodic review of essential health benefits, other sections of the Affordable Care Act, for example, coverage of preventive health services ([ACA section 1001, PHS] section 2713), utilization of uniform explanation of coverage documents and standardized definitions ([ACA section 1001, PHS] section 2715), and other relevant tasks found in the Affordable Care Act for the Secretary HHS. The committee will provide an opportunity for public comment on the tasks of defining and revising the essential health benefits.

The Institute of Medicine Committee has held a number of public hearings and has taken numerous submissions. The American Academy of Pediatrics’ testimony about the coverage of benefits for children is online.⁷ Here are some of the AAP representative’s remarks:

“...the health care needs of infants, children, and adolescents are sufficiently distinct from those of adults that a health care system designed for adults will not meet the needs of America’s children and should not be imposed upon them. ... Consideration

of the unique characteristics of children must and should frame all plans for the design and financing of health care services for this segment of the population. ...

“1) medically necessary services includes prevention, diagnosis, treatment, amelioration or palliation of physical, mental, behavioral, genetic or congenital conditions, injuries or disabilities and needs to be age appropriate; and 2) interventions should be evidence based but since large scale randomized controlled trials are significantly less plentiful for children than for adults, when that standard is lacking observational studies, professional standards of care, or consensus of pediatric expert opinion must serve as acceptable substitutes. ... EPSDT should serve as the standard along with *Bright Futures* recommendations.”⁸

A specific list of the basic pediatric benefits recommended by the Academy of Pediatrics is attached as Appendix 1 (page 7). The complete written statement of the Academy of Pediatrics to the Institute of Medicine is attached as Appendix 2 (page 9).

After the Institute of Medicine submits its recommendations to the Secretary of HHS, she will formulate a proposed rule defining “essential health benefits,” including the benefits specific to children, and the public will have at least 60 days to comment. After receiving and considering public comments, the Secretary will issue a final rule.

The HHS definition of “essential health benefits” will be binding on all individual and small group plans in all the states. In particular, small group and individual insurance plans offered on the exchanges must cover those benefits.

It is possible for individual state exchanges to require additional benefits. However, the state will have to pay for those additional benefits (ACA section 1311(d)(3)(B)). This is a reason that advocates should urge the Secretary to include all appropriate pediatric benefits in the definition of “essential health benefits.”

Conclusion and Opportunities for New Mexico

New Mexico Voices for Children recommends that all interested parties in New Mexico follow the development of the HHS definitions of “essential health benefits” with some care, and comment to the Secretary of HHS if the proposed definitions appear to need modification. Since these requirements will extend to all programs in the exchange, and since about two-thirds of the individuals and families using the exchange are expected to be of low- to moderate- incomes (and therefore able to receive subsidies), it will be critical to extending health equity that the plans on the exchange offer all appropriate benefits, both for adults and children.

After the definitions are adopted, interested parties will have to evaluate them and determine with the health insurance exchange in New Mexico should require insurance companies offering plans on the exchange to offer additional benefits, beyond those required by the HHS definitions. Obviously, that evaluation and determination cannot take place until the final definitions are issued, sometime this fall or winter.

Endnotes

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- 1 Found on the web at <http://brightfutures.aap.org/>.
 - 2 EPSDT broadly includes: medical screens according to a periodicity schedule, including a comprehensive health and developmental history, an unclothed physical exam, immunizations, lab tests, and health education; vision, hearing, and dental services; and the necessary treatments and services (consistent with the scope of benefits under the Medicaid Act, 42 U.S.C. 1396(d)(a)) to correct or ameliorate physical and mental illnesses.
 - 3 http://www.cms.hhs.gov/manuals/pub45/pub_45.asp.
 - 4 Georgetown Center for Children and Families.
 - 5 See, http://www.bls.gov/ncs/ebs/smb_health.htm.
 - 6 The committee's website is <http://iom.edu/Activities/HealthServices/EssentialHealthBenefits.aspx>.
 - 7 The American Academy of Pediatrics' testimony is at http://aap.org/advocacy/washing/Testimonies-Statements-Petitions/01_14_11_%20IOM_EHBCCommittee_RacineTestimony.pdf.
 - 8 See endnote 2 for scope of EPSDT services.

