December 26, 2012

Centers for Medicare & Medicaid Services
Department of Health and Human Services, Room 445-G
200 Independence Avenue SW
Washington, DC 20201

Attention: CMS-9980-P

RE: Notice of Proposed Rulemaking for the Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation.

Dear Administrator Tavenner:

The undersigned organizations write to you in response to the notice of proposed rulemaking on the essential health benefits, released on Nov. 26, 2012. While we are pleased to see progress in developing what constitutes the essential health benefits (EHB) package, we are concerned about the implications of the proposed rule for women's health, including women's reproductive health. Specifically, the Department must: explicitly state the full range of applicable nondiscrimination protections; make clear the federal role in enforcing the nondiscrimination provisions; rescind the extension of § 1303(b)(1)(A) to individual and small group market plans; clarify the drugs included in the exception in § 156.120(b) of the proposed rule; improve the pharmaceutical coverage proposal to ensure it meets the needs of women; clarify that "chemically distinct" includes the full approach outlined in the Medicare Part D Manual; ensure enrollees have access to clinically appropriate drugs; require states to reimburse QHP issuers directly to defray the cost of additional required benefits; define EHB categories and scope of coverage; ensure balance among EHB categories promotes robust coverage, and prohibit reduction of benefits; expressly state that plans may not exclude enrollees from an entire EHB category; and, clarify the enforcement process.

State Explicitly the Full Range of Nondiscrimination Protections, Including Those Under § 1557

We thank the Secretary for discussing the nondiscrimination requirements under the ACA throughout the proposed rule. Protections against sex discrimination are particularly important for women who need access to comprehensive reproductive health services. Unfortunately, most of these discussions are limited to the Department of Health and Human Services' obligations under § 1302 and fail to address the application of § 1557 and thus is incomplete in the guidance it provides. We urge the Secretary to expressly enumerate the full range of nondiscrimination protections in the final rule.

There are four provisions of the statute that must be considered as the Secretary uses her authority to ensure that the EHB and plans offering the EHB do not discriminate:

- § 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.[1]
- § 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]
- § 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."[3]
- § 1302(b)(4)(D) requires the Secretary to ensure "that health benefits established as essential not be subject to denial to individuals against their wishes on the basis of the individuals' age or expected length of life or the individuals' present or predicted disability, degree of medical dependency, or quality of life."[4]

The Secretary's obligations under § 1302 must be read in concert with § 1557. The proposed rule makes no direct reference to § 1557 and only indirectly refers to its requirements.[5] The final rule must make clear that § 1557 requires nondiscrimination in the essential health benefits. In addition, the rule must give guidance as to what §1557 requires.

It is important that the final rule enumerate explicitly the full range of nondiscrimination protections. The proposed §156.125 nondiscrimination standard references the requirements that apply to Qualified Health Plans (QHPs) and issuers of QHPs.[6] The proposed rule, however, applies to issuers of plans both inside and outside the exchange—not only to QHPs. We therefore urge the Secretary to state specifically in the final rule that the EHB and plans providing the EHB must not discriminate based on race, color, national origin, sex, age, disability, gender identity, or sexual orientation.[7]

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[1] Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 1557 (2010), *amended by* Health Care and Education Affordability and Reconciliation Act, Pub. L. No. 111-152 (2010) (to be codified at 42 U.S.C. § 18116).
[2] Patient Protection and Affordable Care Act, § 1302(b)(2)(B).
[3] Patient Protection and Affordable Care Act, § 1302(b)(4)(C).
[4] Patient Protection and Affordable Care Act, § 1302(b)(4)(D).
[5] Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation, 77 Fed. Reg. 70,644, 70,670 (proposed Nov. 26, 2012) (to be codified at 45 C.F.R. § 156.125(b)) (referring to 45 C.F.R. § 156.200(e) (2012), (prohibiting a Qualified Health Plan from discriminating based on race, color, national origin, sex, age, disability, gender identity, or sexual orientation).
[6] Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation, 77 Fed. Reg. at 70,670 ("A QHP issuer must not, with respect to its QHP, discriminate on the basis of race, color, national origin, disability, age, sex, gender identity or sexual orientation.").
[7] Specific references to nondiscrimination appear in three places in the proposed rule: Sections 156.110, 156.125, and 156.130. *See* Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation, 77 Fed. Reg. at 70,669-70. The references to nondiscrimination in sections 156.110 (EHB-benchmark Plan Standards) and 156.130 (Cost-Sharing Requirements) simply cite the standards defined in § 156.125, thus amplifying the impact of § 156.125's failure to describe the universe of applicable nondiscrimination requirements. In addition, the preamble notes that while issuers may use utilization management techniques, issuers cannot use these techniques in "to discriminate against certain groups of people." *Id.* at 70,653. It goes on to note, "[f]or example, an issuer could use prior authorization, but could not implement prior authorization in a manner that discriminates on the basis of factors including age, disability, or length of life." *Id.* Again, the protections in § 1557 and ACA regulations are not included. The preamble must explicitly enumerate the full range of nondiscrimination protections.

Make Clear the Federal Role in Enforcing the Nondiscrimination Provisions
We also urge the Secretary to make clear the federal role in ensuring that the EHB and plans providing the EHB do not discriminate based on sex and other prohibited characteristics.

