December 26, 2012

VIA ELECTRONIC SUBMISSION

Centers for Medicare & Medicaid Services
Department of Health and Human Services
PO Box 8016
Baltimore, MD 21244-8016

Attention: Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation

Dear Sir/Madam:

We welcome the regulatory guidance provided to states and policy makers on Essential Health Benefits ("EHB") in the *Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation* regulation. We appreciate the opportunity to provide comments on these proposed rules. The National Health Law Program (NHeLP) protects and advances the health rights of low income and underserved individuals. The oldest non-profit of its kind, NHeLP advocates, educates and litigates at the federal and state levels.

We have written to you previously about the EHB standard, particularly regarding our concern that under the law this benefits package must be based on a strong national standard for coverage, developed and implemented by HHS, not states or issuers. Our previous comments also articulate the importance of having a robust and comprehensive national standard for EHB that meets the needs of the population served. Our previous comments are available online and we incorporate them by reference to the comments below.[1]

Fundamental Structural Flaw

Setting aside our concerns with a state-selected benchmarking system, the proposed rule still suffers from a fundamental flaw: **the EHB regulation fails to implement the legal requirement to provide coverage for "the items and services covered within"**

[1] Comments available at: http://www.healthlaw.org/images/stories/nhelp_ehb%20comments_1.31.12_final.pdf.

the ten statutory EHB categories. While we agree that the ACA sets typical employer coverage as the baseline for the EHB standard, it then layers on the *additional* requirement to ensure coverage of "the items and services covered within" the ten statutory categories. The proposed regulation provides that this coverage requirement is met by "any" coverage within one of the ten benchmark plans available in the state. This violates the ACA. The ACA does not only require coverage of the category; it also requires that coverage to include "items and services covered within the categories." Thus, HHS must ensure that EHB coverage is based on the typical employer coverage, that the coverage also includes ten additional categories, and that that coverage includes items and services adequate to meet the needs of the population to be insured.[2]

HHS' interpretation paradoxically suggests that Congress intended that the EHB should include typical employer coverage levels for specific services, such as habilitative services, which typical employers rarely cover. The EHB regulation then attempts to cure this nonsensical outcome by creating special processes to deal with each of the services that typical employers rarely cover.

The fundamental problem in HHS' approach is that the regulation misinterprets the EHB requirement, ultimately leading to a policy that contradicts legislative language and intent and that will lead to insufficient access to health care services for individuals. HHS must correct this flawed framework and, consistent with the ACA, create a baseline typical employer benefit and require it to be expanded with meaningful coverage in each of the ten statutory categories.

Serious Procedural Concerns

We have grave concerns with the 30-day review process HHS is using to implement these regulations. We are cognizant of the extremely challenging timeline for HHS to develop and implement the EHB standard prior to state preparations for 2014. (We note, however, that this is to some extent a self-inflicted problem, resulting from HHS' decision to ignore the ACA requirement for a national EHB standard and instead pursue a complex state benchmarking system.)

Yet, the proposed rule creates an impossible process for stakeholders. The rule requests that advocates analyze and provide comment on the selected benchmark for their state, as well as the non-selected benchmarks since the states may still change their selection up to the last day of the comment period. Furthermore, HHS requests (as it must) that stakeholders review each base-benchmark plan option as it might be supplemented by each of the other benchmark options and provide comment on all possible supplementing options. With ten benchmarks serving as potential base benchmark plans and supplementing plans, this yields a

[2] We note that while HHS' preamble to the proposed regulation implies, at 77 Fed. Reg. 70646, that this regulation might not apply to Medicaid benchmarks or the Basic Health Plan, we currently have no legal basis to believe it does not apply. If anything, recent HHS guidance on the content of Medicaid benchmarks indicates Medicaid benchmarks will explicitly rely on the EHB standard (except where there is a direct conflict with Medicaid law). As such, we must assume for the purposes of this regulation that Medicaid and BHP populations may in fact be impacted, and are part of the vulnerable population that will depend upon the EHB standard set forth in this regulation. Our comment therefore considers the EHB rule's impact on Medicaid and BHP populations, in addition to "individual and small group markets."

total of ninety (90) different combinations a stakeholder would need to consider for each of the ten EHB categories.

We commend HHS for providing information regarding each state's selected base benchmark plan in Appendix A. However, it requires significant additional research to clearly understand the specifics of these plans. Furthermore, for the other nine plans in each state that are not listed in Appendix A, advocates may have little information, if any. Yet, advocates are asked to carefully review and provide comments within a 30 day comment period spanning two major national holidays. This is an unreasonable procedural requirement.

To address these procedural deficiencies, we recommend that HHS extend the comment period to 90 days total and make publicly available information for each state's benchmark options, including specific services covered and applicable coverage limits, in an easy-to-use, comparison-friendly format.

Specific Comments

§ 155.170 Additional Required Benefits

We commend HHS for proposing to include state-required benefits enacted on or before December 31, 2011 as part of the EHB. We further appreciate the clarification that this policy applies to state mandates enacted prior to 2012 which are not effective until a later date. These policies will ensure many individuals continue to receive important health benefits and minimize disruption and costs for states as they will not be required to defray the costs of these state-required benefits. We recommend that HHS reverse the decision to treat differently state mandates specific to provider types, cost-sharing, or reimbursement methods, as this may lead to complications and costs for states that have such mandates in effect.

We urge HHS to create a process by which *new* state-required benefits may be added to the EHB with no additional cost to the state. We recognize that HHS cannot allow states complete discretion to add mandates to the EHB standard given the state incentives and federal costs. There should, however, be some public process by which new mandates that respond to important market coverage gaps and meet important health goals in the state can be included as EHB. HHS should develop a controlled and limited process by which states can demonstrate the significance of including new state-required benefits as EHB at no extra cost to the state.

§ 155.170(b)

For state-required benefits in addition to EHB, we seek clarity in how states will be required to defray the costs associated with these benefits. The NPRM proposes that states will defray these costs by either making payments to the individual enrollee or to the issuer on behalf of the enrollee. This language is open to the interpretation that individual enrollees may sometimes first pay additional costs associated with these benefits, after which the state will make payments to the individual enrollee reimbursing this cost. We urge HHS to clarify this language and require that states defray these costs by making payments directly to the issuer (who should be the party at risk) on behalf of enrollees.

RECOMMENDATION: We recommend amending § 155.170(b) as follows:

> § 155.170(b) Payments. The state must make payments to defray the cost of additional required benefits specified in paragraph (a) of this section ***directly to the QHP issuer on behalf of an individual enrollee, as defined in § 155.20 of this subchapter.*** ~~to one of the following:~~
>
> ~~(1) To an individual enrollee, as defined in § 155.20 of this subchapter; or~~
> ~~(2) Directly to the QHP issuer on behalf of the individual described in paragraph (b)(1) of this section.~~

§ 155.170(c)

HHS proposes that qualified health plan (QHP) issuers will quantify the costs attributable to each additional required benefit. We commend the requirement that these calculations be performed in accordance with generally accepted actuarial principles and methodologies, conducted by a member of the American Academy of Actuaries, and reported to the Exchange. This proposed process for calculating and reporting the cost of additional required benefits reduces the likelihood that QHP issuers will overstate the costs associated with these additional required benefits and will provide an important opportunity for oversight by the Exchange. As HHS notes, QHP issuers will have access to claims data, utilization rates, and other trends in benefits access.

We urge HHS to require QHP issuers not only report the cost calculation but also to include the underlying data on which that calculation is based. This will ensure an additional layer of accountability in these cost estimates. Importantly, this data is critical for monitoring discriminatory benefit design and collecting demographic data required to measure and identify health disparities and other gaps in coverage. This data can serve multiple purposes, and to the extent issuers are collecting and analyzing it for purposes of this cost calculation, the Exchange should also be able to utilize this data for other purposes.

HHS seeks comment as to whether the state should make payments based on the statewide average costs for additional state-required benefits, or based on each QHPs actual cost. We recommend that the state make payments based on each QHPs actual cost. This will ensure that QHPs do not engage in “balance-billing” to the extent that the statewide average cost is lower than a particular QHPs cost calculation.

RECOMMENDATION: We recommend amending § 155.170(c) by adding the following new subclause:

> ***(3) All data relied upon by the QHP issuer to calculate the cost of additional required benefits shall be reported to the Exchange.***

§ 156.20 Definitions

NHeLP believes that one of the Exchanges' greatest problems will be the inability of consumers to understand the value of plans or how to compare them. Consumers will not only have varying levels of copays, co-insurance, deductibles, and annual limits, but they will also have to navigate the potential myriad of ways that plans may actually define and apply these terms. NHeLP strongly recommends that HHS standardize these terms and their application so that individuals understand their options and make informed selections.