Appendix 1

American Academy of Pediatrics Scope of Health Care Benefits for Children from Birth Through Age 21 (2006)

(excerpt, complete list of benefits--full text at
<http://aappolicy.aappublications.org/cgi/reprint/pediatrics;117/3/979.pdf>)

MEDICAL CARE

1. Medical care including (a) health supervision with preventive care (including immunizations, hearing and vision screening, developmental surveillance, and anticipatory guidance) according to the AAP "Recommendations for Preventive Pediatric Health Care,"³ the most current version of the "Recommended Childhood and Adolescent Immunization Schedule,"⁴ *Guidelines for Health Supervision III*,⁵ and *Bright Futures: Guidelines for Health Supervision of Infants, Children, and Adolescents*⁶ and (b) diagnosis, treatment, and educational counseling of children with acute and chronic conditions, including developmental delays and disabilities, behavioral and emotional problems, and learning disorders
2. Pediatric medical subspecialty services
3. Family planning and reproductive health services
4. Pregnancy services including (a) genetic counseling and related services as needed, (b) prenatal care, (c) prenatal consultation with a pediatrician, (d) peri-natal case management, (e) care of all complications, (f) counseling and services for all pregnancy and fetal management options, and (g) care for the pregnancy of a covered dependent of a policyholder; prenatal care should include evaluation of psychologic risk factors
5. Care of all newborn infants, including (a) attendance and management at high-risk deliveries or those mandated by hospital regulations, (b) health supervision, (c) treatment of congenital anomalies and other medical and surgical conditions, (d) newborn intensive care services, (e) newborn hearing screening,⁷ (f) newborn screening for metabolic and genetic disorders, (g) a follow-up visit in the child's home or in the physician's office within 48 hours of discharge when indicated by the infant's physician, (h) lactation counseling to increase successful breastfeeding initiation and

- duration, and (i) a reasonable pediatric length of stay to allow for identification of early problems and to ensure that the family is able and prepared to care for the infant at home if the mother has to remain hospitalized because of complications⁸
6. Vision services including screening, examinations, corrective lenses, and access to pediatric ophthalmologists for diagnostic and therapeutic services
7. Audiology services including screening, evaluations, hearing aids, cochlear implants, and recommended therapy
8. Physician-directed, accurate pediatric medical information by telephone, telemedicine, e-mail, and other Internet services for established patients related to pediatric care compliant with regulations of the Health Insurance Portability and Accountability Act of 1996 (HIPAA [Pub L No. 104-191])
9. Laboratory and pathology services
10. Screening for metabolic and genetic disorders
11. Diagnostic and therapeutic radiology services, including age-appropriate sedation as needed
12. Coverage for prescription drugs determined by pediatric standards of care and not limited to labeled indications only⁹

CRITICAL CARE

13. Emergency medical and trauma care services specifically for children, including while traveling outside of the coverage network area
14. Pediatric inpatient hospital and critical care services
15. Emergent and non-emergent transfer/transport to a hospital or health facility, between health facilities, and between home and health facilities when indicated

PEDIATRIC SURGICAL CARE

16. Pediatric surgical care including comprehensive repair of congenital anatomic malformations
17. Pediatric surgical subspecialty services
18. Anesthesia services including monitored anesthesia care and appropriate pain management for acute and chronic pain management

BEHAVIORAL HEALTH SERVICES

19. Mental health services including (a) individual, group, and family therapy, (b) psycho-educational testing, (c) evaluation, (d) crisis management, (e) inpatient and day treatment, (f) residential care, and (g) pharmacotherapy; this should also include the following services: the evaluation and treatment of attention-deficit/hyperactivity disorder and other related behavioral disorders and treatment of eating disorders, learning disabilities, and related disorders^{10, 11}
20. Services for substance use disorders, including (a) screening and early intervention, (b) individual, group, and family therapy, (c) psychological testing, (d) crisis management, (e) inpatient and outpatient treatment, and (f) residential care
21. Comprehensive medical and psychological evaluation and treatment for suspected child physical, emotional, and sexual abuse and neglect in both inpatient and outpatient settings