In the preamble, the Department describes its authority under § 1302 in some detail.[8] The Department should include a similar description of its authority under § 1557 as well, so that (as the Department notes) these provisions can be "[t]aken collectively… as a prohibition on discrimination by issuers."[9] To meet that goal, the preamble must set forth the full range of nondiscrimination protections, the statutory basis for these protections, and the Secretary's obligation to enforce them.

The proposed rule does not address the federal role in enforcing the ACA's nondiscrimination provisions; instead, it encourages states to monitor and identify discriminatory design.[10] While state oversight is important, it is the federal government, including the Department itself, that has an obligation to enforce §1557 among other ACA nondiscrimination standards. Pursuant to this authority, the Department *must* ensure that the EHB and plans offering the EHB do not discriminate based on sex (among other prohibited criteria). It should further be noted that the nondiscrimination provisions of the ACA apply to the entire EHB package, benchmark plans, and plans providing the EHB—not just the prescription drug benefit.[11] The proposed rule fails to make this clear.

The final rule must include a statement that the Department is charged with enforcing the nondiscrimination requirements under § 156.125 in all aspects of the EHB and plans offering the EHB. Without strong federal oversight and enforcement, issuers may develop plans based on the EHB benchmark, and approved by state regulators or exchanges that result in discrimination and insurers could continue current discriminatory practices. The final rule must make clear the Secretary's obligation to ensure that EHB-benchmarks, the EHB, and plans providing the EHB are nondiscriminatory.

Provide Further Guidance As to What Constitutes Discriminatory Plan Design and Evaluate EHB-Benchmark Plans for Discriminatory Design
The Secretary requested comments on her proposed approach to prohibiting discriminatory benefit design.[12] We thank the Secretary for prohibiting discrimination in marketing practices as well as in network and benefit design.[13] This is critically important to guarantee access to reproductive health care. Unfortunately, the proposed rule provides only a cursory indication of what constitutes discriminatory design and how the Secretary will evaluate discrimination in the EHB-benchmark, the EHB, or plans providing the EHB.[14]

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[8] *See, e.g.*, Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation, 77 Fed. Reg. at 70,652 (referring to the Secretary's authority under §§ 1302(b)(4)(B); 1302(b)(4)(C); and 1302(b)(4)(D)).
[9] *Id*.
[10] *Id*.
[11] In the proposed rule, the Department notes the state's role in monitoring discriminatory benefit design only with respect to the prescription drug benefit. *See* Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation, 77 Fed. Reg. at 70,652.
[12] *Id*. at 70,653.
[13] *See* Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation, 77 Fed. Reg. at 70,670-71. In particular, we thank the Secretary for prohibiting discrimination in network design. *See id.* at 70650.
[14] *See* Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation, 77 Fed. Reg. at 70,653.

Because the EHB cannot discriminate,[15] we urge the Secretary to evaluate and affirm that each state's proposed EHB-benchmark plan does not discriminate. Any discrimination in benefit design must be addressed and corrected before the plan is finalized as the state's EHB-benchmark. Further, the Secretary has an ongoing obligation to ensure that the EHB and plans offering the EHB do not discriminate. To that end comments provide a framework for identifying plan design that discriminates based on sex in violation of § 1557 and other applicable antidiscrimination laws.

Existing Civil Rights Law Sets Out Key Rules Regarding Prohibited Sex Discrimination
Some key standards of nondiscrimination in health care are set forth in current civil rights law. Benefits packages must comply with these rules at a minimum to be nondiscriminatory on the basis of sex. Regulations and guidance promulgated under Title VII of the Civil Rights Act of 1964, including the Pregnancy Discrimination Act (PDA), and Title IX of the Education Amendments of 1972, as well as case law interpreting these provisions, provide some key markers for determining when benefit packages discriminate on the basis of sex. Title VII and Title IX make clear that at a minimum, to avoid discriminating on the basis of sex, the EHB and plans providing the EHB:

- Must provide comprehensive coverage for women, including full coverage for gynecological and maternity care on the same terms as other benefits;[16]
- Cannot subject conditions that disproportionately affect women or services primarily used by women, including reproductive health services, to lower standards, arbitrary limitation, or exclusion;[17] and,
- Cannot deny medically necessary tests, treatments, or services, such as contraception or other reproductive health services, to an individual based on sex or gender identity.[18]

These rules, developed from laws that have provided important protections for women, should inform the Secretary's evaluation of discriminatory benefit design in EHB-benchmark plans and her ongoing obligation to ensure the EHB and plans providing the EHB do not discriminate.

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[15] *See* Patient Protection and Affordable Care Act, §§ 1302(b)(4)(B), (b)(4)(C), and (b)(4)(D). *See also* Patient Protection and Affordable Care Act, § 1557.

[16] *See, e.g*., 29 C.F.R. pt. 1604 app. (2012) (stating that Title VII, amended by the Pregnancy Discrimination Act, requires that any employer-provided health insurance must cover expenses for pregnancy related conditions on the same basis as expenses for other medical conditions); 34 C.F.R. § 106.39 (2012) (stating that Title IX requires comprehensive gynecological care when a recipient provides full coverage for health services); U.S. Equal Employment Opportunity Commission Compliance Manual on Employee Benefits, Health Insurance Benefits (Title VII/EPA Issues), *available at* http://www.eeoc.gov/policy/docs/benefits.html#B (stating that an employer's health insurance plan may not exclude pregnancy or related conditions altogether and must offer the same terms for coverage of pregnancy, childbirth, and related conditions as for other medical conditions).