Specifically, NHeLP recommends:

- HHS implement a standardized definition of the terms "copay," "coinsurance," "deductible," along with "annual limitation on cost-sharing."
- HHS implement, or require each state to implement, maximum reasonable limits on "copays" and "co-insurance." Maximum copay limits could be scaled and a maximum set for services from $0-10, maximums on services from $11-50, maximums on services from $51-100, etc. Maximum coinsurance could be set at a fixed amount per tier, such as 30% for silver, 20% for gold, etc. (Copay and coinsurance limits are also an important part of our actuarial value comments below at §156.130(a)).
- HHS implement, or require each state to implement, a standardized way that deductibles will apply. Standardization should clarify which types of services the deductible applies to and how the deductible interacts with the other cost-sharing limits.
- HHS require standardization of counting annual limits such that, for all services, all copay, coinsurance, and deductible payments count towards the annual limit.

To the extent HHS (or states) creates any exceptions to the default rules for out-of-network providers, the exceptions should be limited as per our comments below at § 156.130(c).

HHS must implement these requirements to help end the confusion consumers face regarding their potential financial exposure for health service costs. One survey of workers in various employer HMO plans found that numerous cost-sharing payments did not count toward their out-of-pocket maximum: 50% of workers could not count co-pays for office visits, 72% could not count prescription drug expenses, and 35% could not even count their deductible expenses.[3] Employees with PPOs fared even worse.

If, contrary to our recommendation, HHS does not standardize cost-sharing terms and application thereof (what counts towards a deductible, what counts towards and annual limit, etc.), then NHeLP recommends that HHS require that plans clearly disclose on plan materials and the Summary of Benefits which services/charges apply to the deductible and annual limit, and which do not.

[3] Henry J Kaiser Family Foundation & Health Research & Educational Trust. *Employer Health Benefits: 2011 Annual Survey*, Menlo Park, CA and Chicago, IL, September 2011, at 118. Available at: http://ehbs.kff.org/pdf/2011/8225.pdf.

Furthermore, the proposed rule at 77 CFR 73169 ("Notice of Benefit and Payment Procedures") states that new state-mandated benefits will *not* be part of the EHB, and presumably expenditures for new mandates will not count towards an individual's cost-sharing limits. (We have recommended above at § 155.170 that HHS develop a mechanism for states to fold worthy new benefit mandates into their EHB). NHeLP recommends that HHS clarify that all EHB cost-sharing limit rules apply to these mandates. This is the only fair outcome for a consumer subject to a mandate.

§ 156.100 State selection of benchmark

This section of the proposed rule codifies the benchmark approach announced in the 2011 EHB Bulletin. NHeLP strongly opposes this benchmark approach, as it contravenes the clear directive in the ACA requiring the Secretary of HHS to define the EHB. (*See* note 1)

HHS suggests that the current EHB standard will be revisited for subsequent years (2016 and beyond) and otherwise seeks comment on the process it should use in updating the EHB over time. NHeLP strongly recommends that HHS use lessons learned in 2014 and 2015 to develop a unified national EHB standard for 2016 and beyond. This would bring the EHB standard into compliance with the text of the ACA. The current proposed EHB standard will lead to 51 different EHB definitions and allow further issuer flexibility within those 51 definitions. Monitoring benefit design, access to services, denials, complaints, adherence to non-discrimination provisions, and appropriate coverage among the ten EHB categories will be administratively complex—perhaps impossible—under the proposed scheme.

The proposed approach is likely to be fraught with denials of coverage for services that people truly need, complaints regarding lack of adequate coverage in mandatory categories, and general dissatisfaction with the scope of coverage. If HHS compiles appropriate data on these problems in 2014 and 2015, it will allow HHS to design a more responsive EHB package for 2016 and beyond. During the 2014 and 2015 benefit years, states should be required to report to HHS on a set of federally identified data points related to the EHB. Responsive to a robust public comment process, these data points should include:

- reporting on sufficiency of coverage in all 10 EHB categories, including data on denials of coverage and complaints regarding non-coverage of certain services (including the outcomes of all denials and complaints (appeals/overrides);
- standardized surveys of all EHB recipients with both quantitative and qualitative rating and reporting to assist in determining whether enrollees are facing difficulty accessing coverage due to cost, unlawful practices, or other barriers;
- field testing all surveys with a variety of audiences, including low-income, LEP, and vulnerable populations to ensure that comprehension and usability is maximized;
- ensuring that all major stakeholders, including clinicians, administrators, and consumers, have an opportunity to provide feedback via these surveys; and
- making all information collected and reported publicly available.

Whether HHS develops a national EHB standard in 2016, and particularly if HHS maintains a state-defined methodology, HHS must develop a process for updating the EHB which includes

public input. This requires advance notice of the EHB proposals, sufficient resources to meaningfully evaluate the alternatives, and a robust comment process.

We commend HHS' stated intent to use the enforcement processes and standards established in 45 C.F.R. § 150 to ensure plans adhere to the EHB standards. HHS should be ready to take enforcement actions as provided in §§ 2723 and 2761 of the Public Health Service Act (PHSA) and should use data collected (discussed below) to identify the need for enforcement actions. We believe that HHS will need to be proactive about monitoring and enforcement given the diversity of states and issuers with flexibility to alter the EHB standard.

We recommend against using the largest small group plan as the base benchmark default. We recommend instead that HHS set the default as any of the largest of the other three base benchmark options (federal employee, state employee, or commercial HMO). This ensures better coverage and promotes uniformity with Medicaid (i.e., § 1937 benchmarks).

RECOMMENDATIONS:

- If HHS finalizes the proposed state benchmarking framework (which we oppose) for the 2014 and 2015 benefit years, we strongly urge that HHS use this system only as a transition period, taking the lessons learned to implement a uniform national standard (*see* note 1). We recommend that HHS clarify that the national standard is the EHB minimum and that states can expand upon it.

- In all cases, HHS should develop a process for updating the EHB standard which includes robust consumer stakeholder input.

- HHS should set the default base benchmark plan as any of the largest of the other three base benchmark options (federal employee, state employee, or commercial HMO).

§ 156.105 Determination of EHB for multi-state plans

NHeLP will review and provide comment on the proposed standards announced by the U.S. Office of Personnel Management for EHB coverage in multi-state plans. We note this is yet another problematic consequence of HHS' noncompliance with the ACA's requirement to create a uniform national standard.

§ 156.110 EHB-benchmark plan standards

§ 156.110(a)

Proposed § 156.110(a) requires coverage of the ten statutory categories. The basic structural problem with this proposed regulation is evidenced in the failure of the regulation to require coverage of "the items and services covered within the categories" as mandated by the statute. NHeLP recommends adding the statutory language and implementing the statute so as to cover a meaningful set of items and services in each category.

HHS' interpretation of "pediatric services" to mean services for individuals under the age of 19 years is problematic and could mean that many adolescents are unable to access basic health

services meeting their unique needs.[4] We strongly urge HHS to revise this policy such that "pediatric services" include services for individuals up to and including age 21. This is consistent with federal standards defining a child in the Medicaid program. It also helps HHS achieve the goal of defining an age so as to ensure comprehensive and consistent treatment in every state. If HHS fails to improve this standard per our recommendation, we urge HHS to at a minimum retain the proposed state flexibility to improve the standard.

RECOMMENDATIONS: We recommend amending § 156.110(a) as follows:

> (a) *EHB coverage.* Provide coverage of at least the following categories of benefits**, and the items and services covered within the categories**:

§ 156.110(b)

The ACA defines the EHB package as coverage offered by a typical employer *except* that it also must cover ten categories of coverage. To the extent that a base-benchmark plan is completely missing coverage one of the required categories, the proposed HHS approach correctly recognizes that it must be supplemented to include coverage of that category. However, the proposed policy fails to comply with the statute for two reasons:

1. The proposed policy only requires supplementation if a base-benchmark plan is not providing *any* coverage in one or more of the categories. A base benchmark that is grossly inadequate however, would not need to be supplemented. For example, if the "maternity and newborn care" benefit under a proposed benchmark included one 5-minute nutrition consultation and no other benefit, it would adequately meet HHS' proposed EHB standard. Similarly unacceptable examples could be proposed for the other nine statutory categories. This flies in the face of the statutory intent, which was precisely to ensure *adequate* coverage in these ten areas regardless of the shortcomings of the insurance market.

2. Even when the base benchmark plan does not in fact include *any* coverage, and therefore supplementation is triggered, the methodology for supplementation proposed by HHS is equally problematic. To begin with, § 156.110(b)(1) does not even require the supplementing plan to have "any" coverage in the category – it merely says that if there is no coverage on the base benchmark then the full benefit of another benchmark (which may also contain nothing) should be imported. Assuming (as we do) that it was HHS' intent that the supplementing plan must in fact have *some* coverage in the category, the proposed policy still fails because the supplementing plan could include coverage that is grossly inadequate (as per our example in #1).