SPECIALIZED SERVICES FOR CHILDREN WITH SPECIAL HEALTH CARE NEEDS

22. Care coordination in the pediatric medical home and comprehensive case management from other community agencies and insurers¹²
23. Intermediate or skilled nursing facility care in residential and rehabilitation settings
24. Physical, occupational, speech (including speech generation), and respiratory therapy for rehabilitation and habilitation provided in medical centers, private/public-sector offices, schools, residential settings, and the home
25. Home health care services including but not limited to physician supervision of care, therapies, private-duty nursing, and home health aides¹³
26. Nutritional evaluation and counseling services by pediatricians, dietitians, nutritionists, and other

therapists for eating disorders (including primary obesity, anorexia, and bulimia) and specific nutritional deficiencies

27. Special diets, special infant formulas, nutritional supplements, and delivery (feeding) devices for nutritional support and disease-specific metabolic needs¹⁴
28. Rental or purchase, maintenance, and service of durable medical equipment (see Appendix)
29. Disposable medical equipment (see Appendix)
30. Respite services for caregivers of children with special health care needs
31. Palliative and hospice care for children with terminal illnesses

PEDIATRIC ORAL HEALTH

32. Preventive and restorative pediatric dental care including fluoride varnish, sealants, and oral surgery, including moderate sedation and general anesthesia
33. Functional orthodontia

APPENDIX

Examples of Durable Medical Equipment Required in Pediatrics

1. Equipment necessary to administer aerosolized medications and monitor their effects (nebulizer, spacers for inhalers, peak flow meters)
2. Glucometers, insulin pumps
3. Breast pumps
4. Prostheses/braces
5. Electrical and other types of ventilators
6. Cardiorespiratory monitors
7. Oxygen concentrators
8. Pulse oximeters
9. Wheelchairs
10. Hearing aids

Examples of Disposable Medical Equipment

1. Diapers for physically compromised patients
2. Urine catheters
3. Feeding supplies (tubing, pumps, etc)
4. Intravenous line tubing and intravenous catheters
5. Ostomy supplies
6. Test strips, lancets, and other diabetic supplies

Appendix 2

Institute of Medicine (IOM)
Essential Health Care Benefits
Public Comment Form for Questions
American Academy of Pediatrics' Responses

1. What is your interpretation of the word “essential” in the context of an essential health benefit package?

In addition to the Bright Futures guidelines highlighted below, essential health benefits should include services that are age-appropriate and cover acute care services in both the inpatient and outpatient settings, inpatient and chronic care services, including developmental, pregnancy-related and other reproductive health, newborn care, substance abuse disorders, emergency services, facilitative, habilitative, and rehabilitative services and devices, including hearing aids and speech services, palliative, home health and hospice care services, prescription drugs, vision care services, and oral health services reflecting the scope of benefits recommended by the American Academy of Pediatrics (<http://aappolicy.aappublications.org/cgi/reprint/pediatrics;117/3/979.pdf>) and the National Business Group on Health (Investing in Maternal and Child Health: An Employer's Tool Kit. Washington, DC: 2007.) In fact, essential benefits for children are not just preventive services but all services that promote optimal growth and development.

Section 1302 of the Affordable Care Act delineates essential health benefits, including explicit reference to pediatric services (including oral and vision care). This section could hold the key to guaranteeing that children have access to a structured and stable set of clinically appropriate benefits. However, children represent a population with unique health care needs, often referred to as the “4 Ds”: development, dependency, differential epidemiology, and demographics. It is necessary to consider these child-specific needs in defining “essential” in terms of a health insurance benefit package. Children experience rapid developmental changes during infancy, childhood, and adolescence. These changes need to be taken into account in designing an “essential” health benefit package because the needs of children are not static throughout their life; rather they are dynamic and are directly associated with those services, interventions, and procedures needed to maximize their health and well-being during the stages of their life. It is essential to recognize that a critical contributor to optimal adult health is the provision of social, health, and mental health coordinated care for children.