[17] *See, e.g.,* U.S. Equal Employment Opportunity Commission Compliance Manual on Employee Benefits, Health Insurance Benefits (Title VII/EPA Issues), *available at* http://www.eeoc.gov/policy/docs/benefits.html#B (stating that where an employer uses a facially neutral standard to deny insurance coverage for a condition or treatment that disproportionately affects members of a protected group, the employer must then show that the standards it relied on for the exclusion are based on generally accepted medical criteria).

[18] *See, e.g.,* U.S. Equal Employment Opportunity Commission Compliance Manual on Employee Benefits, Health Insurance Benefits (Title VII/EPA Issues), *available at* http://www.eeoc.gov/policy/docs/benefits.html#B. (stating that an employer cannot provide different coverage to men and women where the underlying condition affects, or the treatment test could be effective for, both men and women). *See also,* Macy v. Holder, E.E.O.C. Appeal No. 0120120821, *7 (Apr. 23, 2012) (interpreting Title VII's prohibition against sex discrimination to include discrimination based on a person's transgender status).

Moreover, some issuers are directly bound by these antidiscrimination laws (in addition to provisions of the ACA including § 1557), so it is important to ensure that plans offering the EHB comply with these laws as well.[19]

Establish a Robust Process to Evaluate Discriminatory Plan Design in All Aspects of the EHB
In the preamble for § 156.125, the Secretary proposes to evaluate discrimination in plan design by identifying outliers through comparison with "typical plan offerings, including unusual cost-sharing and limitations for benefits with specific characteristics."[20] It then notes that CMS subjects the Medicare Advantage Program cost-sharing designs to a similar analysis to find potential discriminatory effects.[21] While this process may be a starting point, it is substantially inadequate as a model for evaluating discrimination in the EHB and by plans providing the EHB for several reasons.

First, while CMS uses the traditional Medicare program as the standard against which it measures whether a Medicare Advantage plan discriminates,[22] no such baseline exists in the context of EHB. The Secretary could identify plans that differ from "typical plan offerings"[23] as a starting point. However, the Secretary cannot assume that "typical plan offerings" are nondiscriminatory: one of the underlying premises of the ACA, and the EHB in particular, is that the current market is discriminatory. Second, and along similar lines, when CMS evaluates Medicare Advantage plans for discrimination, it does so only with respect to cost-sharing—not, for example, with respect to the benefits offered.[24] Discrimination in the EHB and by plans providing the EHB can occur in network and benefit design, including limits and exclusions. The Secretary must be able to identify when discrimination occurs in any of these areas. Third, CMS does not specifically review Medicare Advantage plans for design that discriminates on the bases included under § 1557 and ACA regulations.[25] Individuals enrolled in Medicare Advantage plans have drastically different health needs than those who will enroll in plans offering the EHB—particularly women of reproductive age. The process for monitoring discrimination in the EHB must be able to identify sex discrimination.[26]

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[19] Title VII, for example, covers employers who have fifteen or more employees. 42 U.S.C. § 2000e(b) (2012). Title IX prohibits a program or activity that receives federal financial assistance from discriminating against individuals on the basis of sex. 20 U.S.C. § 1681, et seq. (2012).
[20] Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation, 77 Fed. Reg. at 70,653.
[21] *Id*.
[22] 42 C.F.R. § 422.100(f) (2012). *See also*, U.S. Gov't. Accountability Office, GAO-10-403, Medicare Advantage: Relationship Between Benefit Package Designs and Plans' Average Beneficiary Health Status 2 (2010), *available at* http://www.gao.gov/products/GAO-10-403 (noting that the overall cost-sharing requirements of a Medicare Advantage plan must be actuarially equivalent to lower than those under traditional Medicare).
[23] Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation, 77 Fed. Reg. at 70,653.
[24] 42 C.F.R. § 422.100(f) (2012). *See also*, U.S. Gov't. Accountability Office, GAO-10-403, Medicare Advantage: Relationship Between Benefit Package Designs and Plans' Average Beneficiary Health Status 2 (2010), *available at* http://www.gao.gov/products/GAO-10-403 (noting that the Medicare Advantage plans must provide all services covered by traditional Medicare, except hospice care).
[25] 42 C.F.R. §§ 422.100(f)(2), (f)(6) (2012) (CMS reviews Medicare Advantage (MA) plans to ensure that "MA organizations are not designing benefits to discriminate against beneficiaries, promote discrimination, discourage enrollment or encourage disenrollment, steer subsets of Medicare beneficiaries to particular MA plans, or inhibit access to services" and "Cost sharing for Medicare Part A and B services specified by CMS does not exceed levels annually determined by CMS to be discriminatory for such services").
[26] It should also be noted that the ACA recognized weaknesses in CMS's process for identifying discriminatory benefit design in Medicare Advantage plans. *See* 42 U.S.C. §§ 1395w-22(1)(b)(iii)-(iv) (2012) (to address discrimination against the sickest Medicare beneficiaries, cost-sharing under Medicare Advantage plans for skilled nursing care, chemotherapy, and renal dialysis (and other services, to be determined by the Secretary) can no longer exceed the cost-sharing for these services under traditional

It should also be noted that the ACA recognized weaknesses in CMS's process for identifying discriminatory benefit design in Medicare Advantage plans. The Secretary should thus be aware of the flaws in CMS's process for reviewing Medicare Advantage plans for discrimination and ensure that it creates a better process for evaluating discrimination in benefit design with respect to the EHB if it is used as a model.