To comply with the ACA, HHS must create an objective minimum standard for coverage of each of the ten statutory categories based on adequate coverage of the category. We recognize that HHS does not need to cover "all" services in a category, but HHS' proposed policy is inadequate. HHS should define an "adequate" standard for the categories and require coverage of that minimum. Congress included the ten statutory categories because they are

[4] For more on meeting adolescent health needs, see NHeLP Issue Brief, *Addressing Adolescent Health: The Role of Medicaid, CHIP, and the ACA* (Nov. 2012).

important to health care, and Congress recognized that this coverage was "essential" regardless of the typical employer package. As we have explained in our introduction, it simply makes no sense for the ACA to list these critical services but then require nothing more than bare minimal coverage.

RECOMMENDATION: HHS must require every EHB-benchmark plan to include *adequate* coverage in all ten categories. "Adequate" should be defined by the Secretary by reference to some objective standards for each category and should be based on the services needed to meet the needs of the covered populations.

We recommend amending § 156.110(b) as follows:

> Coverage in each benefit category. A base-benchmark plan not providing **adequate** ~~any~~ coverage in one or more of the categories described in (a) of this section, must be supplemented as follows:
>
> > (1) General supplementation methodology. A base-benchmark plan that does not include ***adequate coverage of*** items or services within one or more of the categories described in paragraph (a) of this section must be supplemented **until the coverage is determined adequate** ~~by the addition of the entire category of such benefits offered under any other benchmark plan option described in § 156.110(a) of this subpart unless otherwise described in this subsection~~.
> >
> > **(i) Adequate coverage shall be defined by the Secretary, based on objective criteria which ensure the coverage meets the needs of the covered population.**

§ 156.110(c)

The proposed policy for supplementing the default base-benchmark plan, to be carried out by HHS, suffers from the same flaws discussed above for supplementation generally; it fails to supplement inadequate coverage, and when supplementing may only supplement with inadequate coverage. HHS should develop a default supplementation methodology requiring adequate coverage of each statutory category, as per our recommendations for § 156.110(b).

RECOMMENDATION: We recommend amending § 156.110(c) as follows:

> *Supplementing the default base-benchmark plan*. A default base-benchmark plan as defined in § 156.100(c) of this subpart that lacks ***adequate coverage in*** any categories of essential health benefits will be supplemented by HHS **until the coverage is determined adequate, as defined in § 156.110(b)(1)(i)** ~~in the following order, to the extent any of the plans offer benefits in the missing EHB category:~~
>
> ***… [delete subsections (1)-(6)].***

§ 156.110(d)

We commend HHS for reiterating that EHB-benchmark plans must not include discriminatory benefit designs and referencing the standards in § 156.125. (Our concerns and comments regarding the non-discrimination standards appear below in § 156.125).

§ 156.110(e)

We commend this requirement for balance, but we do not believe HHS has provided meaningful criteria for evaluating compliance. Given the benchmarking system, exacerbated by state and issuer flexibilities, we believe enforcement of this requirement will be arduous if not impossible. We note that requiring objective minimum standards in the ten statutory categories effectively eliminates this concern.

§ 156.110(f)

While we appreciate HHS' goal of encouraging state innovation in the development of a definition of habilitative services, the proposed approach for supplementing habilitative coverage is inadequate. Until recently, this category of services has been historically ignored in health coverage to the serious detriment many vulnerable individuals living with chronic illnesses and/or disabilities.

By requiring that rehabilitative and habilitative services and devices be covered as one of the ten mandatory EHB categories, Congress clearly indicated its intent to meet the health needs of individuals with functional limitations following illness, injury, disability, or due to a chronic condition. Therefore, as per the framework we have recommended above, we suggest that HHS develop an objective minimum standard for habilitative services based on "adequate coverage" of the services. States and insures can then be encouraged to innovate by allowing flexibility to add more than the minimum "adequate" habilitative services package in ways that may improve care for individuals or save money by avoiding institutionalization, hospitalization, or other more expensive interventions.

RECOMMENDATION: We recommend amending § 156.110(f) as follows:

> *Determining habilitative services*. If the base-benchmark plan does not include **adequate** coverage for habilitative services, **the plan must be supplemented until it is determined to cover at least the adequate habilitative services as defined by the Secretary of HHS. States may determine that additional services should be included in the category** ~~the state may determine which services are included in that category.~~

§ 156.115 Provision of EHB

§ 156.115(a)(1)

In this section, HHS suggests that insurers will be considered in compliance with EHB coverage requirements so long as they provide benefits that are "substantially equal" to the EHB-benchmark plan. The use of "substantially equal" terminology creates an additional loosening of the EHB standard which has no basis in law and threatens to further weaken an EHB standard. This concern is exacerbated by the fact that HHS provides no guidance or

framework for analyzing whether covered benefits or limits on coverage meet the "substantially equal" standard. NHeLP recommends that HHS eliminate this language. Failing to do that, HHS must set a strong standard for "substantial" equivalence and will need to monitor this proactively.

RECOMMENDATION: We recommend amending § 156.115(a)(1) as follows:

(a) Provision of EHB means that a health plan provides benefits that—
(1) Are ~~substantially~~ equal to the EHB benchmark plan including:

§ 156.115(a)(2)

NHeLP commends the proposed language requiring that mental health and substance use disorder services, including behavioral health treatment services, comply with the parity standards set forth in 42 C.F.R. § 146.136. Mental health, behavioral health and substance abuse conditions ("MH/BH/SA") services have been historically excluded in private market health coverage, and parity is an important step. However, parity itself is not sufficient to ensure coverage and, as a practical matter, has proven difficult to enforce. NHeLP recommends that in addition to parity requirements there should be comprehensive coverage of screening, assessment and treatment of MH/BH/SA conditions to meet the ACA requirement for coverage.

RECOMMENDATION: In addition to requiring parity, HHS should require that the following essential services for people with MH/BH/SA conditions be covered:

- Health Homes;
- Prevention and Wellness Services;
- Engagement Services;
- Outpatient and Outpatient Clinic Services;
- Community Supports and Recovery Services;
- Intensive (Community) Support Services;
- Other Living Supports; and
- Acute Intensive Services

§ 156.115(a)(3)

NHeLP commends the proposed rule's explicit application of PHSA § 2713 to the EHB. With certain exemptions, § 2713 requires group health plans and issuers offering group or individual coverage to offer evidence-based preventive health services without cost-sharing. Recognizing that some EHB-benchmark plan benefits may be based on grandfathered plans not subject to § 2713, we thank HHS for including this regulation in the proposed rule. In addition, we appreciate that HHS for clarified in § 156.130(f) that nothing in the EHB rule will derogate the cost-sharing protections for plans subject to the § 2713 requirements.

We commend the proposed rule's clear inclusion of all § 2713 preventive *services* in § 156.115. We seek the same explicit inclusion of the § 2713 *cost-sharing protections in the*

EHB as it applies to Medicaid.[5] Without this amendment, any remaining ambiguity could result in some of the neediest enrollees being subjected to cost-sharing for these services when higher income populations in the group and individual markets are not. Cost-sharing is shown to reduce the use of preventive health services and is therefore antithetical to the ACA's commitment to ensuring increased access to and utilization of preventive care.[6] It is critical, therefore, that the robust § 2713 provision requiring coverage of preventive services with no cost-sharing be wholly and explicitly integrated into all health coverage standards.

Second, the critical reproductive services required under § 2713(a)(4) for women should extend to men, where appropriate. Men should also be able to gain access to annual counseling and screening for sexually transmitted infections and HIV/AIDS, as well as FDA-approved contraceptive methods (e.g., condoms), sterilization procedures, and family planning education and counseling. We ask that HHS make the application of these services to men explicit in the EHB standard.

§ 156.115(a)(4)

NHeLP urges HHS to eliminate the proposed additional flexibility in § 156.115(a)(4) allowing insurers to define habilitative services in certain circumstances. The proposed rule would allow a plan to either provide parity by covering habilitative services that are similar in scope, amount, and duration to benefits covered for rehabilitative services, or to independently design a coverage standard for habilitative services that must be reported to HHS. Neither of these approaches adequately implements the statutory requirement to cover habilitative services for the following reasons:

- Setting parity with rehabilitative services as a standard is insufficient because there is no certainty that there is an adequate level of coverage in rehabilitative services in the first place.
- The proposed approach also fails because comparison to rehabilitative services is not appropriate. Rehabilitative services are designed to enable a person to retain or regain some prior level of function or to maintain or prevent deterioration of a function or skill, while habilitative services focus on attaining function or skill that the individual has not previously possessed. Both services are critical, serve different purposes, and should be meaningfully covered as required by the ACA.
- Allowing insurer flexibility with regard to habilitative services is also not a valid implementation of the statutory requirement to cover these services. We have grave concerns with insurer flexibility in defining a coverage standard for habilitative services. The proposed rule indicates an extremely hands-off approach in monitoring insurer decisions, with only the definitions reported to HHS, and no language suggesting that HHS will review, comment on, or otherwise approve the standard defined by the insurer. HHS must not abdicate its role as the sole statutory authority in defining the EHB coverage standard.