Also, the implementation of the Patient Protection and Affordable Care Act (PPACA) created Section 2713 of the Public Health Services Act, Coverage of Preventive Health Services. This vital provision requires new health plans to cover, with no cost-sharing, “with respect to infants, children, and adolescents, evidence-informed preventive care and screenings provided for in the comprehensive guidelines supported by the Health Resources and Services Administration, “meaning the services outlined in *Bright Futures: Guidelines for Health Supervision of Infants, Children and Adolescents.*”

Bright Futures was updated most recently in 2008 and offers **the** only existing comprehensive clinical guidelines for pediatric preventive health care. Development of the current third edition was led by the AAP in partnership with the Health Resources and Services Administration's Maternal and Child Health Bureau. Its development was an evidence-informed, active

collaboration with a wide range of organizations, including those representing other physicians, nurses, insurance companies, mental health providers, dentists, school health, families, and consumer groups, and many others. Representatives from the Centers for Disease Control and Prevention, Substance Abuse and Mental Health Services Administration, and the Indian Health Service also contributed to the development of these national guidelines.

Perhaps the best-known aspect of *Bright Futures* is the schedule of “well-child visits,” also known as the “periodicity schedule”. Guidance for these visits is divided between Health Supervision and Anticipatory Guidance. Health Supervision covers medical history, observation of the parent-child interaction, surveillance of development, physical examination and immunizations. Anticipatory Guidance comprises the array of topics in which pediatricians are expected to give parents guidance to prevent illness and promote health. These topics help parents address nutrition, physical activity, behavioral issues, discipline, safety, and injury prevention and much more.

2. *How is medical necessity defined by insurers and then applied in coverage determinations? What are the advantages/disadvantages of current definitions and approaches?*

Medical necessity as defined in current Medicare language continues to be a major influence in medical necessity definitions deployed by private health plans. Most health plans invoke the term in the coverage of benefit information; however, it seems to be defined mostly by its own words. With respect to the clinician or patient, the term is usually used only when services are reviewed for denial. It may be because of this that services to which the term applies are generally only high cost. By default then, other provided services are medically necessary. Pediatricians often report that all manner of laboratory studies can be ordered without question and without correlation to a diagnosis and then reimbursed as presumed medically necessary. While Medicare recently introduced safeguards to prevent this, those guidelines are inconsistently applied.

The claimed advantage to application of the term medical necessity is that it holds the promise of creating some standardization to diagnosis, evaluation and treatment. Advocates claim that medical necessity is being based on sound evidence or that it is at least evidence informed. But reliance on adult-oriented disease management and definitions of evidence do not serve to identify or describe evidence relating to health care for children in whom growth, development and greatly extended time horizons need to be considered.

Based on this, there are some additional special considerations the American Academy of Pediatrics (the Academy) wishes to highlight. First, large-scale clinical trials, and in turn evidence-based medicine, are not as extensive in pediatrics as in adult medicine; therefore, in considering specialized contracts for urgent care appeals and for experimental and investigational treatments, HHS and/or DOL should ensure that any organization sanctioned to conduct benefit and/or coverage reviews are equipped with appropriate knowledge of pediatric medical necessity model contract knowledge and include pediatric-specific medical expertise. Bright Futures guidelines (which are referred to in section 2713 of the Affordable Care Act as the appropriate preventive services package for no co-pay (note: if the patient stops paying a co-pay or cost share for a preventive service, the health plan should pay that amount in its payment to physicians – in short, make the physician “whole”) coverage in non-grandfathered health plans) state: “For many interventions that are commonly performed in child or adolescent care, no, or few, properly constructed studies have been done that link the intervention with intended health outcomes. Absent evidence does not demonstrate a lack of usefulness, however. The lack of evidence of

effectiveness most often simply reflects the lack of study.” Second, while the National Association of Insurance Commissioner’s Uniform Health Carrier External Review Model Act (the Model Act) Section 8(H)(3) requires that appropriate health care professionals be consulted for external review, it is unclear whether pediatric expertise must be included. External reviewer criteria include having a scope of practice encompassing the service or treatment in question and having experience in managing patients with the condition under review. Though seemingly obvious, it is critical to appreciate the fact that children are not simply small adults. The standard of care for pediatric medicine can often differ significantly from that of adult medicine. For example, having treated an adult with diabetes, seizure disorder, or depression is markedly different from having treated a child with similar diagnoses. The AAP recommends that primary care and subspecialty pediatricians be involved in “medical necessity” decisions involving children.