In short, we thank the Secretary for prohibiting discrimination in benefit design but urge the final rule indicate clearly what the Secretary considers discriminatory benefit design. Specifically, we urge the Secretary to evaluate state's proposed EHB-benchmark plans and address any problems of discriminatory design before the plan becomes the state's benchmark.

Rescind the Extension of § 1303(b)(1)(A) to Individual and Small Group Market Plans

The Department's proposal in § 156.115(c) to extend the application of § 1303(b)(1)(A) of the ACA to all individual and small group market plans conflicts with the plain language of the statute. The only plans specified in Section 1303 are qualified health plans. If Congress had intended to apply § 1303(b)(1)(A) to plans other than qualified health plans, Congress would have drafted the section to do so.[27]

Nor can there be any doubt that the statutory language in § 1303(b)(1)(A) is an accurate reflection of Congress's intent. The language of this section was very carefully drafted to specifically address abortion coverage by qualified health plans in the Exchanges. By extending § 1303(b)(1)(A) beyond qualified health plans, the Department is contradicting Congress's intended resolution of this issue.

Furthermore, Congress explicitly gave states the ability to make determinations about coverage of abortion in the insurance plans being offered in their states.[28] By applying the provisions of § 1303(b)(1)(A) beyond the statutory requirement, the Department is creating a new limitation on women's access to abortion that would override state decision-making, contradicting the plain language and intent of Section 1303.

In the final rule, the Department should remove the extension of this statutory language to plans other than qualified health plans.

Medicare). The Secretary should thus be aware of the flaws in CMS's process for reviewing Medicare Advantage plans for discrimination and ensure that it creates a better process for evaluating discrimination in benefit design with respect to the EHB if it is used as a model.

[27] For example, while the EHB applies to all plans in the individual and small group market, § 2711 of the Preventive Health Service Act, as added by § 1001 of the ACA, prohibits plans in the individual and small group market *as well as* plans in the large group market and self-funded plans from establishing annual or lifetime limits on the EHB. Congress explicitly expanded the principle on annual and lifetime limits on EHB beyond those plans required to provide EHB. If Congress had intended to apply § 1303(b)(1)(A) to plans other than qualified health plans, Congress would have drafted the section to do so, much like it drafted § 2711 to apply a requirement regarding EHB to plans that do not have to provide EHB.

[28] Section 1303(c)(1) says, "Nothing in this Act shall be construed to preempt or otherwise have any effect on State laws regarding the prohibition of (or requirement of) coverage, funding, or procedural requirements on abortions, including parental notification or consent for the performance of an abortion on a minor." Thus, states' determinations about abortion coverage preempt anything in the ACA regarding abortion coverage.

Clarify the Drugs Included in the Exception in § 156.120(b)

In § 156.120(b), the Department states that a health plan does not have to cover "drugs for services described in § 156.280(d)" in order to be EHB-compliant.[29] The Department should provide guidance as to which drugs fall into that category. Unfortunately, there is great deal of misinformation about this issue provided to the public. There are some who falsely claim that commonly used contraceptives like birth control pills, intrauterine devices, and emergency contraception are forms of medical abortion. As you are aware, this is not the case. For example, emergency contraception is sometimes confused with medical abortion. However, whereas medical abortion is used to terminate an existing pregnancy, emergency contraception (EC) is effective only before a pregnancy is established. Thus, EC is not an abortifacient.

Rather than risk a lay-person using inaccurate information to determine which drugs must be included in a plan, the Department must make sure that the final rule is clear as to which drugs are actually exempted. Otherwise, women may find that plans are not providing coverage for contraception they are legally bound to cover. The final rule should be amended to read as follows:

> **§ 156.120 Prescription drug benefits.**
> …
> (b) A *qualified* health plan does not fail to provide EHB prescription drug benefits solely because it does not offer drugs *approved by the Food and Drug Administration as* services described in § 156.280(d) of this subchapter.

Additionally, the Department should include this language in the two places in the preamble that refer to medical abortion. The first is in the preamble's discussion of § 156.120(b). There, the language should be amended to read: "In paragraph (b) we clarify that a *qualified* health plan does not fail to provide EHB prescription drug benefits solely because it does not offer drugs *approved by the Food and Drug Administration as* § 156.280(d) services."[30] The second is in the preamble's discussion of § 156.115 which should be amended to read: "We note that this provision applies to all section 1303 services, including pharmacological services *approved by the Food and Drug Administration as services described in 156.280(d).*"[31]

Include § 2713 Preventive Health Services in EHB for the Medicaid Expansion and Basic Health Program and Issue Sub-Regulatory Guidance on These Services

We thank the Secretary for clarifying in § 156.115(a)(3) that EHB must include all preventive health services described in § 147.140 of this subchapter, which includes the preventive services in § 2713 of the Public Health Service (PHS) Act, as added by § 1001 of the ACA. This clarification ensures that important preventive health services like well-woman visits, mammograms, and contraception will be included in EHB with no cost sharing. Because EHB base-benchmark selections could be grandfathered plans and thus not subject to PHS § 2713, it is necessary for regulations to explicitly apply § 2713 to all plans subject to EHB. Additionally, any relevant forthcoming regulations should clarify that all plans subject to the EHB

