January 31, 2012

The Honorable Kathleen Sebelius
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Essential Health Benefits Bulletin, Center for Consumer Information and Insurance Oversight

Dear Secretary Sebelius,

The National Women's Law Center strongly supports the Department of Health and Human Services' efforts to implement the Patient Protection Affordable Care Act (hereinafter the Affordable Care Act) and make quality, affordable health insurance available to millions.

Since 1972, the National Women's Law Center has worked to protect and advance the progress of women and their families in core aspects of their lives, with an emphasis on the needs of low-income women. With a staff of over sixty, supplemented by legal fellows, interns, and pro bono assistance throughout the year, the Center utilizes a wide range of tools—including public policy research, monitoring, and analysis; litigation, advocacy, and coalition-building; and public education—to achieve gains for women and their families in education, employment, family economic security, health, and other critical areas. The National Women's Law Center has long advocated for women's health care and reproductive rights. The Center's efforts reflect extensive research regarding women's specific health needs.

We are pleased to submit the following comments in response to the Essential Health Benefits Bulletin issued on December 16, 2011. We want to thank you for releasing the Bulletin and providing an opportunity to comment on these important issues prior to rulemaking. In addition the providing an opportunity for us to give you feedback, the Bulletin has provided important direction to states and advocates working to implement the Affordable Care Act.

In addition to the comments contained herein, the National Women's Law Center urges the Department of Health and Human Services to consider additional comments we endorsed as part of The Leadership Conference on Civil and Human Rights' Health Care Task Force and in conjunction with a coalition of organizations committed to protecting and advancing women's reproductive health.

I. Overview of Comments

We drafted our comments with a focus on providing recommendations on how forthcoming regulations implementing the Essential Health Benefits (EHB) requirements of the Affordable

Care Act will best meet the needs of women. While we believe a federal EHB package would provide consistent coverage and ensure the same protections to women in every state, we understand that is not the direction the Department is taking. Our recommendations therefore focus on how we believe the proposed benchmark model could be strengthened to ensure the EHB package and health plans providing the EHB package meet the health care needs of women and do not discriminate.

Even using a state benchmark approach, we believe the statute requires—and the health needs of women are best met—with a robust federal overview of the process. In particular, we believe forthcoming regulations need to:

- Provide strong protections to ensure that the EHB package and plans providing the EHB package do not discriminate according to all applicable nondiscrimination provisions of the law— including the protections against discrimination based on sex in § 1557;

- Guarantee the EHB package is a robust package that meets all the requirements of the law by providing a definition for each of the ten categories listed in the statute and ensuring all potential benchmarks provide the required level of coverage;

- Ensure that all women have access to the services included in the EHB package and that insurance plans are not able to prevent women from accessing essential benefits through design flexibility or the use of limits and restrictive management techniques; and

- Create a system for updating and monitoring the EHB package and plans required to offer the EHB package to be certain the package is meeting the needs of women and that there are no discriminatory impacts.

II. HHS Must Provide Strong Protections to Ensure the EHB Package and Plans Do Not Discriminate

Sections 1302 and 1557 of the Affordable Care Act contain specific nondiscrimination requirements which the Secretary must adhere to and enforce. The Bulletin notes that "[b]enefits must not be designed in ways that discriminate" but does not provide direction on how the Department will ensure the EHB package does not discriminate and fails to discuss the application of § 1557.[1] Forthcoming regulations must include strong protections to ensure that the EHB package and plans providing the EHB package do not discriminate according to all applicable nondiscrimination provisions of the law—including the protections against discrimination based on sex in § 1557.

There are three provisions of the statute that must be considered as the Secretary uses her authority to ensure that the EHB package and health insurers do not discriminate:

> § 1302(b)4(B) requires that the Secretary "not make coverage decisions, determine reimbursement rates, establish incentive programs, or design benefits in ways that discriminate against individuals because of their age, disability, or expected length of life."[2]
>
> § 1557 prohibits discrimination on the basis of race, color, national origin, sex, age and disability in health programs or activities that receive federal financial assistance, are administered by an Executive agency, or were established by Title I of the ACA.[3]
>
> § 1302(b)(4)(C) requires the Secretary to "take into account the health care needs of diverse segments of the population, including women, children, persons with disabilities, and other groups."[4]

a. <u>The Nondiscrimination Goals of the Department Must be Expanded</u>

The Bulletin specifically states that one of the goals of the Department in approaching the EHB is to "[e]nsure there are no incentives for coverage decisions, cost sharing or reimbursement rates to discriminate impermissibly against individuals because of their age, disability or expected length of life."[5] This is an important goal and we appreciate the broad view that includes coverage decisions, cost sharing and reimbursement rates as potential areas for discrimination. However, the goal does not go far enough. The Department's goal must be expanded to prohibit discrimination on the basis of race, color, national origin and sex in order to be in compliance with § 1557. In addition, the goal must ensure not only that there are no incentives for discrimination, but that the regulations are clear in giving guidance to states and insurers about the nondiscrimination provisions and that the regulations create a strong enforcement process to ensure plans providing the EHB package do not discriminate.

b. <u>The EHB Package Must Not Discriminate Based on Sex</u>

Section 1557 of the Affordable Care Act prohibits discrimination in the EHB package based on sex and other personal characteristics. Unfortunately, the Bulletin makes no mention of § 1557 or its requirements. Forthcoming regulations should specifically indicate that the EHB must not discriminate in accordance with § 1557. The regulations should also ensure compliance by all entities playing a role in every aspect of developing and administering the EHB package over time as they are also subject to § 1557. Expressly prohibiting discrimination on the basis of race, color, national origin, sex, age and disability as required by § 1557 will also help the Secretary meet her requirements under § 1302(b)(4)(C) to take into account the needs of diverse segments of the population. Without strong nondiscrimination prohibitions and enforcement, the needs of diverse groups, including women, are likely to be dramatically underserved.