[5] To the extent that this rule will form the foundation of the EHB in Medicaid benchmark and Basic Health coverage packages, it is important that the PHSA § 2713 cost-sharing protection be explicitly included within § 156.115(a)(3) of this final rule. *See* note 1.
[6] Inst. Of Med., Clinical Preventive Services For Women: Closing The Gaps 109 (2011).

HHS has already defined habiliatitive services at § 156.110(f), and instead of allowing issuers flexibility should require coverage of the § 156.110(f) standard. (We have earlier recommended that this standard should require adequate coverage, as defined by the Secretary, with state flexibility to provide more.)

RECOMMENDATION: We recommend deleting § 156.115(a)(4) and using only the recommended language for § 156.110(f) (above).

§ 156.115(b)

HHS proposes explicit insurer flexibility to substitute benefits *within* a category of services so long as they meet certain actuarial equivalence requirements. Although NHeLP disapproves of any such substitution policy, we commend HHS for at least limiting the substitutions *within* categories, as opposed to *across* categories, which would be even more problematic.

Nonetheless, we urge HHS to eliminate any provision for issuer flexibility. This authority completely undercuts the letter and intent of the ACA in a number of areas, including nondiscrimination and meaningful coverage of the ten statutory categories. Allowing insurers this flexibility to substitute services creates dangerous potential for discrimination or insurance rating through benefit design. The EHB standard should serve as a floor, not a ceiling, such that issuers have flexibility to add services but not substitute them.

We commend the following protections created by HHS:

- Exclusion of drug coverage from substitution;
- State flexibility to limit or eliminate substitution; and
- General prohibition against plans excluding enrollees from any category of coverage.

However, the final requirement appears only in the preamble to the regulation (77 Fed. Reg. 70651). We recommend explicitly including it in the regulation at § 156.115(e). Moreover, the preamble's prohibition against excluding dependent children from the category of maternity and newborn coverage is critical and should be included in the regulatory text. *Id.*

RECOMMENDATIONS: We recommend deleting § 156.115(b) and instead requiring that EHB-benchmark standards serve as a minimum for states or insurers to add to, but not reduce, the scope of services. We urge HHS to affirm that insurers should have no role in setting or altering the EHB standard, under any conditions.

We also recommend adding the following language:

> **§ 156.115(e) A plan may not exclude an enrollee, including a dependent, from coverage in an entire EHB category covered by the plan.**

§ 156.115(c)

NHeLP strongly opposes the proposed section § 115.115(c) for several reasons. First, while the ACA includes some limitations and procedural requirements pertaining to insurance

coverage of abortion for QHPs, HHS has impermissibly proposed to extend the provisions in ACA § 1303(a)(1) to health insurance issuers that offer non-grandfathered coverage in the individual or small group market. The ACA restricts the use of federal premium and cost-sharing support funding for abortion services for individuals enrolled in QHPs offered through the Exchanges and in BHP programs. *See* ACA § 1303(a)(1) (Exchange); ACA § 1331(d)(4) (BHP). Nothing in the ACA restricts abortion coverage by health plans outside of this very specific context. *See, e.g.*, ACA § 1303(a)(1). HHS' regulatory proposal to expand the restriction therefore has no statutory basis and must be reversed. Subject to some explicit limits set by the U.S. constitution and federal laws, states have historically legislated and regulated whether, when, and how women may access abortion services. *See also* ACA § 1303(b)(1)(A)(i). HHS' proposed rule would improperly subvert state authority.

Second, NHeLP strongly opposes HHS' proposed exception that would give insurers flexibility to refuse to cover services otherwise required under a state's EHB selection. The ACA sets the EHB package as the minimum floor for services which issuers must cover. States can, however, exceed this federal floor. While the ACA makes clear that there is no federal requirement for states or issuers to provide abortion coverage, the ACA does require issuers to cover state-selected benefits packages and to defer to state law. *See* ACA § 1303(c). HHS' proposed rule would give QHPs unrestricted flexibility to violate the state's benefits package and could adversely impact a state's right to determine its benefits package and set state law. This proposed policy has no valid basis in law and it should be deleted.

Finally, we note that there is no legitimate health policy basis for extending restrictions on abortions—health care coverage that women currently have and need. According to the Guttmacher Institute, 87% of typical employer-based insurance policies in 2002 covered medically necessary or appropriate abortions.[7] Abortion coverage is critical for a woman facing an unintended pregnancy, as well as for a woman who has decided to carry a pregnancy to term only to later develop a condition that puts her health at risk. It would be unconscionable for HHS to dictate that women lose abortion coverage that is currently included in their health care policies.

RECOMMENDATION: HHS' should delete § 156.115(c) in its entirety.

§ 156.115(d)

This provision excludes certain services from being covered as EHB (non-pediatric dental or eye exam services, long-term/custodial nursing home care benefits, or cosmetic orthodontia).

To the extent that these services are covered by the base-benchmark plan selected, and under HHS' own proposed approach, these services represent the scope of typical employer coverage. To remove these services from the EHB-benchmark plan or otherwise exclude them as EHB would violate the statutory directive to include services that are typically covered in private market health plans. This approach also fails to recognize the importance of these services to overall health and well-being. For example, adult dental care is essential to quality

[7] Adam Sonfeld et al., *U.S. Insurance Coverage of Contraceptives and the Impact Of Contraceptive Coverage Mandates, 2002*, 36 Perspectives on Sexual & Reprod. Health 2 (March/April 2004), http://www.guttmacher.org/pubs/psrh/full/3607204.pdf.

pre-natal care and improved birth outcomes. Gum disease has been linked to preterm birth and is as large a risk factor for a low birth weight babies as smoking or alcohol. This policy also undermines the ability of states, as discussed above, to include benefits they deem worthy in their EHB packages.

RECOMMENDATION: We recommend deleting § 156.115(d).

§ 156.120 Prescription drug benefits

§ 156.120(a)

This provision requires EHB benchmark plans to cover prescription drug benefits by reference to at least the greater of: (1) one drug in every category and class; or (2) the same number of prescription drugs in each category and class as the EHB-benchmark plan. NHeLP agrees that this proposed approach is an improvement over the approach proposed in HHS' EHB Bulletin, which required only one drug per class. However, this standard still fails to meet the requirements of the ACA to provide meaningful coverage of prescription drugs and meet the needs of the covered population. We urge HHS to reconsider several aspects of this proposal.

First, we recommend that HHS explicitly reiterate that none of the potential limits in this framework (e.g. "one drug per class") supersede the independent and enforceable requirement for every plan to cover all PHSA § 2713 services, including *all* FDA-approved methods of contraception. This is true for *all* plans subject to the EHB because of the applicability of § 156.115(a)(3) (and of course many of the plans are also directly subject to PHSA § 2713).

Second, in all cases, the rule should set the minimum level of coverage at *two* drugs per class. This ensures clinicians will have sufficient clinical options to treat patients who may have medical limits. This also is the best and most congruent policy given that two drugs per class is the norm under Medicare Part D and it would promote uniformity among programs.

Third, HHS should include the Medicare Part D requirement to cover "all or substantially all" of the drugs in six protected classes of drugs which are critical to vulnerable populations.[8] We note that these classes were explicitly included in Part D "because it was necessary to ensure that Medicare beneficiaries reliant upon these drugs would not be substantially discouraged from enrolling in certain Part D plans."[9] It would violate the nondiscrimination requirement for EHB coverage (*see* ACA § 1302(b)(4)) if this Medicare policy, specifically designed to prevent discrimination against certain populations, were not adopted in the EHB. For example, the current standard of care for treating HIV includes the simultaneous use of multiple antiretroviral medications that may be from the same drug class. The proposed rule would make meeting this standard of care impossible under some existing plan designs. We therefore urge HHS to supplement the proposed required drug benefit with the Medicare Part D "all or substantially all" standard for these classes.

Fourth, we strongly commend the use of a standardized classification for the *coverage requirement* ("drugs per class") and *reporting purposes*. However, we urge HHS to clarify that

[8] See *Medicare Prescription Drug Benefit Manual § 30.2.5.*
[9] *Id*.

the uniform classification system should also apply to all public *formulary descriptions*. Consistent classes of drugs will facilitate the ability of consumer, providers, and employers to compare plans and evaluate formulary status of medications.

Finally, we urge HHS to re-evaluate reliance on the USP classification system for drugs. The USP system was created for the Medicare Part D program and its beneficiaries, and therefore may not adequately classify and categorize drugs for individuals who do not meet the Medicare eligibility standards. For example, in terms of *reporting* for contraceptives (*coverage* is independently required by § 156.115(a)(3) and PHSA § 2713), many contraceptives are combination hormone therapies that are not classified by the USP classification system and therefore may not be represented in EHB-benchmark plans reporting. If only those drugs that can fit within the USP classification system are reported, then HHS will experience data deficiencies, comparison of base-benchmark and supplementation coverage will be difficult, and other problems will ensue. Similar examples in other areas could create problems for coverage, reporting, or public descriptions of other drugs. NHeLP recommends that HHS implement the most comprehensive classification system available (or otherwise expand upon the USP system), to ensure coverage, reporting, and public descriptions are optimized.

