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Secretary Kathleen Sebelius
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

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

Dear Secretary Sebelius:

The National Health Law Program (NHeLP) submits the below comments in response to the Health and Human Services' (HHS) "Essential Health Benefits Bulletin" ("Bulletin") issued December 16, 2011. NHeLP is a non-profit law firm working to advance access to quality health care and protect the legal rights of low-income and underserved people.

In its Bulletin, HHS proposes an approach to establishing the Essential Health Benefits (EHB) standard in the Affordable Care Act (ACA) based in part on the report and recommendations of the Institute of Medicine (IOM). We believe the IOM report is a flawed foundation upon which to build the new national standard. The IOM report explicitly prioritizes costs over meeting the health needs of the general public. The IOM suggests reliance on small employer plans, when these plans are known to provide less coverage (including higher cost-sharing and utilization barriers) and when large employer coverage in fact represents a much better model for the careful balancing of consumer needs and costs. It is illustrative, as noted in the Bulletin, that during the IOM deliberations there was consistent consumer emphasis on the need to develop uniform benefits that meet the needs of consumers, and yet the IOM report focused primarily on cost and largely ignored consumer input.

Using the IOM report as a starting point, the Bulletin has erred on the side of reducing costs and protecting state flexibility while falling short of the goal of providing consumers the health care coverage they need. For the millions of low-income and vulnerable consumers who will depend most on the EHB standard, the results will be catastrophic. Our comments below reflect the changes in the proposed EHB standard necessary to meet the needs of consumers. In summary, our proposal addresses the following recommendations, with a summary of suggested regulatory approaches at the end of each section. We recommend that the HHS EHB Bulletin and regulations should:

1) Meet the needs of those who will receive the EHB
2) Require a uniform set of national benefits
3) Not provide benchmarking or other flexibility to states or health plans

4) Require comprehensive coverage of all ten statutory categories of services
5) Minimize use of utilization management
6) Broadly include state benefit mandates
7) Implement high standards for preventive services and children's health
8) Prevent discrimination and reduce disparities
9) Require a transparent and inclusive process for developing EHB standards

We urge HHS to implement these recommendations to ensure the EHB standard works for all those who will depend upon it.

1. Meet the Needs of Those Who Will Receive the EHB

The ACA establishes the criteria that the Secretary must use in defining and updating the EHB package. The intent of the ACA is to promote health and well-being by expanding coverage to meet the needs of underserved individuals as well as fill existing gaps in the private insurance market. NHeLP believes that the ACA's statutory framework requires HHS to define the EHB in a way that meets the health needs of low-income and vulnerable populations.[1] HHS should avoid reliance on an approach that is driven by costs alone and should focus on the statutory intent that defines EHB to expand access to comprehensive and robust coverage.

A weak EHB standard will harm low-income and vulnerable individuals

The EHB will apply to the Medicaid expansion populations (individuals below 133% of the Federal Poverty Level (FPL)), set the standard for Basic Health Plans (which can only cover individuals below 200% FPL), enrollees in Medicaid benchmark plans, and will cover individuals in the Exchanges with income as low as 133% FPL.[2] These are extremely low-income populations that are more likely to be in worse health than their wealthier counterparts and unable to pay out of pocket for extra services.[3] Communities of color also tend to be

[1] *See generally* U.S. DEP'T OF HEALTH & HUMAN SERVS., HEALTHY PEOPLE 2020, (2011), http://www.healthypeople.gov/2020/topicsobjectives2020/default.aspx; Rural Assistance Center, *Rural Health Disparities Frequently Asked Questions*, (Feb. 8, 2011), http://www.raconline.org/topics/disparities/faq.php. Disparities in health status and outcomes exist among rural dwellers, racial and ethnic groups, people with disabilities, women, individuals with limited English proficiency, LGBTQ communities, and people with lower incomes.

[2] According to the ACA, individuals at or below 133% FPL will qualify for Medicaid under the new category of eligibility and those above 133% FPL will qualify for coverage in the Exchanges. However, application of new income rules using modified adjusted gross income rules as required by the ACA will result in income disregards bringing this income threshold to 138% FPL.

[3] AGENCY FOR HEALTHCARE RESEARCH AND QUALITY, U.S. DEP'T OF HEALTH & HUMAN SERVS., NATIONAL HEALTH DISPARITIES REPORT (2010), http://www.ahrq.gov/qual/nhdr10/nhdr10.pdf. Several health indicators demonstrate that low-income people continue to have worse results in several core health measures than those with higher incomes, such as: timeliness in receiving immediate care, hospital admissions for short-term complications of diabetes, and adults with major depressive episodes who received treatment within the last 12 months.

disproportionately represented among very low income populations.[4] The EHB standard must match the needs of the population it is designed to serve and be affordable.