The Academy has worked for decades to ensure that medical products used in children are studied in children. Two laws, the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA) are giant strides towards achieving this goal and nearly 400 drugs have been relabeled with pediatric information as a result of these laws. However, there is much more work to be done and information about the safety and efficacy of medical products in children lags far behind that for adults. As a result, many drugs, biologics, and medical devices are prescribed for off-label use by pediatricians.

Pediatric clinical interventions are less frequently tested in double-blinded, randomized controlled trials, though providers’ clinical judgment deems them appropriate and/or necessary. Moreover, some products today that are cleared or approved by the Food and Drug Administration (FDA) for use in pediatrics are subsequently denied coverage under the auspices that the FDA-cleared or approved product is investigational or experimental. External reviews must adequately reflect the reality that children and adolescents require special consideration. We strongly recommend that pediatric primary care and subspecialty pediatricians be included in any external review process conducted by reviewing bodies authorized by the federal government.

Children are also disadvantaged in traditional medical necessity determinations because of the long-term impact of early interventions in their care. Insurance is a risk management science and one element of that science is time. Many pediatric benefits are only realized over a lengthy period of time and in the short term may not be considered medically necessary, e.g. speech or occupational therapy. This is another reason that habilitation, and not just rehabilitation, was so important

From an operational perspective, the Academy recommends that health plans describe the processes by which physicians and other health care professionals must provide justification for the medical necessity of health interventions they prescribe or order. Descriptions of these processes should include:

- How to provide clinical evidence supporting coverage of interventions that meet the needs of the individual child;

- How to incorporate appropriate pediatric medical or surgical specialty or expert opinion or testimony supporting coverage of interventions;

- How to assist families or physicians who wish to appeal medical necessity denials; and,

How and when coverage decisions are made.

3. *What criteria and methods, besides medical necessity, are currently used by insurers to determine which benefits will be covered? What are the advantages/disadvantages of these current criteria and methods?*

The Academy's current policy statement "Model Contractual Language for Medical Necessity for Children" should be consulted in designing a system to determine benefit coverage.
<http://aappolicy.aappublications.org/cgi/reprint/pediatrics;116/1/261.pdf>

Beyond this policy statement, insurance is risk management. Any payout is considered a loss. Actuarial data is used to calculate the likelihood of any future event or expected cost, based on available data or historic data. Real costs can be predicted for healthy individuals and the likelihood of an anticipated need as well as for individuals with known medical conditions. Real costs and value of new treatments and technologies are difficult to predict as is their medical necessity. Fortunately for children, some of these will be covered and paid for as a benefit. In addition to medical necessity, consumer and purchaser demands influence the scope of benefits with or without regard to costs.

The Academy recommends that the "Early and Periodic Screening, Diagnosis, and Treatment" (EPSDT) program definition should serve as the medical necessity standard for all children. EPSDT requires states to assess a child's health needs through initial and periodic examinations and evaluations to assure that health problems are diagnosed and treated early, before they become more complex and costly. EPSDT also requires states pay for the treatment of those conditions. While health care must be made available to treat, correct or ameliorate defects and physical and mental illnesses or conditions discovered by the screening services, conditions need not be newly discovered during a screen. All conditions must be treated.

4. *What principles, criteria and processes might the Secretary of HHS use to determine whether the details of each benefit package offered will meet the criteria of the requirements specified in the Affordable Care Act.*

The Secretary should recognize that children need different health services from adults. Far beyond the Bright Futures Guidelines, children need treatment for conditions found during routine periodic screens as outlined in the Bright Futures periodicity schedule. Medical necessity for children should also be different than it is for adults (as outlined in the AAP Model Medical Necessity Contract Language policy statement noted above) and no child should be denied prescribed treatment unless the review of the proposed treatment is conducted by pediatric experts. Evidence of the effectiveness of specific treatments in children is scant but improving, and no child should be hurt as a result of the lack of research in the pediatric population. This is another opportunity to link benefits for children to their ultimate adult health. Rather than viewing an insurance payment as a "cost," it should be considered an investment in lifelong health, with the potential to save considerable health-care dollars over the lifespan.