c. HHS Must Provide Strong Protections Against Discrimination in Future Rulemaking

While the Bulletin acknowledges that § 1302 of the Affordable Care Act requires the Secretary to consider the health care needs of diverse populations, it does not address what federal protections will be in place in order to assure benchmark plans and plans providing the EHB package are subject to strong, enforceable standards to protect women from discrimination.[6] The Secretary must assure that the EHB package adheres to nondiscrimination standards required in both §§ 1302 and 1557 in every aspect, from scope to definitions to benefit design, including cost sharing. These protections do not end at the design of the EHB package, but extend to all plans providing the EHB package.

We urge the Secretary to indicate, clearly, to all parties, including states and insurers, the type of activity that is prohibited under the nondiscrimination provisions. Without strong regulations, states may unknowingly create EHB packages that result in discrimination and insurers could well continue current discriminatory practices. Direction must come from the Secretary to signify the type of activity that is not tolerated under the Affordable Care Act. The Secretary must create an enforcement mechanism to ensure compliance with the nondiscrimination provisions.

d. Current Civil Rights Law Provides a Basis for Nondiscrimination Principles

Current civil rights laws provide guidance on the types of benefits packages that comply with nondiscrimination principles. Looking to Title VII of the Civil Rights Act of 1964, the Pregnancy Discrimination Act (PDA), which amended Title VII, and Title IX of the Education Amendments of 1972 will assist in determining whether benefit packages discriminate on the basis of sex. For example, the Equal Employment Opportunity Commission has interpreted Title VII to require routine sonograms during the course of a pregnancy to be covered if the costs of routine dental X-rays or PAP smears are covered, and to a comparable extent.[7] Similarly, the Department of Justice makes it clear that Title IX's provisions requiring nondiscrimination in providing health and insurance benefits or services "do not prohibit a recipient from providing any benefit or service that may be used by a different proportion of students of one sex than of the other, including family planning services" and that "any recipient that provides full coverage health service must provide gynecological care."[8] In the time that these laws have been in existence, they have provided important protections for women. The Secretary should consider these laws when developing the essential health benefits and ensuring they are nondiscriminatory.

Throughout our comments, we note the need for future regulations to address issues in a way that ensures the EHB package and plans providing the EHB package do not discriminate against women and that the health care needs of women are met.

III. Guarantee the EHB Package is a Robust Package That Meets All the Requirements of the Law

a. The EHB Must Build Off of The Typical Employer Plan

Section 1302(b)(2)(A) of the Affordable Care Act states that "[t]he Secretary shall ensure that the scope of the essential health benefits …is equal to the scope of benefits provided under a typical employer plan."[9] This sentence must be interpreted to mean that the scope of a typical employer plan is a minimum scope for the EHB, therefore ensuring the EHB package is no lower than the scope of benefits provided under a typical employer plan. However, the Secretary must make the benefits more robust than the typical employer plan in order to meet all the requirements of § 1302.

There are multiple requirements that require the EHB to be different than the typical employer plan. First, the statute requires categories of coverage, including behavioral health treatment, habilitative services and devices, pediatric oral, and pediatric vision, that are likely not in the typical employer plan.[10] Adding services within these categories will have to expand the scope of EHB beyond that of a typical employer plan. Second, there are numerous requirements within § 1302(b)(4) that will require additional scope of benefits. Requiring "an appropriate balance among the categories" may require additional scope of coverage if one or more categories is out of balance.[11] The nondiscrimination provisions discussed earlier may also require additional scope of coverage.[12] Many individuals who will receive insurance under the ACA may not be covered under typical employer plans and the scope of benefits may need to be expanded to meet their needs according to the requirement that the Secretary "take into account the health care needs of diverse segments of the population, including women…"[13] Finally, as noted earlier, § 1557 prohibits discrimination based on the basis of race, color, national origin, sex, age and disability. It may be necessary to expand the scope of benefits in order to adjust for discriminatory practices in the current insurance market. It will not be possible for the EHB to meet these requirements and remain in the scope of the typical employer plan. The Bulletin appears to recognize this by proposing ways to define coverage for certain services that may not be in any benchmark plans. However, we urge the Department to recognize the need to move beyond the scope of a typical employer sponsored plan not only to include all ten categories, but also to come into compliance with the requirements of §§ 1302(b)(4)(A)-(D) and 1557.

b. Benchmark Plans Must Provide Sufficient Scope of Benefits

We are concerned that some of the benchmark options may not provide sufficient scope of benefits to meet the statutory requirements of the EHB. To meet the statutory requirements, plans eligible to serve as the state's benchmark for EHB must provide a sufficiently robust level of coverage and should not arbitrarily restrict the benefits needed by people with significant, specialized, or high-cost health care needs. Unfortunately, there is not good research on the scope of coverage of many of the markets chosen as the benchmark plans, leaving us with

concerns that some potential benchmarks are inadequate. We appreciate the work the Department has done to release information, including the illustrative list of the largest three small group products by state.[14] We hope to provide follow up comments when we have an opportunity to look closely at the scope of coverage offered by those plans along with other potential benchmarks.