Access to comprehensive health services that meets their needs is a matter of life or death for low-income and vulnerable individuals. A limited scope of benefits will lead to individuals living in poor health and with their health conditions deteriorating faster. For example, failure to include adequate mental health screenings will lead to expensive "crisis" treatments, hospitalizations and emergency department use, complications treating co-morbidities, and poor quality of life for individuals.

Even where the scope of benefits is not limited, restrictive utilization management tools such as heightened cost-sharing requirements will also restrict access. Numerous studies have shown that even a small co-payment constitutes a barrier to care, especially for low-income individuals. One study showed that a $12 co-payment resulted in a significant reduction in access to breast cancer screening.[5] A 10% increase in copayments for certain drugs (statins) decreased medication adherence by more than 12% for patients living in an area with median household incomes of less than $30,000.[6]

While a robust benefits package may slightly push up premiums, failure to cover necessary services drives medical debt and bankruptcies that overwhelm consumers financially. A weak EHB package will leave millions of individuals underinsured, generating financial hardship that will overshadow the marginal premium increases associated with a comprehensive benefit.

A weak EHB package will fail to reduce long-term health spending

While we agree cost is one of a number of factors HHS should weigh in the development of the EHB standard, NHeLP does not believe that cost considerations should be elevated as the chief factor framing the entire formation of the EHB standard. The ACA attempts to "bend the cost curve" by investing in those services which promote long-term health and well-being. The EHB package should be viewed as a tool to defray health care costs over the long term, and we urge HHS to strengthen the Bulletin to provide for a stronger EHB standard that will meet the needs of low income populations and promote long term savings. Failing to provide the benefits that this population needs, in contrast, will lead to unnecessary emergency room visits, unnecessary hospitalizations, costly mismanagement of chronic illness, and other cost-drivers.

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[4] *See* RAKESH KOCHHAR, ET AL., PEW RESEARCH CENTER, WEALTH GAPS RISE TO RECORD HIGHS BETWEEN WHITES, BLACKS, AND HISPANICS 1, 5 (2011), http://www.pewsocialtrends.org/files/2011/07/SDT-Wealth-Report_7-26-11_FINAL.pdf. As a result of the declining housing market and the recession, the median net worth of Black households was $5,677 (assets minus debts) in 2009; the typical Hispanic household had $6,325 in wealth; and the typical white household had $113,149. The median Asian household net worth also declined to $78,066.

[5] Amal Trivedi *et al.*, *Effect of Cost Sharing on Screening Mammography in Medicare Health Plans*, 358 New Eng. J. Med. 375 (2008). *See also* NATIONAL HEALTH LAW PROGRAM, COST SHARING STUDIES AND THE IMPACT ON MEDICAID BENEFICIARIES (2011).

[6] Michael Chernew *et al., Effects of Increased Patient Cost Sharing on Socioeconomic Disparities in Health Care*, 23 J. Gen. Intern. Med. 1131 (2008).

The ACA was designed to ensure that people have access to care that they need. If the EHB package is defined or altered based significantly on considerations other than the health needs of the populations being served, such as up-front cost, it is likely to leave low-income and underserved individuals in worse health and lead to higher costs over the long term as individuals' conditions deteriorate and they require more expensive care. Below we set forth our comments to the Bulletin along with our suggested approaches for the final Bulletin and forthcoming regulations.

2. Require a Uniform Set of National Benefits

The Bulletin suggests that instead of a single uniform standard for defining the EHB, HHS will allow states to benchmark to a ~~"r~~eference plan" that is based on a currently available health plan in the state, modified as needed to meet the EHB requirements found in the ACA.

Allowing states to create their own variations of the EHB package undermines the intent of the ACA to create a comprehensive and national standard for health insurance coverage. Clear federal minimum EHB requirements and standards are necessary to ensure that vulnerable populations can access comprehensive care that consistently meets their needs across the states.

The ACA directs the Secretary of HHS to define the EHB package and that is what the Secretary should do. There is no authority in the ACA for delegating the development of EHB to states or insurers.

The ACA Requires Federal Standards

As a legal matter, there is no authority in the ACA for delegating the EHB package to states or health plans. The ACA explicitly and repeatedly requires the Secretary of HHS to develop standards, factoring a number of considerations (with emphasis added):