[29] Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation, 77 Fed. Reg. at 70,670.
[30] Clarifying language originally appearing on p. 70,652 of the proposed rule. *See* Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation, 77 Fed. Reg. at 70,652.
[31] Clarifying language originally appearing on p. 70,651 of the proposed rule. *See* Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation, 77 Fed. Reg. at 70,651 (proposed Nov. 26, 2012).

requirement—including Medicaid benchmark plans for the expansion population and Basic Health Plans—provide the preventive services in § 2713. This additional clarification is critical to ensure that women enrolled in Medicaid expansion programs or Basic Health plans do not face barriers in accessing these important preventive health services. Failure to explicitly alert Medicaid expansion programs or Basic Health programs that they must comply with § 2713's otherwise general coverage guarantee would undermine enforcement of a core tenet of the ACA.

While we thank the Department for recognizing the importance of the preventive services in § 2713 by including them as part of the essential health benefits, we reiterate the importance of issuing sub-regulatory guidance to ensure the preventive services provision is fully implemented in compliance with the ACA's intent.

Proposed Pharmaceutical Coverage Standards Are Stronger Than the EHB Bulletin, But Need Further Improvements

We thank the Secretary for developing regulatory language on prescription drug coverage that improves upon the policies outlined in the December 2011 EHB Bulletin. Section 156.120 requires plans subject to EHB to cover the same number of prescription drugs in each category and class as the EHB-benchmark plan. In the absence of coverage in a particular category or class, the EHB plan must cover at least one drug. The proposed rule better serves consumers and more closely mirrors typical employer coverage by aligning coverage within each drug category and class with the EHB-benchmark plan. Requiring the EHB package to cover the same number of drugs per category or class as the benchmark plan also enables plans to continue negotiating prices with prescription drug manufacturers and designing cost-effective formularies.

While we are thankful for this improvement, we have concerns about continued gaps in coverage that will result from the proposed regulation. These concerns include the Department's overall responsibilities with regard to prescription drug coverage within EHB and within § 2713 preventive health services, the United States Pharmacopeia system, coverage of chemically distinct drugs, and access to clinically appropriate drugs.

EHB and § 2713 Preventive Health Services Have Separate Legal Requirements

We reiterate our thanks to the Department for recognizing that to provide the EHB, a plan must provide the preventive health services described in 45 CFR § 147.130, particularly as this applies to the women's preventive services. However, we remind the Department that while the women's preventive health services are part of the EHB, this does not change the need for, or the legal requirements obligating, the EHB to provide complete and non-discriminatory pharmaceutical coverage. Nor does the fact that the preventive health services are part of the EHB change the legal requirements for plans to provide the § 2713 preventive health services without cost-sharing. The EHB and the § 2713 preventive health services have separate legal requirements which must be met by all plans to which they apply.

The United States Pharmacopeia Classification System Is Inadequate for Women

In the preamble, the Department explains that it is considering the United States Pharmacopeia (USP) classification system for inclusion in the rule because it is a "common organizational tool" that is, among other things, "comprehensive." Unfortunately, when it comes to women's health care needs, the USP is far from comprehensive and is, in fact, inadequate. The USP category and

class system was not designed to meet the needs of women (or anyone) under age 65, classifies drugs with different clinical purposes together, does not classify drugs women regularly use, and adopts a definition of "chemically distinct" which could limit coverage of forms of drugs important to women. We remind the Department that the ACA requires the Secretary to "take into account the health care needs of diverse segments of the population, including women," when designing EHB.[32] In addition, the Secretary must consider the statutory obligation for nondiscriminatory plan design and the nondiscrimination requirements of § 1557. The USP classification system must meet these important standards.

The USP Was Not Designed for the Population that Will Receive EHB

The USP category and class system was not designed for use with plans required to provide the EHB. Because USP created this category and class system for the purposes of the Medicare Part D program, the system was created in the context of plans in which the majority of enrollees are age 65 or older.[33, 34] Plans required to comply with the EHB will predominantly enroll individuals under the age of 65. These individuals—particularly women of reproductive age—have health needs that are drastically different than those of Medicare Part D enrollees. Furthermore, pregnant women may need to take different drugs while pregnant. In fact, the FDA has a special categorization system to inform pregnant women about safety hazards of certain drugs.[35] In addition, women are more likely than men to use prescription drugs.[36]

Grouping drugs for different clinical purposes in the same class

Some of the USP classes are structured in such a broad way that drugs for different clinical purposes are grouped together. Because plans can cover one drug per class to satisfy the EHB benchmark, there may be no drugs covered to meet critical health needs. For example, the USP category "Hormonal Agents, Stimulant/Replacement/Modifying (Sex Hormones/Modifiers)" includes a class titled "Progestins." This class includes drugs used for hormone replacement therapy in post-menopausal women, hormones used to treat infertile women with a progesterone deficiency, as well as multiple types of contraceptives. Women use these drugs to address very different health needs. Because of the way they are classified by USP, a woman who needs contraception may find that it is not included in her supposedly EHB-compliant plan because the plan covers an infertility drug instead. This is not acceptable.