We understand that the Department has analyzed the markets for the benchmark options, however many of our concerns come from the lack of detail within the information released by the Department. The December 2011 ASPE (Assistant Secretary of Planning and Evaluation) Research Brief on Essential Health Benefits raised many questions as to how robust the plans reviewed covered each service. The brief noted that "more than 94 percent of the small group market, and all State and Federal employee plans examined appear to generally cover… maternity care." [15] However, there is no detail provided as to what services are covered under maternity care. Appendix A of the report provides a table that shows the percentage of the three largest small group products in each state and the District of Columbia that cover certain services, but that column header says "including with limits."[16] This raises the concern that some of these plans may have limits that would bring the benefits below the scope of coverage provided by the typical employer plan. We have no information if the plans limit the number of prenatal care visits, the number of paid hospitals days for delivery, or certain conditions that are associated with pregnancy. The column providing information on the percentage of State employee plans that cover certain services includes "if mentioned" in parenthesis so it is not clear that all these services are provided in a comprehensive fashion.[17] In addition, the research brief only looked at 10 State employee plans when there are up to three potential benchmarks in each of the 50 states and the District of Columbia. We understand that detailed plan information on all the potential benchmarks is not publicly available and were not available to ASPE for this analysis.

We urge the Department to analyze the potential benchmark plans and make sure that all the options fit the scope required by the statute prior to issuing future rulemaking. If adequate information is not available about potential benchmark options or if the benefits are not provided in a manner robust enough to meet the requirements of the EHB and the needs of women, then the approach must be adapted. Perhaps the benchmark options may be limited to the choice of the two largest small group products rather than three if the third largest product in some states provides benefits that are less comprehensive than the scope required. Alternatively, there may need to be a requirement that a benchmark plan enroll a certain percentage of a state's population in order to keep small plans that do not represent the true market from being used as a benchmark. There may also be the need to provide ways for states to add scope of benefits where a category is offered by a benchmark but in an insufficient manner.

c. Need to Define 10 Categories in Order to Meet Requirement of Defining Essential Benefits

In order to fulfill the requirements of the statute under a state benchmark approach, the Secretary must provide some definitions of the 10 required categories. Section 1302(b)(1) directs the Secretary to define "essential health benefits" with the caveat that the benefits need to include at least the ten listed categories.[18] The statute gives the Secretary the flexibility to include services above the ten listed categories. However, the ten categories represent a minimum level of coverage. In order to know if the benchmark plans chosen by the states meet this minimum requirement, it must be clear what the minimum requirement is for purposes of comparison. The 10 required categories must therefore be defined so that states are aware of the minimum and so that the Department can be certain that each state's essential health benefits are indeed meeting the requirement of the statute.

The statute also requires definitions of some of the categories in order to meet the requirement in 1302(b)(4)(C) that the Secretary take into account the health care needs of women. The EHB provision was meant to address longstanding gaps in coverage. Because of this, the provision specifically notes categories of services that are often not covered by health plans. For example, while the ASPE issue brief found that 95% of small group market plans analyzed covered some level of maternity coverage and the other 5% offered optional maternity coverage, many women are unable to receive maternity coverage on the individual market.[19] There are also other gaps in coverage that impact women, such as access to contraceptive coverage and other preventive services and lack of coverage for eating disorders. In order to properly take into account the health care needs of women, the Secretary needs to understand what health services women need and determine which category each of the services belongs in. The Secretary can then ensure that those services are provided by each state's EHB package. We are particularly concerned about the lack of definition or standards for maternity care, preventive services, and mental health services as well as the very limited proposal in the Bulletin for prescription drug coverage.

Providing definitions of the ten benefit categories will help to provide important guidance to states. Many insurance plans do not categorize benefits following the ten categories so it will often be unclear what covered benefits should be considered as part of each of the ten categories. Overarching definitions can provide important guidance while still maintaining the flexibility desired by the Secretary.

d. Need to Precisely Define Scope and Services Within Maternity Care Definition

The Secretary should precisely define the scope and services within maternity care. Congress explicitly intended maternity care, and the nine other benefit categories within § 1302 of the ACA, to be considered essential health benefits in order to ensure consumers have access to comprehensive coverage—especially for conditions that are not covered, or are covered inadequately in the individual and small group markets. Maternity care was specifically included

to correct longstanding gaps in coverage that women face in the individual and small group markets. In 2009, only 13% of plans sold in the individual market included comprehensive maternity coverage.[20] In some states, women may be able to purchase supplemental maternity benefits (called a "rider") for an additional premium, but this coverage is often expensive and limited in scope.[21] It is important that the Secretary provide clear standards for what must be covered under maternity and newborn care, given that plans have historically failed to cover these services and would likely continue to provide limited coverage if no guidance is provided. These standards should ensure that the scope of maternity coverage is comparable with the scope of coverage under each of the nine other essential health benefit categories.

We recommend a comprehensive and robust package of benefits, based on the American College of Obstetrician and Gynecologists' *Guidelines for Perinatal Care*, which includes preconception, prenatal, labor and delivery, and post-partum care.[22] In addition, the EHB package should include coverage for maternity care services, such as midwifery services, that are provided by professionals licensed by the laws of the state in which the care is provided or practicing in conjunction with a facility licensed by the laws of the state in which it is located.

Because traditional plans do not categorize their services within the same benefit categories or using the same terminology, it is unclear how, without a definition, the maternity care category in the EHB package could be compared to maternity care in a potential benchmark plan to ensure that it complies with the Affordable Care Act. A clear definition would ensure that women are not denied the coverage Congress intended and would enable an effective comparison of potential benchmark plans to the EHB package.