Moreover, the generally accepted medical principles of autonomy, beneficence, non-maleficence and justice should guide all plans in offerings to health care purchasers. Children need care that is safe and of the highest quality – two ingredients that are essential in the design of essential benefits.

5. ***What kind of limits on specific or total benefits, if any, could be allowable in packages given statutory restrictions on lifetime and annual benefit restrictions? What principles and criteria could/should be applied to assess the advantages and disadvantages of proposed limits?***

One factor directly affecting the high cost of care is that the current system may at times be biased towards individual preferences and idiosyncrasies e.g. the desire for proprietary vs. generic drugs. The following criteria could be used to assess the advantages/disadvantages of proposed limits:

The elimination of duplicate services and medical supplies would be an example of one benefit limitation.

Resources are limited. In the adult population, consideration could be given to provision of basic services accessible to all but upgraded services would come at a cost not unlike automobile purchases e.g. basic versus customized wheelchairs. However, this should not apply to children whose needs change throughout their life course trajectory; particularly so for children with special health care needs. As an example, a child should never be limited to one wheelchair per life because their bodies grow. In fact, children's hospitals often keep banks of wheelchairs of different size as private insurance often fails to recognize the unique developmental needs of children.

Services should be diagnosis specific, and consideration should be given to expectation for period of use.

There should be no limits on evidence-informed interventions that support growth and development.

6. ***How could an “appropriate balance” among the 10 categories of essential care be determined so that benefit packages are not unduly weighted to certain categories? The ten categories are: ambulatory patient service; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; pediatric services, including oral and vision care.***

The Secretary could analyze the current ratio of these service areas, one to the other, as they occur in today's market place. This could be highly problematic for children, however, as they consumer far fewer resources than do adults in the US health system. The resources necessary for preventive care, chronic care, mental health care and full pediatric services for children with special healthcare needs and habilitative needs must be included in any weighing or analysis.

7. ***How could it be determined that essential benefits are “not subject to denial to individuals against their wishes” on the basis of age, length of life, present or predicted disability, degree of dependency or quality of life? Are there other factors that should be determined?***

According to Dan Brock, PhD in his paper “Children's Right to Health Care,” the issue of defining just standards and procedures for health care so that resource allocation can be

determined are complex and difficult. These procedures and standards depend on creating and applying medical necessity terminology in the decision-making process. In the experience of pediatricians, the term “medical necessity” is often used as a cover for benefits denial, and pediatricians report that medical necessity is used and applied in an arbitrary and capricious manner and is rife with ambiguity. It might be assumed that children would benefit if the health insurance industry uses tools such as cost-effectiveness and cost-benefit analysis to aid in decision-making. But even these tools lead to subjective results, and should not be relied upon solely. Often the cost-effective analysis and/or cost-benefit analysis become tools of choice in determining the structure of and access to health care services. Both are fraught with risk when applied to children’s health care. For example, since many benefits of health interventions for children are lifelong benefits or occur only later in children’s development, those benefits will be assigned progressively less value if the window of time for analysis of impact is too brief.

Of significant importance for children is the complex issue of end of life care. In the US, more money is spent on health care in the last 90 days of life than any country in the world. The system should clearly have in place advance directives for all persons beyond the age of majority, and in their absence a state-specific “default” advance directive that can be implemented when signed by one family member and a state designated agent. Too often life is sustained because “it can be”, without sufficient regard for the patient’s well being, for fear of medical liability, or because of family discord. Hospice and palliative care service philosophy needs to be incorporated more clearly into chronic disease management. Again the system needs to incorporate more widespread use of an electronic health record, diagnosis specific treatment prescriptions, and encouragement of palliative care measures within the hospital as well as the home care environment.