Unclassified drugs

The Department compares the USP system to "an organizational system, similar to an outline or a taxonomy."[37] However, in an outline or taxonomy, every possible item to be classified has a specific placement in the organizational system. This is not the case for the USP system, which

[32] Patient Protection and Affordable Care Act, § 1302(b)(4)(C).
[33] Medicare Prescription Drug, Improvement, and Modernization Act of 2003 § 1869D-4(b)(3)(C)(ii), 42 U.S.C. § 1395w-104(b)(3)(C)(ii) (2012) (directing the Secretary to request the United States Pharmacopeia to develop a list of categories and classes for Medicare Part D plans).
[34] Medicare Part D enrollees under the age of 65 are eligible because they receive Social Security Disability Income or because they have end-stage renal disease. However, this is a relatively small population with their own special health care needs. It is not a population whose experiences with Part D coverage could be appropriately used to determine if the USP system meets the needs of the population who will enroll EHB-compliant plans.
[35] *See* 21 C.F.R. § 201.57(c)(9)(i) (2012).
[36] NWLC analysis of data on page 321 of Nat'l Ctr. for Health Statistics, Health, United States, 2011: with Special Feature on Socioeconomic Status and Health, *available at* http://www.cdc.gov/nchs/data/hus/hus11.pdf#099.
[37] Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation, 77 Fed. Reg. at 70,652.

fails to place many drugs in specific classes. If a drug is not included in any class, it will not be counted in the determination of the EHB coverage requirement at all. Therefore, even if the EHB-benchmark plan exemplifies comprehensive coverage of a group of unclassified drugs, that coverage will not be translated into the coverage requirement for EHB-compliant plans in that state.

Often, the unclassified drugs are combination drugs, meaning drugs with multiple active agents. A number of commonly used contraceptives are combination drugs, including many types of oral contraceptives, the ring, and the patch. Contraception use is widespread among women, and it is used not only to plan and space pregnancies but for other health benefits as well, including reducing excessive menstrual bleeding, menstrual pain, and the risk of ovarian cancer. The exclusion of these drugs would have serious health implications for many women.

It is imperative that the Department amend the EHB-benchmark formulary requirements in the proposed rule to address unclassified drugs. Prior to 2014, the Secretary must implement a system that ensures that unclassified drugs covered by EHB benchmark plans are counted towards the minimum coverage requirements for plan providing the EHB. This system should create classes for the unclassified drugs for the purposes of the EHB-benchmark formulary. The new classes must recognize the differences between unclassified drugs, both in terms of the active agents in the drugs and their clinical purpose. For example, a system which simply counted all unclassified drugs in the EHB benchmark formulary and required coverage of that number of unclassified drugs by EHB plans would not be sufficient. Furthermore, it would be unacceptable for the Department to propose to categorize unclassified drugs solely by their primary active agent. This could inappropriately group unclassified drugs with drugs that have a different clinical purpose, resulting in barriers to care and replicating an existing problem in the USP system.

Clarify that "Chemically Distinct" Includes the Full Approach in the Medicare Part D Manual

In the preamble, the Department proposes that in meeting the minimum number per category and class requirement, drugs listed must be "chemically distinct." The Department refers to this concept as it is used in the Medicare Part D Manual. The Manual states that, while plans are expected to cover multiple dosage forms and strengths of drugs, this and coverage of brand name drugs and their generic equivalents alone are not enough to meet the standard of coverage of two "chemically distinct" drugs.[38,39] Therefore, while two dosage forms or strengths of a drug do not meet the minimum requirement for coverage, multiple dosage strengths and forms have to be available to provide adequate drug coverage in Part D plans. This is particularly important for women where access to a particular dosage strength or form can determine whether a woman has access to the appropriate prescription for her health needs.

[38] Ctrs. for Medicare & Medicaid Srvcs., Dep't of Health & Human Srvcs., Medicare Prescription Drug Benefit Manual, Ch. 6, Sect. 30.2.1 (2010), *available at* http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Chapter6.pdf.

[39] The Manual states: "Aside from the inclusion of two drugs in each category or class, multiple strengths and dosage forms should also be available for each covered drug. CMS may require more than two drugs for particular categories or classes if additional drugs present unique and important therapeutic advantages in terms of safety and efficacy, and their absence from the sponsor's formulary would substantially discourage enrollment by beneficiaries with certain disease states." *Id.*

In guidance on "EHB Benchmark Drug List Counts" which the Department released in conjunction with the proposed EHB rule, the Department indicates that for the purposes of determining the minimum number per category and class requirement, the concept of chemically distinct means that the Department counts drugs with different dosage strengths or forms or routes of administration as *only one* chemically distinct drug.[40] Thus, the Department only explicitly adopts the first part of the Medicare Part D Manual's concept of "chemically distinct," and does not adopt the principle that multiple dosage strengths or forms or routes of administration should be available. Given that the Department has recognized the importance of this principle in the context of Part D, it should be extended to the EHB coverage requirements. If it does not clarify in the final rule its intention to adopt the Medicare Part D Manual's full approach to "chemically distinct" drugs, including the availability of multiple dosage forms and strengths, the Department could limit inclusion of drugs that are important for women. For example, some plans have already attempted to limit access to the contraceptive vaginal ring by claiming that it has the same progestin as covered oral contraceptives and that women can simply use the oral contraceptive as an alternative. However, the ring provides a unique route of administration as compared to oral contraceptives. To avoid this type of adverse effect, in the final rule, the Department must clarify its intent to adopt the full approach to "chemically distinct" in the Medicare Part D Manual, not only the portion of the concept described in the guidance on "EHB Benchmark Drug List Counts."