This definition would also provide guidance when benefits could be encompassed in both maternity care and another of the ten categories. The statute and Bulletin require that the ten categories within the EHB package be balanced across the categories.[23] However the Bulletin does not suggest a method for determining whether the categories are balanced. For example, how will the maternity category be balanced if certain services recommended for pregnant women can also be considered to fall within other nine categories.

e. <u>Preventive Services Definition Should at a Minimum be Services Covered by § 2713</u>

In addition to defining maternity care and medical necessity, the Secretary should explicitly state in future regulations that the preventive services category of EHB includes the preventive health services guaranteed under § 2713 of the Preventive Health Services Act, as enacted in § 1001 of the Affordable Care Act, and specifically the women's preventive services guaranteed under § 2713(a)(4).[24] By including the preventive health services guaranteed under § 2713 in the preventive services category of the EHB, the Secretary would ensure that individuals receiving coverage through any plan subject to the EHB requirement would have access to all preventive services. This is particularly important to ensure that women enrolled in the Medicaid expansion program or a Basic Health program do not face barriers when securing access to preventive

services.[*] Failure to explicitly alert the Medicaid expansion program or Basic Health programs that they must comply with § 2713's otherwise general coverage guarantee would undermine enforcement of a core tenet of the Affordable Care Act. Since all non-grandfathered health plans have to comply with § 2713, the typical employer plan will be covering these services in 2014. The Department of Health and Human Services' own estimates show that by 2013, only an estimated 55% of plans offered by large firms and 34% of plans offered by small firms will remain grandfathered.[25]

Alternatively, forthcoming regulations could require that any plan used as the benchmark be a non-grandfathered plan. Since non-grandfathered plans are required to cover all preventive services guaranteed under § 2713, those services would be part of the EHB package if the benchmark plans were non-grandfathered plans. However, this may not be an ideal policy because one of the requirements for a plan to maintain grandfathered status is that the plan must not eliminate all or substantially all benefits to diagnose or treat a particular condition.[26] Therefore, requiring benchmark plans be non-grandfathered plans could result in a plan that has made significant cuts in benefits since passage of the Affordable Care Act from being a benchmark, while a plan that has maintained benefits is prohibited from being a benchmark.

f. Prescription Drug Benefit Requirement Should be No Less than Benchmark Plan

Generally, the Bulletin proposes that the EHB package will be equal in scope to the benefits covered by the benchmark plan. However, in the instance of prescription drugs, the Bulletin mentions a proposal that would have the EHB for prescription drug coverage be only one drug per category or class covered by the benchmark plan, which will be well below the scope of coverage provided by the benchmark plan. This proposal does not meet the requirement in the statute that the scope be equal to the typical employer plan and will result in women not having access to real prescription drug coverage.

The Bulletin discusses Medicare Part D as a model, but the level of coverage is less than half of what is required by Medicare Part D. Medicare Part D requires the coverage of two drugs per category or class in addition to protected classes. However, even using Medicare Part D would be below the statutory requirement of the EHB package. Even if the Department incorporated protected classes into the EHB package and a two drug per category or class requirement, the requirement would be below the scope of many plans. An analysis of formulary coverage in potential benchmark plans found that the plans consistently covered a significant number of drugs in each class.[27] It is of particular note that the Federal Employees Health Benefit Plan

[*] Although not contemplated in this bulletin, the Secretary should use future guidance on Medicaid and the Essential Health Benefits to clarify that the requirements of § 2713 apply to traditional Medicaid plans. Currently, some state Medicaid programs do not cover the full range of contraceptive options. Requiring Medicaid plans to comply with § 2713 would ensure that all women in traditional Medicaid plans have access to the method of contraception their health care provider advises as most appropriate for their medical needs.

(FEHBP) plan used in the analysis has an open formulary which means that all drugs per category or class are covered.

The proposed limit fails to take into consideration the health needs of women and may result in discriminatory plan designs. The study of benchmark formulary coverage included two classes treating conditions primarily impacting women, multiple sclerosis and fibromyalgia. Multiple sclerosis affects about twice as many women as men.[28] The analysis indicates there are nine brand-named multiple sclerosis agents and all nine are covered by the FEHBP plan. The four small group plans cover six or seven of these agents.[29] If the EHB package were to allow a lower limit, then many women with multiple sclerosis would not have their health needs met. Many of the medications used to treat multiple sclerosis agents have significant side effects with high risks that will impact each person differently. Limiting the covered medications to one or two would force many women with multiple sclerosis to choose between a medication that gives her significant side effects, paying for the full cost the medication she needs, or forgoing treatment and potentially facing a faster progression of the condition.

The study also looked at coverage for fibromyalgia agents, a condition that impacts women seven times more often than men.[30] In the analysis, there are only three fibromyalgia agents, but all three agents were covered by four out of the five plans.[31] Fibromyalgia is a difficult condition to treat and many women need to try multiple medications and treatments before finding the right combination. Not covering the medications that meet women's health needs also impact their jobs. The average working adult without fibromyalgia misses 6 days of work per year. In comparison, the number of days missed by working adults with fibromyalgia is almost triple, at 17 days of work per year.[32] Access to necessary medication to treat the condition will likely impact a woman's ability to go to work. If her insurance does not cover the medication she needs, she may be taking a medication that is less effective or has worse side effects. Both could result in days of missed work. In worst scenarios, she may become unable to work because of lack of necessary treatment.

As we note earlier, we believe all services covered by § 2713 should explicitly be a part of the EHB package. However, it is unclear how the EHB package related to prescription drugs will interact with the requirements of § 2713, especially contraceptives. We believe that § 2713 supersedes the EHB package and that, if there is an allowed limit on the number of drugs covered per category or class, that it will not apply to contraceptive coverage. We ask the Department to clarify that plans providing the EHB package must provide coverage for all Food and Drug Administration approved contraceptive methods with no cost sharing.

