

March of Dimes Foundation

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Jim Mayhew
Office of Consumer Information and Insurance Oversight
US Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: OCHIO-9992-IFC

September 10, 2010

Dear Mr. Mayhew:

The March of Dimes Foundation submits the following comments in response to the Interim Final Rule (IFR) regarding “Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act,” published by the Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; and Office of Consumer Information and Insurance Oversight, Department of Health and Human Services. The March of Dimes Foundation is a unique collaboration of scientists, clinicians, parents, members of the business community, and other volunteers affiliated with 51 chapters in every state, the District of Columbia and Puerto Rico. The Foundation’s mission is to improve the health of women of childbearing age, infants and children by preventing preterm birth, birth defects and infant mortality. The March of Dimes is pleased to express support for the coverage of preventive services; particularly those of importance to women of childbearing age, infants and children; and to offer recommendations for strengthening the regulation to ensure proper access to these services.

The March of Dimes has long been committed to prevention and to guaranteeing that women of childbearing age, infants and children have access to preventive services that help lead to healthy pregnancies and child development. While the US Preventive Services Task Force guidelines include some key health services, such as gestational diabetes screening and tobacco cessation counseling, the March of Dimes was one of the organizations that made the case to Congress regarding the need for additional preventive services for children and women of childbearing age. The Foundation strongly supports the IFR’s affirmation of *Bright Futures* as the standard for pediatric preventive health care. Coverage of the services outlined in *Bright Futures* will ensure that all children have access to preventive services necessary for their healthy growth and development.

Development of Guidelines for Women’s Preventive Services

The March of Dimes also looks forward to the development by the Institute of Medicine of a similar set of recommendations for preventive care guidelines for women. The Foundation strongly urges that the new guidelines include coverage for family planning services and supplies as well as preconception and interconception care. Coverage of these essential services would ensure that more women will be under the care of a health professional before pregnancy, increasing the likelihood that when they do become pregnant, they will obtain timely prenatal care. In addition, numerous studies have shown that pregnancies spaced too closely together present a medical risk factor for preterm birth, the principal cause of newborn death. Appropriately spacing pregnancies — for which access to family planning services is critically important — has been shown to reduce the risk of preterm birth.

In addition to family planning services, studies show that certain health services, if provided to a woman before pregnancy, can improve the health of a future pregnancy. Often, women do not realize that they are pregnant at the outset, and the first prenatal visit with a physician typically does not occur before 6-12 weeks after conception. Beginning care at this point misses opportunities to intervene before crucial early weeks of fetal development. Preconception and interconception care allow providers to identify conditions or behaviors that can impact a future pregnancy and provide appropriate intervention. Examples include tobacco cessation services, nutrition counseling, and controlling chronic conditions such as hypertension or diabetes. Key preconception care services include the following: (1) screening and assessment; (2) health promotion and counseling; (3) interventions as recommended by the American College of Obstetricians and Gynecologists, the American Academy of Pediatrics and the U.S. Centers for Disease Control and Prevention. The March of Dimes strongly recommends that all health plans be required to cover a preconception care visit to provide access to these services for women before they become pregnant or between pregnancies.

Coverage for Secondary and Tertiary Prevention, and Conditions Identified Through Screening

As more people are given access to preventive services under this provision, it is important to consider that some forms of preventive care are actually secondary and tertiary prevention—i.e. early detection rather than primary prevention—and it is expected that some preventive services covered under this provision will identify critical health needs that require treatment. For example, screening women of childbearing age for sexually transmitted infections, as recommended by the US Preventive Services Task Force, will yield positive test results for some individuals. It is critical that these women be given treatment to prevent further health problems such as infertility or future pregnancy complications. Similarly, if newborn bloodspot screening finds that an infant has PKU, he or she would require coverage for medical formulas and foods to prevent serious mental retardation. The March of Dimes strongly supports coverage of these secondary and tertiary preventive services and interventions. Services that cannot be covered under this provision should be considered part of the essential benefits package established by the Patient Protection and Affordable Care Act. As the Departments define the essential benefits

package, the Foundation urges inclusion of coverage for any medically necessary treatment to address conditions identified through the required preventive services.