Ensure Enrollees Have Access to Clinically Appropriate Drugs

The Department should clarify in § 156.120(c) of the final regulation that plans must have procedures in place that ensure enrollees have *access* to clinically appropriate drugs. Although the preamble includes a statement of this standard, the proposed rule does not.[41] Instead, the proposed rule states, "A health plan providing essential health benefits must have procedures in place that *allow an enrollee to request* clinically appropriate drugs not covered by the health plan."[42] (emphasis added) It is vital that enrollees not just be able to request clinically appropriate drugs, but that they be ensured access to those clinically appropriate drugs. When a provider determines that a specific drug is medically necessary to meet a patient's needs, based on the best scientific evidence available, onerous procedures should not come between the patient and their provider's determination. The Department recognized this important principle in the preamble to § 156.120, and should clarify this requirement in § 156.120(c).

In addition, we strongly urge the Department to gather data on the number of individuals requesting clinically appropriate drugs that are not otherwise covered, what drugs were requested, and what drugs were approved. The Department should review this data to improve prescription drug access and is vital to improving the EHB to ensure women have access to the medications they need.

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[40] Ctrs. for Consumer Info. and Insurance Oversight, Ctrs. for Medicare & Medicaid Srvcs., Dep't of Health & Human Srvcs., EHB Benchmark Drug List Count (2012), *available at* http://cciio.cms.gov/resources/files/ehb-benchmark-drug-list-count.pdf.

[41] Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation, 77 Fed. Reg. at 70,652 ("We propose that a plan offering EHB have procedures in place to *ensure that enrollees have access to* clinically appropriate drugs that are prescribed by a provider but are not included on the plan's drug list, which is consistent with private plan practice today." (emphasis added)).

[42] Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation, 77 Fed. Reg. at 70,670.

Require States to Reimburse QHP Issuers Directly to Defray the Cost of Additional Required Benefits

We ask that the Department require states to reimburse QHPs directly for any state-required benefits that are in excess of EHB. The statute requires that states must make the payments "(I) to an individual enrolled in a qualified health plan offered in such State; or (II) on behalf of an individual described in subclause (I) directly to the qualified health plan in which such individual is enrolled."[43] There is no language in the statute requiring states to provide both options for payments; rather the statute is laying out two possible payment options. The use of "or" provides flexibility to the Department to allow only one of the options.

We are concerned that payments made directly to an enrollee may be confusing, misleading, unduly burdensome, and limit enrollees' ability to access services. We are also concerned it would be economically burdensome if the premium is due before the reimbursement is received or if an individual has to pay a check cashing fee to cash the reimbursement check. In addition, enrollees could easily mistake the payment for state-required benefits with medical loss ratio rebates, or otherwise keep the payment without realizing they should use this payment to cover part of their QHP premium. Given the number of insurance market changes brought about by the ACA and the fact that some women and families will be entering this market for the first time, we encourage the Department to streamline as many administrative complexities as possible. Requiring states to reimburse QHPs directly would eliminate the risk of an enrollee receiving a payment upfront, failing to forward this payment to their QHP, and incurring a new financial liability.

Define EHB Categories and Scope of Coverage

We remain concerned that the benchmark approach proposed by the Department does not sufficiently define the scope of coverage in any statutorily required EHB category. We are particularly concerned about the lack of definitions or standards for maternity care. Because plans in today's market do not compare their covered services to EHB categories, it is unclear how benchmark plans can be analyzed to ensure compliance with the ACA. For example, base-benchmark plans may include "coverage of maternity services," but the plan documents do not specify precisely which services constitute maternity coverage or provide details on the scope of coverage including duration and frequency of services that are covered as part of maternity care. Further, the benefits and limits described by the Center for Consumer Information and Insurance Oversight (CCIIO) for each state's proposed benchmark plan do not provide details on the scope of coverage, making it difficult to compare or recommend benchmark plan options.[44]

The Secretary must provide clear standards for what must be covered under the 10 categories as required by section 1302 (b)(1) and 1302 (b)(4)(C) to ensure a standard from which to compare proposed state benchmark plans. 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 women have access to comprehensive coverage—especially for conditions that are not covered, or are covered inadequately in the individual and small group market.

[43] Patient Protection and Affordable Care Act, § 1311(d)(3)(B)(ii).

[44] *See* Ctr. for Consumer Info. and Ins. Oversight, U.S. Dep't of Health & Human Serv., Additional Information on Proposed State Essential Health Benefits Benchmark Plans, http://cciio.cms.gov/resources/data/ehb.html.

A lack of clear definitions further complicates the substitution and supplementation methodology described in the proposed rule. The Department must define the scope of coverage in each EHB category to create adequacy standards to guide the supplementation methodology and balance requirements. Additionally, the final rule should specify that inadequate, and not just missing, coverage in a benchmark category requires supplementation. The Department must also ensure that the adoption of supplemental coverage does not result in a discriminatory benchmark.