Requiring the EHB package to cover the same number of drugs per category or class as the benchmark plan will not eliminate flexibility for plans. Plans will still have much of the flexibility they currently have to negotiate with prescription drug manufacturers on price and use a tier based copay system to encourage use of certain medications. For example, if the

benchmark plan covers all nine multiple sclerosis agents, a Qualified Health Plan (QHP) can have nondiscriminatory cost sharing, , including place some of the drugs on different cost sharing tiers, as long as the cost sharing is in compliance with §1302(c) and any applicable state laws or regulations.[33]

The recommendation that the number of drugs covered per category or class to the benchmark plan assumes the benchmark plan chosen is equal in scope to the typical employer plan and does not discriminate. Protections need to be in place, similar to protections for other limits we discuss in our comments, to ensure the EHB package is sufficient in scope and does not discriminate.

g. Mental Health and Substance Use Disorder Services Must Consider Women's Health Needs

Women are disproportionately impacted by a number of mental health conditions including depression, post-partum depression and eating disorders. For example, Women are twice as likely as men to develop depression and 1 in 8 women will be diagnosed with the condition in her lifetime.[34] We appreciate the requirement that mental health services be provided at parity with medical services. This is an important step to ensure expanded access to mental health services for women. It is also consistent with the statute as so many employer plans have to comply with mental health parity. However, parity is not enough to ensure women's health needs are met.

Unfortunately, the Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) does not include a definition of mental illness. The Bulletin applies MHPAEA to the Mental Health and Substance Use category of the EHB.[35] However, because there is no definition of mental illness, coverage for treatment for eating disorders is widely unavailable under current insurance practices. Eating disorders must be covered in order to meet the needs of women and girls. It is estimated that up to 95% of people with anorexia or bulimia are women and young girls.[36] Only 10% of people with eating disorders ever receive treatment for their eating disorder.[37] The high instance of the conditions in women and girls and the lack of coverage for eating disorders compared to other mental health conditions creates a discriminatory impact on women and girls that must not be allowed to continue under § 1557.

IV. **Ensure That All Women Have Access to the Services Promised in the EHB Package**

The Bulletin notes that the statute distinguishes between covered services and cost sharing features.[38] We agree with the distinction. Although cost sharing can have a tremendous impact on access to the benefits covered by the EHB package, cost sharing should have no bearing on the decision of what is covered in the EHB package. Rather, the EHB package should be

designed based on actual services to be covered and rulemaking should then make sure individuals and diverse groups have access to those services. However, in issuing rulemaking, the Secretary should be cognizant of the impact that cost sharing and other technique used by insurers—such as a restrictive medical necessity definition, service limits, so-called medical management techniques and flexibility in benefit design—has on access covered benefits. Future rulemaking should assure that insurers are not allowed to undercut the EHB package by preventing individuals from accessing covered benefits and that it is clear to states and insures that designing cost sharing and using management techniques that result in discriminatory access are prohibited under the law.

a. Should Provide a Strong Definition of Medical Necessity

The Secretary should use her authority under § 1302 to provide a standardized definition of medical necessity. Medical necessity is a management tool used by insurers to determine if a covered benefit will actually be covered for a specific consumer. The tool should be used to ensure the plan is only paying for medically necessary care, but is often used as a cost control tool. Definitions of medical necessity vary with insurance plans and can result in different access to services even when benefit designs are similar. Without a federal definition of medical necessity, women will not, in effect, have the ability to compare plans and choose coverage that is most important for their medical issues. Instead, insurers will have a tool to deny women access to medically necessary treatments that should be covered in the EHB package. Furthermore, a clear and uniform definition of medical necessity at the federal level will lead to greater consistency of care, transparency for consumers and providers, and improved procedures for grievances and appeals. There is currently no commonly applied standard or accepted definition within the health insurance industry of what "medical necessity" means or how it should be used. This leads to consumer confusion and potentially to insurance company misconduct.

Together with a commonly applied standard definition, so too the application of medical necessity must be informed by a consumer's unique health care needs and circumstances. To ensure that women have access to the care they need, including the full scope of reproductive health services, a medical necessity definition should not consider medically-necessary services as only those which relate to illness, injury or disease. A broader definition, such as one that includes services appropriate to a health plan member's diagnosis or condition, better addresses women's needs. A broader definition is especially important because any definition set by the Secretary has the potential to become an industry standard, adopted by those plans that are not subject to the EHB requirements. Moreover, a medically necessary standard as defined by the Secretary is likely to guide coverage determinations beyond the EHB covered services for those plans who are subject to the requirements but decide to provide coverage for services beyond those considered essential.

The medical necessity definition should not be narrowly defined by acute treatment outcomes but rather broad enough to include services that improve, maintain, or prevent deterioration of a patient's capacity to function. This is particularly important for women. For example, women are prone to a condition called pelvic floor dysfunction, particularly after delivery of a child. Pelvic floor dysfunction can have a profound effect on a woman's ability to engage in basic functions without pain, such as urinating or passing a bowel movement. If the definition of medical necessity were narrowly defined by acute treatment outcomes, pelvic floor dysfunction could be excluded. However, a broad definition of medical necessity would enable women to seek treatment for this condition and improve, maintain, and prevent deterioration of these basic functions.