RECOMMENDATION: We recommend amending § 156.120(a) as follows:

§ 156.120(a) A health plan does not provide essential health benefits unless it:
(1) ~~Subject to the exception in paragraph (b) of this section, c~~**C**overs at least the greater of:
(i) ~~One~~ ***Two*** drugs in every ~~United States Pharmacopeia (USP)~~ **[insert broader classification system]** category and class; or
(ii) The same number of prescription drugs in each category and class as the EHB-benchmark plan; ~~and~~
(2) Covers all or substantially all drugs in the immunosuppressant (for prophylaxis of organ transplant rejection), antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic classes; and
(3) Submits its drug list to the Exchange, the state, or OPM.
…
(d) Nothing in this section is in derogation of the coverage requirements in 156.115(a)(3) of this subpart.

§ 156.120(b)

Please see our comment above to § 156.115(c) regarding the impermissible flexibility given to insurers related to coverage of abortion services. If, against our recommendation, HHS finalizes § 156.120(b) as proposed, HHS must not permit health plans, issuers or states to define "drugs for services described in § 156.280(d) of this subchapter." The final rule must reaffirm that only prescription drugs approved by the U.S. Food and Drug Administration (FDA) as drugs for services described in § 156.280(d) of this subchapter fall within this exception.

RECOMMENDATION: HHS must delete § 156.120(b) in its entirety.

§156.120(c)

We commend HHS for requiring an exceptions process that would allow an enrollee to request appropriate drugs that are not covered by the health plan. Many individuals, such as those with complex medical interactions or allergies, will be unable to safely use medications that are on formulary. We ask for clarification from HHS on this exceptions process, including how it will ensure transparency and usability for all enrollees, including LEP individuals.

We urge HHS to consider making this exceptions process broader than the prescription drug coverage category. With the significant insurer flexibility proposed in this rule, it is especially important that there be a consistent and easily navigated exceptions process for accessing all services recommended by an individual's treating provider but not covered by the health plan. Cost-sharing for such clinically appropriate services and use of the exceptions process should not add any additional burden or barrier to this process.

§ 156.125 Prohibition on discrimination

We commend HHS for the inclusion of a prohibition against discrimination. However, we ask HHS to strengthen this provision.

Discrimination in benefit design is a persistent practice in the insurance industry, and eradicating such discrimination has historically been a challenging process. For example, breast reconstruction following mastectomy was widely considered cosmetic and routinely excluded from coverage until the passage of the Women's Cancer Recovery Act of 1998. Similarly, carriers continue to argue that exclusions for services or drugs commonly provided for the treatment of conditions such as HIV/AIDS are not discriminatory because they apply to all plan enrollees, regardless of their specific negative effect on people with these conditions. As a result, these discriminatory exclusions persist. As one example, an estimated 30 percent of Americans living with HIV are unable to access coverage despite nondiscrimination laws such as the Americans with Disabilities Act (ADA) and the Health Insurance Portability and Accountability Act (HIPAA).[10]

Thus we disagree with HHS' unsubstantiated prediction "that it is unlikely that an EHB-benchmark plan will include discriminatory benefit offerings." (77 Fed. Reg. 70650). Gender disparities in current private market norms are an instructive example. Historic exclusions or insufficient inclusion of critical women's health services in private market coverage means the current HHS' approach is likely to perpetuate historic gender inequities in health coverage, and the obligation lies with HHS to guard against insurer practices that exacerbate these inequities. This role will be all the more important in the context of the current flawed approach Any failure to require a strong EHB standard that guarantees robust and comprehensive coverage of preventive and reproductive health benefits will therefore lead to discrimination against women.

Health plans employ a variety of benefit design and administration practices in ways that discriminate unfairly against groups of consumers. These practices include broad coverage

[10] AIDS.gov. 2012. "The Affordable Care Act Helps People Living with HIV/AIDS." Available from http://aids.gov/federal-resources/policies/health-care-reform/

exclusions (e.g. for maternity care), condition-based exclusions (e.g. for eating disorders or asthma), service limits, medical necessity definitions, and other utilization management policies. Reimbursement rates and limited provider definitions for certain benefits can also have the effect of limiting access to care for certain groups of consumers.

The following are some illustrative examples of long-standing discriminatory barriers to care that need to be dismantled:

- Maternity coverage has been largely unavailable in the individual market, with virtually no improvement in access. As of 2009, only 13 percent of the health plans available to a 30-year-old woman provided maternity coverage, only a one percent increase from the previous year.[11] While the ACA specifically addresses this barrier, the regulations should provide specific non-discrimination guidelines to address this gap in maternity and prevent insurers from enacting new barriers to maternity care. Individuals undergoing breast cancer treatment can typically go home on the day of surgery, but some women with disabilities may require higher levels of post-operative care that are not covered because their insurance procedurally characterizes breast cancer follow-up treatment as "outpatient care."
- Many insurance plans do not cover medically necessary treatment for eating disorders, such as anorexia or bulimia, which affect 10 women for every one man.[12]
- Transgender and gender nonconforming people are commonly denied coverage for a wide range of critical services solely because they are enrolled as a gender different from that typically associated with needing a particular service. Commonly excluded services include cervical or prostate exams, bone density scans, hysterectomies, and treatment for breast cancer and polycystic ovary syndrome.[13]
- Exclusions for otherwise-covered services for cases other than those in which the purpose of the treatment is to recover lost functioning or to restore previous levels of functioning. Such exclusions have a disparate impact on individuals with developmental disabilities who rely on services to attain certain functions or to avert their loss or deterioration. While the Affordable Care Act requires coverage of both rehabilitative and habilitative care, this requirement will mean little if issuers are permitted to continue to employ limited ideas of how broad the range of services covered under the category of habilitative care must be.
- Restrictions on "medically necessary" treatment within a benefit category to cases in which the services are required for the treatment of "illness, injury, diseased condition, or impairment." This type of limitation is frequently used to deny coverage for health conditions classified as being present at birth rather than the result of a disease process.
- Exclusions for otherwise-covered benefits when provided for the purpose of treating Gender Identity Disorder, gender dysphoria, or related conditions. These

[11] National Women's Law Center, *Still Nowhere to Turn: Insurance Companies Treat Women Like a Pre-existing Condition,* (2009) http://www.nwlc.org/sites/default/files/pdfs/stillnowheretoturn.pdf.
[12] National Eating Disorders Association, *National Eating Disorders Association Statistics: Eating Disorders and Their Precursors,* (2005),
[13] Lambda Legal, *When Health Care Isn't Caring: Lambda Legal's Survey of Discrimination against LGBT People and People with HIV,* (New York: Lambda Legal, 2010), http://data.lambdalegal.org/publications/downloads/whcicreport_when-health-care-isnt-caring.pdf.

transgender-specific exclusions contradict the consensus of leading professional medical associations regarding the medical necessity of these treatments for many patients, and they unacceptably limit access to otherwise covered benefits on the basis of health condition and gender identity.

- Exclusions for mental health, substance use disorder, and behavioral health treatments that fail to meet the parity standards required by the Mental Health Parity and Addition Equity Act of 2008 (MHPAEA). Despite these existing parity requirements, state implementation and enforcement of MHPAEA has varied widely. Additionally, patients seeking mental health services are frequently subjected to excessive and inappropriate non-quantitative limitations.

Without strong anti-discrimination regulations – as well as vigorous monitoring and strong enforcement – the ACA's explicit ban on pre-existing condition exclusions would be undermined by insurers' assumption that they could use benefit design as a proxy for health status. The ACA has four specific nondiscrimination requirements that provide direction to the Secretary in the development of the Essential Health Benefits package. These include:

- Section 1302(b)(4)(B): Requiring 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."

- Section 1302(b)(4)(C): Requiring 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."

- Section 1302(b)(4)(D): Requires that the Secretary ensures "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 of the individuals' present or predicted disability, degree of medical dependency, or quality of life."

- Section 1557: Prohibiting discrimination on the basis of race, color, national origin, sex, age and disability in health programs or activities that receive federal financial assistance (including credits, subsidies, or contracts of insurance), are administered by an Executive agency, or were established by Title I of the ACA.

The proposed rules states that Sections 1302(b)(4)(B), 1302(b)(4)(C) and 1302(b)(4)(D) collectively be viewed as a prohibition on discrimination by insurers. Specifically the proposed rule states that an insurer will not be considered to be providing an EHB if its benefit design, or the implementation of its benefit design, discriminates based on an individual's age, expected length of life, present or predicted disability, degree of medical dependency, quality of life of other health conditions. Further, the proposed rule prohibits marketing practices and benefit designs that discriminate against individuals with significant or high cost health care needs and also prohibits discrimination based on race, disability, age and other factors.