Ensure Balance Among EHB Categories Promotes Robust Coverage, and Prohibit Reduction of Benefits

In the preamble, the Department indicates that a base-benchmark plan that has been supplemented to cover all 10 EHB categories must meet standards for non-discrimination and balance.[45] *After* meeting these requirements, it would be considered the EHB-benchmark plan (emphasis added). This language indicates that *only* when categories are balanced does the base-benchmark plan meet the requirements for EHB. The Department must therefore review every EHB-benchmark plan to ensure that the plan meets the balance requirements as necessary.

The final rule should clarify in §156.110(e) that the requirement for balance among EHB categories ensures robust coverage in each benefit category and that balance requirements cannot be used to lower other categories to a lesser denominator if one or more categories lacks robust coverage. Adjustments that lower coverage in robust benefit categories to achieve balance with inadequate coverage in another category would result in a proposed benchmark that no longer features the scope of benefits and services at the level of a typical employer plan should be prohibited. We recommend that the final regulations specify that balance cannot be used to reduce coverage across categories, regardless of which benefit category provides inadequate coverage.

Expressly State that Plans May Not Exclude Enrollees from An Entire EHB Category

The preamble's discussion of § 156.115 states, "With the exception of the EHB category of coverage for pediatric services, a plan may not exclude an enrollee from coverage in an entire EHB category covered by the plan. For example, a plan may not exclude dependent children from the category of maternity and newborn coverage."[46] We thank the Secretary for this clarification with respect to maternity coverage. It is important that the final rule include this language from the preamble, because many insurance plans currently exclude dependent children from maternity coverage. For example, Washington State's proposed benchmark plan, the Regence Innova small employer plan, excludes maternity coverage for dependent daughters.[47] The preamble correctly indicates that the ACA does not allow any such exclusion from EHB.[48] The ACA allows young women to have health coverage under a parents' plan until age 26, therefore it is even more important that non-spousal dependents have access to the full EHB,

[45] *See* Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation, 77 Fed. Reg. at 70,649-50.
[46] Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation, 77 Fed. Reg. at 70,651.
[47] Ctr. for Consumer Info. and Ins. Oversight, U.S. Dep't of Health & Human Serv., Proposed Washington EHB Benchmark Plan, *available at* http://cciio.cms.gov/resources/EHBBenchmark/proposed-ehb-benchmark-plan-washington.pdf.
[48] Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation, 77 Fed. Reg. at 70,651. It should also be noted that excluding dependents from maternity coverage violates § 1557 of the ACA, which prohibits sex discrimination in programs or activities that receive federal assistance, are administered by an Executive agency, or are established under Title I of the ACA. *See* Patient Protection and Affordable Care Act, § 1557.

including maternity.[49] We ask that the Department expressly state in the text of the final rule that plans may not exclude enrollees from an entire category of a plan (with the exception of the pediatric category), and that maternity coverage must be available to all enrollees, regardless of dependent status.

Clarify the Enforcement Process

We thank the Department for specifying the enforcement process that will be used to ensure that plans adhere to many EHB requirements.[50] The ability of the Department to intervene when it determines that a state is not adequately enforcing the provision is an important component of a strong enforcement process. There are several clarifications that the Department should make to ensure that enforcement is happening at the state level and that if it is not, the Department is notified and able to step in quickly. While the process laid out in 45 C.F.R. 150 provides several sources of information that could trigger an investigation, including complaints, we ask the Department to provide a publicly advertised and easily accessible format through which consumers and advocates can submit complaints when a state is not enforcing provisions of the ACA, including the EHB. Additionally, we ask that the Department clarify that merely passing conforming or enforcement legislation is not adequate to prove enforcement. A state must actively oversee and enforce all aspects of § 1302. The Department should develop clear standards that the Center for Consumer Information and Insurance Oversight (CCIIO) can use to determine if a state is actively enforcing the provision. The Department should also clarify that it will step in if a state is failing to enforce any part of § 1302, even if other parts of the provision are being actively enforced.

As organizations committed to ensuring women have access to the full range of reproductive health services, we appreciate the opportunity to comment on the development of the essential health benefits. Thank you for your consideration of our concerns.

Sincerely,

American Association of University Women (AAUW)
American Civil Liberties Union
American Congress of Obstetricians and Gynecologists
American Medical Students Association
Center for Reproductive Rights
NARAL Pro-Choice America
National Abortion Federation
National Council of Jewish Women
National Family Planning & Reproductive Health Association
National Partnership for Women & Families

[49] Patient Protection and Affordable Care Act, § 1001, (requiring extension of dependent coverage to adult dependent children up to age 26). This extension allows adult children to remain on their parents' health plan regardless of whether they are married, living with their parent, financially dependent on their parent, attending school, or are eligible for their employer's plan. *See* Healthcare.gov, Young Adult Coverage (July 6, 2012), http://www.healthcare.gov/law/features/choices/young-adult-coverage/index.html.

[50] We reiterate the concerns expressed in "*Make Clear the Federal Role in Enforcing the Nondiscrimination Provisions*" above that the enforcement mechanisms of Section 1557 are inadequately described in the proposed rule and refer the Department to that section to see our concerns.

National Women's Law Center
Physicians for Reproductive Choice and Health
Planned Parenthood Federation of America
Raising Women's Voices for the Health Care We Need
Religious Coalition for Reproductive Choice