8. *How could it be determined that essential health care benefits take into account health care needs of diverse segments of the population, including women, children, persons with disabilities and other groups?*

Children and Youth with Special Health Care Needs (CYSHCN) are this country’s most vulnerable population and any system that values their contributions and lives must be established to ensure essential health benefits are designed with their needs in mind. These children must be remembered. The federal Maternal and Child Health Bureau (MCHB) defines children with special health care needs as those who have or are at increased risk for a chronic physical, developmental, behavioral, or emotional condition and who also require health and related services of a type or amount beyond that required by children generally. As pediatricians treat increasing numbers of children with chronic illnesses, they will more frequently face management of end-of-life issues. Thus, it is imperative that structures to establish the essential benefit package also incorporate considerations of how to provide appropriate levels of service specific to palliative, hospice, and home care.

Additionally, children cannot advocate for their own interests, and thus the Academy would urge that an ombudsman system that has access to electronic health records, registries and other tools and that fully understands the guidelines for care as well as the limitations of current treatment modalities should be established to work in conjunction with health care providers to facilitate the needs of these many individuals. The needs of CYSHCN also speak to the need to form smaller, targeted advisory committees for maternal and child health and other more vulnerable populations. These committees should have representation from both clinicians and families. Families are at the center of a child’s life, and learning about the family experience of care and

the family's needs are critical in developing health care benefits that are "essential" – and may be surprisingly inexpensive yet impactful in their lives - to preserving and promoting a child's health and welfare.

9. *By what criteria and method should the Secretary evaluate state mandates for inclusion in a national essential benefit package? What are the cost and coverage implications of including current state mandates in requirements for a national essential benefit package?*

The Academy believes that all children deserve Early and Periodic Screening, Diagnosis and Treatment, Bright Futures preventive services and the medically necessary services their pediatrician determines that they need. If state mandates do not require state-based insurance to include these services, they should be changed to do so.

The common response to this position is that the cost of providing medically necessary services in private plans would be prohibitive. But children are low cost and represent just a small fraction of overall US health care expenditures, including those for CYSHCN. In the context of medical necessity for children, this analysis should be conducted with a lens toward the pediatric population apart from adult costs. However, separating children from adults ignores the fact that each adult was once a child. His or her current health status has been determined, to a large degree, by the adult's health status as a child. Consequently, investment in optimal child health has tremendous cost-savings potential. The cost of adding children to a family's insurance is absorbed by the insurance company and not passed on to the family in most instances. This is because insurers hope to add children to risk pools because of their relative lack of cost and balancing impact versus adults in the risk pool. Allowing children to have equal weight in terms of cost would clearly lead to allowing CYSHCN to get the services that are needed. Children should be able to access the medically necessary services that their pediatrician indicates if they are covered by any insurance in the United States.

10. *What criteria should HHS use in updating the essential package? How should these criteria be applied? How might these criteria and methods be tailored to assess whether: (1) enrollees are facing difficulty in accessing needed services for reasons of cost or coverage, (2) advances in medical evidence or scientific advancement are being covered, (3) changes in public priority are being identified through public input and/or policy changes at the state or national level?*

The ACA already tasks the Secretary with overseeing the creation of a body that manages and responds to queries from the public regarding insurance. We would also urge that a structure be established to field questions from physicians and physicians' offices. Physicians and physicians' offices deal with many more insurance questions than the average consumer and advocate for their patients' interests with insurers. Another option is to develop and implement a consumers' report function whether it be by direct survey or an on-line tool.

There should also be a regular commitment to a structured and periodic review of the benefit plan to ensure it reflects changes in clinical science. The Secretary in conjunction with an Advisory Committee with strong pediatric representation should be empowered to make changes in the benefit package to make the process more expedient. It is instructive that a prescription drug benefit took almost forty years to establish in Medicare. Structures to modify new, improve existing and retire outmoded benefits should be much more nimble. These changes must be vetted through a public comment process. It is critical to elicit the expert input of primary care

pediatricians, pediatric medical subspecialists and pediatric surgical specialists in designing the criteria that will be deployed to update the essential benefit package. It also would be critical to elicit the formal input of families as they are the primary caregivers and guardians of their child's health.