Clinical evidence and best practice standards of care should guide medical necessity. At the same time, there are limitations to using strict clinical evidence recommendations. This is especially true for populations traditionally excluded from clinical trials, such as women, people with disabilities, children and certain racial and ethnic groups. There are many examples of instances in which women have been underrepresented in clinical trials, resulting in a lack of evidence for certain treatments. For example, women with diabetes have a four-to six-fold increase in the risk of developing coronary artery disease, which is double the increase in risk that men with diabetes have. However, investigators note that most research on the subject "has not effectively distinguished between the sexes, thus complicating the job of examining sex-based differences in care or response to treatment."[39] Medical necessity must therefore allow deference to the clinical judgment of the treating physician or treatment team when there is competing evidence or evidence is not available.

b. <u>Scope of Services and Limits Should Not Allow Restrictive Practices to Prevent Access to EHB</u>

The Bulletin states that the EHB will be based on "the scope of services and any limits" in the benchmark plan.[40] We are concerned about the inclusion of "any limits" for two reasons. First, given the lack of data about what kinds of service limits are in the proposed benchmark plans, we are not assured that all benchmarks will have reasonable limits that are truly within the scope of the typical employer plan. Second, there are many insurer management techniques that do not fit the definition of scope of services nor limit, but could be used to prevent access to EHB services if they are not addressed in the statute or if they are allowed to be incorporated into the benchmark as part of the scope of services or limits.

As noted previously, detailed plan information is not currently available for many of the benchmark plans. ASPE has reported that there are limits in the small group market, without providing details as to what services are limited or how the limits work. There is also insufficient information, publicly available, about limits in the largest HMO in each state. Given this lack of data, it is extremely difficult to support deriving the EHB on these unknown limits.

We must therefore oppose the use of service limits in the EHB package. If a plan uses service limits to reduce coverage of any aspect of the EHB package, that limit should reduce the actuarial value in the same way that cost-sharing will reduce the actuarial value of the plan.

However, if the rule does allow service limits, then there must be some restrictions. Any limits should be within the scope of a typical employer plan. HHS should analyze all the potential benchmark plans and make publicly available a report that provides states and stakeholders with a basis for understanding if certain benchmark plans have service limits that are outliers and not similar to the typical employer plan. A plan that deviates from the service limits that are "typical" should not be a benchmark. It should also be recognized that, in some cases, service limits may be new as plans are redesigned to accommodate the ban on dollar value annual and lifetime maximums. It is important that Congress' intent to ban certain limits be recognized and that any benefit changes that limit services in response to that ban should not be incorporated into the EHB package.

There must also be protections to ensure that service limits in the benchmark or any plan providing EHB are reasonable, not based solely on cost, non-discriminatory both in intent and application, and based on the best available medical evidence.[†] For example, there is at least one small group plan that has a 35 visit limit on doctor visits. That limit is not reasonable—it sets a limit on the number of visits allowed to the doctor in order to reduce costs without any correlation to medical need. This limit does not appear to be based on medical evidence because it is clearly below the number of visits medically necessary to treat certain conditions, such as cancer treatment that requires weekly chemotherapy visits. For a patient that is being treated for breast cancer and needs weekly chemotherapy treatment for a year, such a limit would prevent the benefit from covering all of her chemotherapy visits, let alone other visits related to her cancer treatment and other possible conditions. If insurers are concerned that there are some situations where consumers or providers are abusing the system with unnecessary doctor visits, a good medical necessity definition and other utilization review should be able to address those instances without unreasonably limiting services for everyone.

Coverage limits for inpatient therapy for plans that cover eating disorders are an example of unreasonable limits, not based on medical evidence, that pose a significant threat to the health of women and girls. As noted earlier, the vast majority of people with anorexia or bulimia are women and young girls. Eating disorders can lead to major medical complications, including cardiac arrhythmia, cognitive impairment, osteoporosis, infertility, and death. The complications

[†] There are limitations to using strict clinical evidence recommendations. This is especially true for women and other minorities. Women and communities of color often experience illness and treatments differently and have not always been adequately included in clinical trials—a robust body of evidence to support what treatments work best for women may not have been developed yet. However, women and other groups should not be prevented from receiving adequate care. The EHB should be based on the most up-to-date and reliable clinical evidence available, but if that evidence is not available or differs by demographic group, there should be allowance for physician or other health provider discretion.

are so severe that eating disorders have the highest mortality rate of any mental illness and are the number one cause of death of young women ages 15-24.[41] Anorexia is the 3rd most common chronic illness among adolescents, yet insurance often does not cover treatment for anorexia and eating disorders and those plans that do cover treatment impose unreasonable limits.[42] While most patients with eating disorders require at least 6 weeks of inpatient therapy, insurance usually only pays for 10 to 15 days of therapy a year.[43] Given the Secretary's requirement to consider the needs of women and children,[44] the EHB must be designed in a way that prohibits an unreasonable limit on life saving services for a condition that is the number one cause of death among young women ages 15-24.

c. Restrictive Practices Should Not Be Allowed as Part of the Benchmark or to Undermine Access to EHB

We are concerned that the use of the phrase "scope of services and any limits" in the Bulletin could be interpreted to include a broad array of restrictions, such as provider limitations, step-therapy protocols, and arbitrary condition based exclusions.[45] These types of restrictive techniques should not be incorporated into the EHB package or allowed to be applied by a plan to any benefits that are part of the EHB package. These techniques would make it more difficult for women to access vital health care and would dismantle the comprehensive coverage intended by Congress.

If a state incorporates provider limits into the EHB package, women could potentially have far fewer choices of providers than prior to the Affordable Care Act. Health plans sometimes define benefits as "covered if provided by" a certain type of medical professional. If a provider limit becomes part of the benchmark plan, we are concerned that many plans will change their benefits to incorporate the EHB rule. As a result, many plans will limit the types of providers patients can go to for care, *regardless of the fact that the state licenses other professionals to provide the specific service*. We understand that plans are allowed to add benefits in addition to the EHB. However, the premium tax credits are tied to the EHB which adds administrative hurdles to any plan that intends to offer additional benefits. Even if there is no additional cost from expanding providers, the plan may have to provide documentation that would require performing expensive analysis.