The proposed rule would also address discrimination by allowing states to monitor and identify discriminatory benefits designs or the implementation of these benefit designs. The rule states HHS would not prohibit issuers from applying utilization management techniques – like prior

authorization – as long as these techniques do not discriminate against certain groups of people.

While we commend HHS for being more explicit in its prohibitions against discrimination in the EHB package, the rule must explicitly address the various forms of discrimination prohibited by the ACA. HHS should be guided by Section 1557 of the ACA which prohibits discrimination on the basis of race, color, national origin, sex, age and disability in health programs or activities that receive federal financial assistance (including credits, subsidies, or contracts of insurance), are administered by an Executive agency, or were established by Title I of the ACA. We strongly support the use of Section 1302 as a guiding standard for the Secretary but we believe Section 1557 – which encompasses critical prohibitions against specific types of discrimination – must also be a guiding standard. To this end HHS should publish as soon as possible rules implementing Section 1557.

Further, HHS should also consider and refer to existing civil rights laws – which provide a basis for determining what types of benefits packages comply with nondiscrimination principles. 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, offer a baseline for 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.[14] 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."[15]

We also urge greater oversight of plan techniques like utilization management policies and cost-sharing which have the potential to create discriminatory barriers. At a minimum, health plans should be required to disclose information regarding these plan features to state regulators and the public, including prospective applicants and enrollees. We also urge HHS to consider options for more rigorous oversight, such as review and approval or auditing requirements, to ensure these features are not being used in ways that violate § § 1302 and 1557.

In circumstances where a health provider's clinical treatment plan is denied or limited due to utilization management criteria, the EHB standard should require a clear and easy exceptions process that will be applied in an expedited manner to determine access to the prescribed treatment. For example, if a plan is allowed to impose increased cost-sharing for non-preferred drugs, there are likely to be instances where a prescribing provider determines that a preferred drug is not as effective for the individual or would have adverse effects (or both). In this case, the provider should be permitted to protect the patient's health by prescribing the non-preferred

[14] U.S. Equal Employment Opportunity Commission Compliance Manual on Employee Benefits, available at http://www.eeoc.gov/policy/docs/benefits.html#B. Health Insurance Benefits (T7).
[15] U.S. Department of Justice, Civil Rights Division, Title IX Legal Manual, Jan. 11, 2001, *available at* http://www.justice.gov/crt/cor/coord/ixlegal.php

drug, without additional cost or delay to the individual. This position is currently reflected in the Medicaid Act's policies and should also be applied to EHBs.[16]

The insufficiency of the nondiscrimination provision is exacerbated by the fact that the regulation itself includes numerous provisions which are likely to lead to discriminatory practices. For example, issuer flexibility to modify the EHB (such as through "substitution," or even ignore the EHB (by dropping required abortion coverage without consequences), are likely to lead to benefit designs which discriminate against vulnerable population groups based on their demographic characteristics or health status. We urge HHS to strengthen the regulation's nondiscrimination standards.

Ultimately, the Secretary can and should work with states to ensure adherence to the various nondiscrimination provisions related to EHB, but the sole authority to monitor, report, and enforce these provisions must rest with the Secretary.

We suggest HHS develop a clear standard for what constitutes a discriminatory benefit design. This standard must address both individual cases of intentional discrimination and benefit designs that are facially neutral but that have the effect of systematically disadvantaging members of protected classes. Ultimately, this standard must make clear that the determination of whether a coverage limitation or exclusion is discriminatory should turn on the degree to which the benefit design is based on sound standards of clinical appropriateness rather than on arbitrary distinctions between health conditions or personal characteristics.

To assist federal and state regulators and insurance carriers in rectifying discrimination in benefit design, HHS should follow up on the final rule with subregulatory guidance explaining how to evaluate products for impermissible discrimination and providing examples of discriminatory benefit designs such as those listed above. In addition, HHS should require trained evaluators in each state to regularly and transparently review insurance contracts for discriminatory benefit designs and to ensure that issuers act quickly to remedy identified instances of discrimination. Where HHS determines that a state is not fulfilling its responsibilities in this area, HHS should establish a review procedure that goes beyond existing procedures for Medicare Advantage and Medicare Part D to focus on ensuring that all services deemed part of the essential benefits are available to all eligible individuals for whom they are medically necessary, without arbitrary discrimination on the basis of any protected personal characteristic.

These reviews should consider not only the impact of exclusions and other limitations, but also in- and out-of-network cost sharing. Specifically, we are concerned that the proposed rule will not count out-of-pocket spending on out-of-network treatments and services toward caps on cost sharing. This appears to be contrary to the language in the Affordable Care Act, which limits "cost sharing incurred under a health plan." HHS should revise its position and count copayments and coinsurance on covered out-of-network services toward the out-of-pocket maximum. We are also concerned that HHS proposes to not factor these costs into the

[16] Deficit Reduction Act of 2005 § 6042, Pub. L. 109-171 (109th Cong. 2d Sess.) (Permits states to apply cost sharing levels for preferred drugs to non-preferred drugs, "if the prescribing physician determines that the preferred drug for treatment of the same condition either would not be as effective for the individual or would have adverse effects for the individual or both." (citation omitted)).

calculation of actuarial value. If actuarial value calculations do not account for out-of-network cost sharing, insurers are incentivized to keep networks small and formularies narrow and may use them to avoid some populations. It is important to ensure that plan benefit designs and formularies do not discourage enrollment by individuals with significant health needs and that they provide patients with access to the medications and other health care services they need.

We believe that the history of the insurance market makes plain that discriminatory benefit design is a critically serious concern for any insurance program. Indeed, we believe that this is precise the reason why Congress made sure to include multiple nondiscrimination protections in the ACA – from the sweeping nondiscrimination provisions (*see* ACA § 1557) to the specific statutory EHB nondiscrimination requirements HHS proposes to codify (*see* ACA § 1302(b)(4)(B)). Allowing insurers to use benefit design as a proxy for health status will undermine the intent behind not only the non-discrimination provisions of the ACA but also the explicit bans on pre-existing condition exclusions and rating. HHS should develop straightforward discrimination standards which include specific criteria for avoiding intentional discrimination and actions that have the effect of discriminating, data collection, and monitoring and enforcement protocols.

RECOMMENDATION: 156.125(a) should be amended as follows:

> *An insurer does not provide EHB if **fails to meet the requirements of 45 C.F.R. § [implementing ACA § 1557] or if** its benefit design, or the implementation of its benefit design, discriminates **or has the effect of discriminating** based on an individual's **age, gender,** expected length of life…..*

To further prevent the potential for discrimination the Secretary should also incorporate explicit protections in regulations pertaining to medical necessity, condition-based exclusions, and cost-sharing. Specific recommendations follow.

Medical Necessity

The Secretary should issue clear, transparent standards for medical necessity in regulations defining the EHB package that ensure that the decisions of the treating provider or team are given great weight and deference. When decisions are reviewed, the purpose of the review by health plans should be to determine:

- Whether the treatment accords with professional standards of practice (but where clear standards are due to the condition or nature of a patient's need or illness, medical necessity should be based on clinicians' experiences in practice);
- Whether it will be delivered in the safest and least intrusive manner and least restrictive setting, or is necessary to facilitate living in the community; and
- Whether there are equally effective treatments, services, and care that are actually available and accessible to the enrollee.

The Secretary should also specify that medical necessity must accommodate treatments which maximize, maintain, or reduce the degeneration of functional status. We also recommend an explicit understanding of medical necessity for children living at or below 400

percent of the Federal Poverty Level (FPL) and children with special health needs that is defined using the EPSDT standard. Thus, the standard for these children should focus on whether the care and/or treatment are necessary to correct or ameliorate the child's physical and mental conditions.

We urge the Secretary to restrict the use of definitions that deny coverage if the health plan deems that use of an otherwise covered item or service is primarily for the convenience for enrollees/policy holders. This indistinct standard can be abused to deny coverage for services that could greatly improve the health and well-being of individuals, such as contraception. Medical necessity should not be a mechanism to intrude upon the patient and physician relationship or interfere with communications regarding the treatment options between the patient and provider.

Final regulations should also include transparency requirements. Today, insurers define and apply medical necessity differently, even across plans, while many consumers do not understand that something their health care provider orders or prescribes could be denied as not medically necessary by their health plan. Health plans should be required to publicly disclose when and how they apply medical necessity to coverage decisions so consumers can understand their basis and challenge decisions that affect their access to a benefit.

We agree with HHS that § 1302(b)(4) of the Affordable Care Act prohibits discrimination by issuers, and we strongly support the inclusion of health condition, sexual orientation, and gender identity among the protected categories in the proposed rule. By prohibiting arbitrary discrimination while permitting insurers to continue using utilization management techniques that help determine the medical necessity, appropriateness, and efficacy of various health care services, we believe the proposed rule fairly balances nondiscrimination protections against existing market practices. These nondiscrimination protections will help consumers access coverage for the care they need while still allowing insurers to encourage effective and economical use of health care services.