Process for Updating Guidelines for Preventive Services

As scientific advancements are made, it is critical that guidelines for preventive services are periodically updated to reflect the latest clinical knowledge. It is equally important that covered benefits reflect the updated guidelines in a timely manner. *Bright Futures* is currently in its third edition, and periodic updates should be anticipated as new evidence on pediatric care is generated. The Foundation supports the IFR's requirement that plans comply with changes to *Bright Futures* for plan years beginning one year after those changes are accepted by the HRSA Administrator. The IFR does not, however, set any timeline by which the HRSA Administrator must accept or reject proposed updates to *Bright Futures*. The March of Dimes urges the Departments to stipulate in the IFR a timeframe by which the HRSA Administrator must accept or reject any proposed updates to *Bright Futures*.

Similarly, while the IFR indicates that guidelines for women's preventive services are expected to be issued no later than August 1, 2011, the regulation does not include any process for updating these guidelines. The March of Dimes recommends that this omission be addressed in the final rule.

Plan Use of Medical Management

The IFR states that if a recommendation or guideline for a recommended preventive service does not specify the frequency, method, treatment or setting for the provision of that service, the health plan or insurance issuer can use reasonable medical management techniques to determine any coverage limitation. This policy raises numerous concerns, particularly for the women's preventive health services, as these guidelines have not yet been developed and it is therefore not yet clear how specific they will be regarding frequency, method, treatment or setting for the provision of recommended services. The March of Dimes recognizes that the yet to be developed guidelines will likely have to provide flexibility for providers to determine the most appropriate services to be provided at any given visit based upon an individual patient's family and medical history and other risk factors. For example, a woman with a history of preterm births may require different preventive services than a woman without such prior experience. The Foundation believes strongly, however, that such decisions are best made by health providers in conjunction with consumers and their families. An insurer should not have the authority to limit or deny coverage for a preventive service required under this section when a provider indicates that such a limitation would restrict access to medically appropriate care.

In addition, the March of Dimes strongly recommends that the rule require insurance plans and issuers to have transparent processes for the use of medical management to determine limits on coverage of required preventive services to help lessen the risk of denials of coverage that are arbitrary or otherwise limit access to medically necessary care. Such processes should also provide clear and simple pathways for consumers and providers to appeal coverage denials or limitations.

Timeliness of Implementation

Access to services recommended by the USPSTF and Bright Futures will be made available to individuals in non-grandfathered plans whose plan years begin on or after September 23, 2010. For many, this means access will begin on January 1, 2011, as plan years often begin at the start of a new calendar year. The March of Dimes understands there will be a necessary delay in access to women's preventive benefits, as sufficient time must be given for the guidelines to be developed. The IFR notes that such guidelines are expected to be issued by HHS no later than August 1, 2011. However, the IFR does not require insurers to comply with these new guidelines for women's preventive services until plan years beginning one year after the guidelines are issued. Further, given that plan years often begin with a new calendar year, it is likely that many plans will not begin covering women's preventive services until January 1, 2013, a full 16 months after the guidelines are issued. In the Foundation's view, this delay is unnecessarily long, and the March of Dimes urges the Departments to consider an expedited process to grant access to coverage for women's preventive health services once the guidelines are issued.

Enforcement

The IFR leaves vague which government entities will be responsible for enforcing the requirement to cover recommended services, how that enforcement will take place, and what penalties will be issued to plans who fail to comply. Too often, the burden of enforcing insurance regulations falls to the consumer who must navigate complicated bureaucracies to simply make use of the coverage to which he or she is entitled. The March of Dimes strongly urges the Departments to provide further information on how this provision will be enforced and resources for consumers and providers who have questions or need to report potential problems or violations.

Once again, the March of Dimes thanks you for working quickly to implement these new provisions which take significant steps forward in helping women of childbearing age, infants and children and their families access needed preventive health services. We hope the Departments will find our comments useful as you work to further refine the regulation. All of us at the Foundation look forward to continuing to work with you on ongoing efforts to implement the Patient Protection and Affordable Care Act.

Sincerely,



Marina L. Weiss, Ph.D.
Senior Vice President, Public Policy
and Government Affairs