For example, in a state that licenses midwives to provide prenatal care to women, a woman who would choose a midwife for this service, and whose insurance would have previously covered it, may no longer have that option. This is despite the fact that prenatal services provided by midwives are safe and effective care and the fact that midwives are licensed by the state to perform such services. We recommend all types of providers licensed in the state—such as midwives, nurse practitioners and physicians assistants—that provide services within the EHB package be reimbursed by all plans providing the EHB package. The Department has previously

stated that regulations on provider networks are forthcoming, and more detailed provider issues should be dealt with in those regulations.

So-called "medical management techniques" such as step-therapy, also known as fail-first protocols, are used to reduce access to covered benefits. Step-therapy protocols have significant negative impacts on women, as they are often used in pain treatment. These protocols often apply to prescription medications and require a patient to take an alternate medication that was not prescribed by the physician prior to covering the prescribed treatment. The impact of step-therapy is very significant for women with chronic pain. More women than men experience pain, with women three times more likely to experience migraine headaches.[46] Women also seek help for pain more often than men, but are less likely to receive pain treatment.[47] Given the difficulties women have in receiving pain treatment, any additional burdens added by insurance plans are likely to have a discriminatory impact and will fail to meet the health care needs of women. The negative impact of step-therapy on patients is so great that there are movements in multiple states to ban the practice. Connecticut Public Act No. 11-169 became law on January 1, 2012 and bans the use of step-therapy protocols by insurers for pain medications.[48]

Given the Secretary's obligation to ensure that the EHB package does not discriminate and to comply with the requirements in § 1302 and § 1557, exclusions for coverage of treatments that overwhelmingly affect women should be explicitly prohibited so states and insurers know the practices are not allowed under the statute. For example, although both women and men can suffer from infertility, typically women face the burden of paying for and undergoing treatment. The treatment of infertility is often subject to limits or total exclusion from plans. An example of past practice of discrimination is lack of coverage for breast reconstruction after a mastectomy. Prior to passage of the Women's Health and Cancer Rights Act (WHCRA), reconstructive surgery following a mastectomy was often considered cosmetic and not covered.[49] WHCRA now requires most group health plans to cover services for surgery and reconstruction on both breasts following a mastectomy, however the law does not apply to State employee health plans so it is possible that there is one or more benchmark option that excludes some of the services required by the WHCRA.

In sum, the Secretary should make clear in forthcoming guidance that restrictive management techniques cannot be used to reduce access to EHB—either by inclusion as part of the EHB or used by a plan to limit access to the EHB. In doing so, the Secretary would ensure she complies with the Congressional intent of comprehensive coverage through a set of essential health benefits and states and insurers have a clear understanding of the statute's nondiscrimination requirements.

d. Plans Should Not Be Allowed Flexibility to Reduce Any Benefits from the Benchmark Plan

The benefit design flexibility proposed in the Bulletin raises significant concerns around access to coverage for women and discrimination against women.[50] We are concerned that, if flexibility to reduce any benefits is allowed, it will be too easy for plans to not offer services that meet the needs of women and to discriminate against women. Unless there are strong federal standards, discriminatory plans will enter the market. It is not sufficient to rely on enforcement of the non-discrimination provisions after a woman experiences discrimination because the harm can be irreparable. Forthcoming regulations should prohibit the flexibility proposed in the Bulletin and require insurers to provide—at a minimum—the same benefits provided in the benchmark plan in a given state.

If a benefit design has a discriminatory impact on women, it is because the benefit design does not cover or does not provide adequate coverage for health services women need. Women may go without necessary services because of the discriminatory plan design. For example, if a plan were not to cover a medically recommended breast MRI after a mammogram, a woman may postpone an MRI exam until she changes health plans or saves enough money for the procedure. This delay could result in significant progression of cancer before she is diagnosed and begins treatment.

There is an incentive for health plans to push the legal limit of flexibility in order to "cherry pick" consumers as much as possible. The provision of insurance will change dramatically in 2014, with insurers no longer being able to deny coverage for preexisting conditions or charge more to patients based on their health status. Insurers will look for other ways to reduce their risk knowing that they are unable to deny coverage or charge unaffordable rates to high risk individuals. Because the individual and small group markets have failed to provide women with coverage for health services they need, we anticipate that insurers will find ways to restrict care. As a result, insurers will look to plan design, including scope of benefits and limits as well as the restrictive practices discussed earlier.

We are very concerned that offering the proposed flexibility both within categories and across categories can have discriminatory impacts. Allowing the proposed flexibility could be used as a back-door attempt at rating on gender and health status—rating that is prohibited under § 1201 of the Affordable Care Act. We are concerned that these attempts could be made if flexibility is allowed either across the ten categories or within the ten categories. For example, if a plan is allowed flexibility within categories, a plan may shift coverage within prescription drug coverage in a way that discourages women from enrolling—such as by reducing coverage for a category or class of drugs used to treat a condition women are diagnosed with at a significantly higher rate than men and instead increase coverage for other drugs.[51]

We are particularly concerned that the Bulletin's proposal for benefit design flexibility could allow an insurer to scale back coverage of maternity care, such as reducing the number of covered ultrasounds or doctor's visits, and increase coverage in another of the categories or another service within maternity coverage that is less utilized. Neither of these scenarios would conform to Congress's intent that all insurance plans cover comprehensive maternity care and would make the insurer's offer of maternity coverage meaningless. While we do not believe these types of benefit designs are common in proposed benchmark plans, evidence demonstrates that plans in the individual market do not currently cover maternity or severely limit coverage.