We recommend that HHS utilize a broad definition of medical necessity as it adopted in the glossary of terms for the Summary of Benefits and Coverage. This would include " [h]ealth care services or supplies needed to prevent, diagnose or treat an illness, injury, condition, disease or its symptoms and that meet accepted standards of medicine.[17]

Enforcement

HHS must ensure that carrier obligations under the nondiscrimination provisions of the proposed rule are clearly defined and adequately enforced. We urge HHS to not leave monitoring of potential plan discrimination solely to the states. HHS has the capacity to detect broader trends than a single state could uncover. And HHS should provide a clear process of appeals for consumers who experience discrimination by issuers.

We support HHS's intent to utilize enforcement mechanisms under the Public Health Service Act to ensure that plans adhere to the proposed EHB standards. However, we are concerned

[17] *See* Glossary of Health Coverage and Medical Terms, Summary of Benefits and Coverage, http://cciio.cms.gov/resources/files/Files2/02102012/uniform-glossary-final.pdf.

about the degree to which monitoring and enforcement responsibilities are largely delegated to the states, and we believe that the final rule must better define how individual states will assess, monitor, and enforce the law's nondiscrimination provisions. Moreover, we do not feel it is sufficient to delegate all monitoring and enforcement to states: The final rule must better define how HHS will take enforcement action when states are not ensuring issuer compliance with the nondiscrimination standards established under the ACA.

Enforcement is a major concern for us in two areas: (i) instances of discrimination by issuers against individual consumers, and (ii) discriminatory benefit design. The former is very important for consumers, and we encourage HHS to work with state Exchanges and state insurance regulators to ensure that robust and transparent appeals procedures are equally available to all individuals who need them. With regard to the latter, we are particularly concerned about enforcement in the context of potential disagreement among issuers and state regulators as to what kinds of benefit limitations and exclusions constitute impermissible discrimination in benefit design.

Language Access

Almost 20% of the population speaks a language other than English at home. Over 24 million, or 8.7% of the population, speak English less than very well and should be considered limited English proficient (LEP) for health care purposes.[18]

Not surprisingly, language barriers have been found to be as significant as the lack of insurance in predicting use of health services.[19] Moreover, lack of language services limits the amount and quality of care LEP individuals receive.[20]

We believe QHPs should be required not only to provide but also to pay for the language services in connection with accessing all EHB and health services provided by the plan. The QHP may fund and provide interpreters on the plan level, or reimburse providers for language services they incur. Reimbursable LEP services would include: translation of all vital documents for areas with concentrations of language groups, "taglines" in at least 15 languages to provide LEP patients with a resource to get appropriate language services, in-person interpreter services, and over-the-phone and video interpreting as well as bilingual

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[18] American Community Survey, 2006-2008, *Selected Social Characteristics in the United States: 2006-2008*; also American Community Survey, 2008, *Language Spoken at Home by Ability to Speak English for the Population 5 Years and Over,* Table B16001, available at http://factfinder.census.gov.

[19] Leighton Ku & Alyse Freilich, Urban Institute, *Caring for Immigrants: Health Care Safety Nets in Los Angeles, New York, Miami, and Houston* at ii-iii (Feb. 2001). *See also* Jennifer Cho & Beatriz M. Solis, L.A. Care Health Plan, *Healthy Families Culture & Linguistic Resources Survey: A Physician Perspective on their Diverse Member Population* (Jan. 2001) (51 percent of doctors said their patients do not adhere to treatments because of culture and language barriers).

[20] *See, e.g.,* Flores G, Barton Laws M, Mayo SJ, et al.., *Errors in medical interpretation and their potential clinical consequences in pediatric encounters*, Pediatrics 2003, 111(1):6-14; Ghandi TK, Burstin HR, Cook EF, et al. *Drug complications in outpatients,* Journal of General Internal Medicine 2000, 15:149-154l; Pitkin Derose K, Baker DW, *Limited English proficiency and Latinos' use of physician services,* Medical Care Research and Review 2000, 57(1):76-91. *See also*, Jacobs, et al., *Language Barriers in Health Care Settings: An Annotated Bibliography of the Research Literature*, The California Endowment (2003), *available at* http://www.calendow.org/pub/publications/LANGUAGEBARRIERSAB9-03.pdf.

providers and staff members. Specific language requirements will vary on regional needs. HHS has issued guidance regarding Title VI compliance that specifically enumerates steps HHS-assisted entities should take to include LEP populations.[21] And for the same reasons as described above, QHPs must provide language services to comply with § 1557 of the ACA.

Many plans already are required to provide and pay for language services pursuant to California law. In 2003, the California legislature passed Senate Bill 853, which mandated that all commercial health plans provide language services for their enrollees. Regulations implementing this law from the Department of Managed Health Care (DMHC) mandate that health plans provide enrollees with translated vital documents (for example, explanations of benefits) and ensure the availability of interpreter services at all points of patient contact, including clinical encounters. Services must be provided at no cost to the enrollee. Further, plans must collect patient demographic data, including language information. Health plans also must monitor their language service programs to track plan and provider compliance. [22]

Statutory language, legislative intent, the importance of providing meaningful access to care all provide strong reasons to ensure that the EHB regulations explicitly apply Title VI and § 1557 and require QHPs to provide and pay for language services.

§ 156.130 Cost-sharing requirements

These provisions codify (1) the annual limits on cost-sharing and deductibles for 2014 and beyond and (2) increases in the annual limits based on premium adjustment percentage.

§156.130(a)

We note that in other guidance (at 77 Fed. Reg. 73171) HHS has implemented a policy which favors higher annual limits in place of increasing deductibles, copays and coinsurance. NHeLP strongly supports this approach because the out-of-pocket maximum is, for most people, the least likely to cause them to forgo needed medical care. In contrast, studies show that excessive copays represent a significant barrier to needed care, especially for lower-income individuals.[23] NHeLP recommends that HHS always require plans to address coverage level adjustments through annual limits, and not the other cost-sharing methods, and suggests the following approach:

- Plans should be subject to maximum limits on copays and coinsurance, per our recommendations above at § 156.20.
- If a plan is unable to meet its required actuarial value threshold with all maximum cost-sharing limits in effect (i.e., our recommended limits for copays and cost-sharing, as well

[21] *See* 68 F.R. 47311 (Aug. 8, 2003).
[22] M. Au, et.al, *Policy Brief: Improving Access to Language Services in Health Care: A Look at National and State Efforts* (Mathematica, April 2009)*, available at* http://www.ahrq.gov/populations/languageservicesbr.pdf.
[23] See, for example, Amitabh Chandra et al., *Patient Cost-Sharing and Hospitalization Offsets in the Elderly*, 100 AMERICAN ECONOMIC REVIEW 193 (2010), and John Hsu et al., *Unintended Consequences of Caps on Medicare Drug Benefits*, 354 NEW ENGLAND JOURNAL OF MEDICINE 2349 (2006).

as the existing maximums for annual limits and deductibles), then the plan could raise the annual limit to come into compliance with the actuarial value limit.
- If for some reason the plan still could not reach the actuarial value target, then it could raise the deductible limit.
- (We note that, per our recommendation at § 156.20, the plan would not be able to reduce its actuarial value by changing the applicability of deductibles or annual limits, since these would be standardized.)

NHeLP recommends the above approach as the best method to achieve the multiple aims of allowing plans flexibility to structure their benefit design, creating an exception process to help actuarial value compliance, and, to the greatest extent possible, preventing consumers from forgoing needed care because of high out-of-pocket costs..

§ 156.130(b)

§ 156.130(b)(3) authorizes a small group plan issuer to adjust the deductible limit to maintain actuarial value for a particular coverage level if it cannot reasonably reach the actuarial value of a given coverage level otherwise. As per our recommendation at § 156.130(a), we believe that deductibles should not be increased to help a plan reach its actuarial value target because deductibles (like copays and coinsurance) reduce healthcare utilization indiscriminately for both essential and non-essential care. Exceptions to increase the deductible should only be allowed in circumstances where it is impossible for a plan to reach the actuarial value target even with flexibility to raise the annual limit.

Furthermore, NHeLP is particularly concerned that setting a vague "reasonableness" standard ("reasonably reach") grants issuers too much flexibility and would lead to abuse of this exception. NHeLP recommends that any framework developed by HHS exclude a reasonableness standard or include specific criteria that could guide enforcement and help avoid harmful policies for consumers.

§ 156.130(c)

NHeLP has serious concerns about HHS' proposal to exclude out-of-network cost-sharing towards a plan's annual out-of-pocket and deductible limits.

Elsewhere in the proposed rule, HHS acknowledges that out-of-network expenses need not factor into the actuarial value calculation because "only a small percentage of total costs come from out-of-network utilization" (77 C.F.R. 70655). Since the total expenditures on such care are low enough to disregard from actuarial value calculation, NHeLP recommends the regulation require issuers to include out-of-network cost-sharing in annual limit calculations. This is the simplest policy administratively and will not have a material cost impact.