The EHB standard is intended to ensure a consistent, minimum level of benefits across all non-grandfathered, fully-insured plans in the individual and small group insurance markets so that consumers can make an apples-to-apples comparison of plan options and to prevent insurers from adopting benefit designs intended to attract healthier people and deter enrollment by those in poorer health. The proposal for benefit design flexibility would undermine these goals, regardless of whether variation is allowed within benefit categories or across benefit categories.

The Bulletin's proposed approach to establish the EHB package already provides significant flexibility by allowing each state to set a different benchmark benefit standard. Giving insurers the additional ability to reduce certain benefits from each state's standard would be highly problematic by further diluting the EHB requirement. It is unclear what advantage, if any, the proposal for flexibility holds for consumers since insurers are explicitly allowed under §1302(b)(5) the Affordable Care Act to provide benefits in excess of the EHB.[52]

V. Create a System for Updating and Monitoring the EHB Package and Plans

Forthcoming regulations must outline processes for ensuring all the requirements of the EHB are being met in the EHB package and by plans providing the EHB package. There must be a clear process for updating and monitoring the EHB. A clear process will ensure that all the statutory requirements—including meeting the needs of women and the non-discrimination provisions—are met by the EHB package and the plans providing the package.

a. HHS Should Propose a Process to Update Benefits that Maintains Consistent Access to Treatments and Expands Benefits to Include New Evidence

We are pleased that the Bulletin references the Secretary's statutory requirement, in § 1302(b)(4)(H) of the ACA, to periodically update the EHB based on the review undertaken pursuant to § 1302(b)(4)(G). Nevertheless, the Bulletin does not propose a specific process for updating the benefits or evaluating the benchmark approach. The Secretary should use forthcoming regulations to specifically describe how she will fulfill her requirement under 1302(b)(4)(H).

As mentioned in the Bulletin, the Department must ensure that the review of the EHB takes into account whether enrollees have difficulties with access for reasons of coverage or cost, changes in medical evidence or scientific advancement, market changes not reflected in the benchmarks, and the affordability of coverage as it relates to the EHB. In particular, the Secretary should explain how she plans to take into account changes in medical evidence or scientific advancements that relate to women. There are many examples of instances in which women have been underrepresented in clinical trials, resulting in a lack of evidence for certain treatments. For example, women are inadequately represented in heart disease trials and have been for some time.[53] One study found that male participants outnumbered female participants by a ratio of 3.66-1,[54] even though recent research shows that some drugs used to treat heart disease are less efficacious in women or have troubling side effects not experienced by men. The EHB should be based on the most up-to-date and reliable clinical evidence available, but if that evidence is not available or differs by demographic group, there should be allowances for physician discretion and updates based on new research. Furthermore, technological advances, particularly those related to reproductive health, can change the way that insurers, providers, and women think about the best way to prevent, detect, and treat health conditions. The Secretary should ensure that forthcoming regulations provide a process by which medical evidence and scientific advancements can be used to inform and shape the essential health benefits package over time.

To the extent feasible, the data sources used in the review of the EHB package should be disaggregated by demographic categories. To facilitate this analysis, we urge HHS to require EHB to uniformly report enrollees' race, ethnicity, language, sex, and disability status data, as well as data on other demographic categories, including sexual orientation and gender identity, as described in § 4302 of the ACA.[55] Section 4302 (adding new § 3101 to the Public Health Service Act), requires HHS to ensure that race, ethnicity, primary language, sex, and disability status data are collected throughout all HHS programs, activities, and surveys. It also gives the Secretary authority to require the collection of additional data and, in the summer of 2011, HHS announced a commitment to develop measures for sexual orientation and gender identity data collection.

b. HHS Should Establish Robust Monitoring and Enforcement Mechanisms

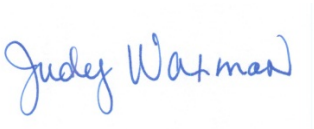
The Secretary should use forthcoming regulations to outline how it plans to monitor state implementation of the EHB benchmark plan and to enforce the requirements states and plans must follow relating to the EHB. The Secretary should propose a process to ensure that plans offer the EHB package to potential enrollees, that enrollees receive the EHB benefits when they are enrolled in a plan and that there is no discrimination in provision of the EHB. In forthcoming regulations on the EHB, the Secretary should provide guidance as to who has the burden of enforcement in each of these situations and the proper enforcement mechanisms. The Secretary

should maintain the enforcement responsibility of the non-discrimination provisions in §§ 1302 and 1557.

During the process to determine a state benchmark, the Secretary should require states to offer a transparent process with ample opportunities for public comment and stakeholder engagement. As the major decision-makers for their families regarding health coverage, women must have the ability to review proposed benchmarks and provide comments. The Secretary should then require states to submit their benchmarks to HHS for review. HHS should review all items and services included in the benchmark, as well as any limits or exclusions that apply, to determine if the benchmark provides substantial coverage of the 10 categories (based on more detailed definitions of the categories than is currently provided in the benchmark) and complies with the required elements for consideration under § 1302 and the nondiscrimination requirements of §§ 1302 and 1557. If HHS finds that a benchmark does not meet all the criteria, it should recommend acceptable changes to the benchmark that would bring it into compliance.

There have already been impressive strides made in expanding health care for women under the Affordable Care Act. The EHB provide a tremendous opportunity to end insurance practices that deny necessary care to women. We thank you for this chance to provide input on this important provision.

Sincerely,



Judith Waxman
Vice President, Health and Reproductive Rights
National Women's Law Center

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