If, however, against our recommendation, HHS maintains an exclusion for out-of-network services, the language in the proposed regulation is overly broad because it may also apply to situations where an individual goes out-of-network precisely because there are insufficient in-

network options. And individual should not be punished with higher cost-sharing in any scenario where they go out-of-network due to the plan's inadequacy or her own special medical needs. NHeLP therefore recommends that HHS include all out-of-network cost sharing towards an individual's annual limit and deductible *unless* the issuer can document that it (1) was generally in compliance with the network adequacy requirement and (2) that the enrollee had actually available in-network option. As part of this requirement, HHS must require that in-network options cannot be deemed "actually available" if the provider was not accepting new patients, had an unreasonably long waiting time to see patients, or an individual's provider has otherwise determined that the in-network option is clinically inappropriate.

NHeLP also recommends that HHS must develop related protections for copays and coinsurance. Specifically:

- Consumers meeting the criteria above for annual limits and deductibles (i.e., those with an inadequate network or no "actually available" provider) should always receive the plan's standard copay and coinsurance charges.
- Consumers not meeting the above criteria could pay a higher copay or coinsurance, with a maximum allowable charge defined by HHS or the state. This would offer limited protection for consumers and allow them to plan for the added financial risk.

NHeLP also recommends that all services meeting these criteria have the out-of-network balance billing protections we describe below at § 156.130(h). Individuals should not face balance billing charges for services which their plan does not adequately cover or ED services.

Protecting consumers who may need to go "out-of-network" is especially important to high need individuals who may require specialized care. For example, women with difficult pregnancies sometimes cannot find adequate in-network high risk maternity care in a timely fashion. Such cases are analogous to the emergency department provision (§ 156.130(h)), where a person has no option but to seek out-of-network care, and should receive the same protections.

Furthermore, we believe that notice to consumers about the potential cost of seeking out-of-network care is critical, will help to minimize unnecessary use of out-of-network services, and help to prevent excessive medical debt. Plans should be required to inform members of the costs they may be charged for the out-of-network care. Also, plans should be required to require their network providers to disclose the cost and the use of non-network providers in advance of a member's decision to use out-of-network services.

§ 156.130(d)

NHeLP commends the requirement at § 156.130(d) to round cost-sharing to the next lowest multiple of 50 dollars. This requirement will help affordability and simplify administration of limits.

§ 156.130(f)

§ 156.130(f) clarifies that cost-sharing requirements do not apply to preventive care described in § 147.130. NHeLP commends this provision that requires compliance with the preventive services requirements of the ACA and PHSA.

§ 156.130(g)

§ 156.130(g) requires cost-sharing requirements to confirm with non-discrimination provisions of § 156.125.

NHeLP commends HHS for applying anti-discrimination provisions to cost-sharing, but refers HHS to our above comments on §156.125 that recommend that HHS should clearly identify a mechanism for adequate oversight and enforcement of this anti-discrimination provision.

§ 156.130(h)

NHeLP generally supports the language in (h)(1) provision, which will extend ED coverage requirements, prior authorization prohibitions, and cost-sharing for in-network EDs to out-of-network ED use. Emergencies that happen during travel or work are outside of an enrollee's control.

However, paragraph (h)(2) cross references §147.138(b)(3), which implies that enrollees may be held responsible for balance billing from the non-network ED providers in certain situations. We oppose this exception for balance billing. The preamble acknowledges that out-of-network expenditures are rare and have little impact on the total actuarial value of a plan, but they will have significant negative impacts on individual beneficiaries. More importantly, individuals often have no choice whatsoever as to what ED they end up visiting, so it is unfair to make them liable for extra costs. NHeLP recommends HHS strictly prohibit any additional balance billing or cost-sharing requirements for out of network ED use or services their plan does not adequately cover. The risk for balance billing on ED use and out-of-network use stemming from inadeuqate networks is most properly placed on the plan, and not individuals, since the plans both control the contractual relationships that establish their network and they are in a far superior position than individuals to negotiate a fair non-par rate.

§ 156.135 AV Calculation for determining level of coverage

Generally, NHeLP commends HHS for developing an AV calculator that will allow for an apples-to-apples comparison of different health plans across a state. The use of a standard population, while possibly sacrificing something in terms of accuracy for individual plans, will assist with comparability.

While the AV calculator will help ensure consumers receive value for their money, it is a blunt tool and does not change the fact that consumers will need critical beneficiary cost-sharing protections. A silver-level plan could vary prescription copays by tens of dollars without significantly shifting the result in the AV calculation. Other protections, per our recommendations at §156.20 and §156.130, must be in place to ensure that plans keep cost-

sharing low enough to keep services accessible. These include substantive limits to cost-sharing and also standardization of cost-sharing application. We recommend that the AV calculator should be modified to these specifications.

§156.135(b)

NHeLP is concerned that this exception is too broad and will result in inconsistency in plan comparison *and* will encourage plans to develop increasingly complex benefit designs and inhibit transparency in benefit design. In particular, the provision (b)(2) allows issuers to "estimate" the AV of complex designs wholly through a certified actuary "in accordance with generally accepted actuarial principles and methodologies." Both the estimating and actuarial comparison described are poorly defined and subject to manipulation. NHeLP believes this broad exception may swallow the rule that requires plans to use the calculator to estimate AV and cost-sharing structure. NHeLP recommends a stricter rule requiring plans to use the AV calculator.

If, contrary to our recommendation, HHS maintains the exception, NHeLP recommends that HHS should at the very least require that the chosen methodologies be posted in a public place or online and establish a mechanism for ensuring their soundness.

§ 156.135(d)

NHeLP supports the option that allows for state-specific standard populations beginning in 2015, provided there is a robust and appropriate source of claims data to support it. This will allow states to develop more accurate AV calculations. We note that once the AV Calculator was used, the California Exchange's previous estimates of cost-sharing amounts had to be significantly increased. It appears that the use of national data led to this different estimate and that California consumers would have been better off if state data could have been used. We request further guidance on how this would work for multi-state plans.

§ 156.140 Levels of Coverage.

§ 156.140(c)

NHeLP believes that any *de minimis* variation should only go in the direction that favors consumers, namely increasing actuarial value. Thus we recommend the variation should be upwards as much as +2%, but not downwards to -2%.

If HHS does allow *de minimis* against consumers, then NHeLP believes the +/- 2% variation allowed by the regulation is too great. At the silver level, two plans with otherwise identical coinsurance and copays can vary the deductible by hundreds of dollars and still qualify as an

"equivalent" silver level plan using the AV. From the consumer perspective, a plan with a $900 deductible and the same plan with a $1400 deductible should not be considered actuarially "equivalent." The variability at the bronze metal tier is even greater. This broad variability dilutes HHS' stated goal of metal levels to establish meaningful comparability across varying benefit designs.

RECOMMENDATION: HHS should only allow *de minimis* variation that favors consumers, or otherwise, HHS should only allow variation of +/- 1%.

§ 156.145 Determination of Minimum Value

NHeLP supports the use of a standardized MV calculator for determining whether employer-based coverage meets minimum value standards. The use of a standard population will also increase comparability.

§156.145(a)(2)

NHeLP agrees with the policy of establishing safe harbors to increase efficiency in determining MV, but recommends that HHS and IRS establish safe harbors that *clearly and substantially* exceed the minimum value standard.

§ 156.145(a)(3)

NHeLP has similar concerns to the above comments on the AV calculator. This exception process gives issuers too much latitude and reduces transparency in the process. The standard "in accordance with generally accepted actuarial principles and methodologies" is overly broad and poorly defined. NHeLP recommends the exceptions to the MV calculator be eliminated, or otherwise, limited and tightly regulated.

§ 156.150 Application to stand-alone dental plans inside the Exchange

NHeLP understands the difficulty of evaluating stand-alone dental plans in EHB, particularly with regard to counting an individual's spending toward her annual limit across two plans. Despite these difficulties, NHeLP recommends that HHS develop a plan to move toward an integrated resolution, either by (1) phasing out the stand-alone dental option or (2) phasing in a mechanism to measure the actuarial value of a stand-alone plans and commensurately adjust cost-sharing and annual spending limits for QHPs that do not offer pediatric dental services.

Within the proposed two-tier system, NHeLP recommends the *de minimis* variation should only be applied in the direction that favors consumers, or otherwise, should be no more +/- 1%, for similar reasons described in our comments on the AV calculator. A two percent range allows

for too much variability and dilutes the goal of establishing meaningful “equivalence” within a benefit tier.

Conclusion

In summary, we believe HHS should strengthen this regulation by requiring adequate coverage of the ten statutory categories of benefits and providing consumers more time and resources to thoughtfully analyze the proposed EHB benchmarks. We urge HHS to adopt our specific recommendations to improve the EHB standard for vulnerable individuals. If you have questions about these comments, please contact Jina Dhillon at (919) 968-6308 or dhillon@healthlaw.org. Thank you for consideration of our comments.

Sincerely,

Emily Spitzer,

Executive Director