- In Sect. 1302(a): ~~"~~…with respect to <u>any</u> health plan, coverage that … provides for the essential health benefits <u>defined by the Secretary</u>…."
- In Sect. 1302(b)(1): ~~"~~…<u>the Secretary</u> shall define the essential health benefits…."
- In Sect. 1302(b)(2)(A): ~~"T~~<u>The Secretary</u> shall ensure that the scope of the essential health benefits … is equal to the scope of benefits provided under a typical employer plan, as determined by <u>the Secretary</u>. To inform this determination, the Secretary of Labor shall conduct a survey … and provide a report on such survey to <u>the Secretary</u>."
- In Sect. 1302(b)(2)(B): ~~"I~~n defining the essential health benefits … <u>the Secretary</u> shall submit a report to the appropriate committees of Congress containing a certification from the Chief Actuary of the Centers for Medicare & Medicaid Services…."
- In Sect. 1302(b)(3): ~~"I~~n defining the essential health benefits … <u>the Secretary</u> shall provide notice and an opportunity for public comment."
- In Sect. 1302(b)(4): ~~"I~~n defining the essential health benefits … <u>the Secretary</u> shall--"

- ~~p~~eriodically review the essential health benefits … and provide a report to Congress and the public….”
- ~~p~~eriodically update the essential health benefits … to address any gaps in access to coverage or changes in the evidence base the Secretary identifies in the review conducted….”

Provisions such as these both require and presume that the Secretary will establish one national EHB standard. These provisions are almost impossible to understand and reconcile if the Secretary can delegate EHB-defining authority. How will the Secretary provide meaningful review and comment for potentially hundreds of state and plan defined standards? How could she periodically review and report to Congress? And how can the Secretary update the EHB based on her review? Neither the letter nor the logic of the ACA sustains an interpretation that the Secretary can allow a local definition of the EHB standard. This is also clearly confirmed by section 1334 of the ACA, which allows for the creation of multi-state plans. Section 1334(c)(1)(A) requires that the multi-state plan ~~o~~ffer[s] a benefits package that is uniform in each State” (reflecting the intent to allow states to add to the EHB), but also requires that it ~~c~~onsist[s] of the essential benefits described in section 1302.” The statute presumes there is only one EHB standard and makes no mention of how to reconcile varying EHB standards.

Nowhere does the ACA authorize states or health plans to define the EHB standard; nor does it authorize the Secretary to delegate that function. In other sections of the ACA, where Congress wanted states to have discretion, it specifically delegated rulemaking authority to states, Exchanges, and plans. Similarly, where Congress wanted to allow the Secretary to delegate decision-making authority, it did so.[7] The plain language of the ACA‘s definition of ~~E~~ssential Health Benefits” at section 1302(b) unequivocally states that ~~…~~*the Secretary shall define* the essential health benefits…” (emphasis added). Congress intended the Secretary of HHS, and not states or health plans, to develop EHB standards.

State and insurer flexibility to go below a national floor should be eliminated

The intended regulatory approach introduced in the Bulletin would allow each state to define its own EHB package based on an existing benchmark plan in the state. The selected plan would serve as a reference plan, reflecting both the scope of services and limits that are offered by a ~~t~~ypical employer plan” *in that state*. This is likely to create widely varying coverage from state to state, as services offered in many existing health plans (including mandated services) vary depending on the types of employers located in that state and the health of the individuals served. While it is less clear whether states will have strong financial incentives to choose a weak benchmark in defining the EHB, it is certain that if every state is choosing among various health plans in setting the standard, the political process will be fraught with tension and concessions as groups representing various economic and ideological positions lobby for the services they

[7] For example, section 1321 of the ACA sets out state flexibility to implement federal Exchange standards. Although the ACA requires the Secretary to develop federal Exchange standards, section 1321(b) then offers the states the option of implementing the federal standard *or* ~~a~~ State law or regulation that the Secretary determines implements the standards within the State.” With the EHB provision, there is no such grant of authority.

would like included, or not included. For example, states may make decisions contrary to medical evidence or fiscal prudence based on strong pressure from organizations opposed to reproductive health services. These are services that are medically appropriate and represent the general standard of care in ensuring women's health and well-being, and they also represent economically sound health coverage policies. The process for including comprehensive and responsive health services should be completed with minimal political interference but allowing each state to run its own process opens the coverage policies up 50 times to these potentially harmful pressures. Nothing contained in our comments, infra, should be construed as supporting a policy that allows the Secretary to delegate statutory EHB responsibilities to states, insurers, or any other entity.

Even more problematic is the suggestion in the Bulletin that insurance issuers may have the flexibility to adjust the scope of benefits defined as "essential." As a matter of law, there is simply no authority in the ACA to delegate this role to insurers within states, and such a delegation sits completely in conflict with the objectives of insurance simplicity and uniformity in the ACA. We also believe this approach is flawed as a matter of policy.

HHS reasons that its approach reflects the notion that insurers construct benefits packages by holistically balancing comprehensiveness and affordability. We strongly disagree with this approach, and question the validity of HHS' reasoning. Insurers are often profit-driven entities that have immense financial incentives to reduce their own costs, minimize utilization rates, and offer coverage to healthy individuals with low health needs. Even if overall actuarial value and medical loss ratio is controlled, insurers will be able to find ways to reduce actual utilization and use benefit design to adversely select against sicker individuals. No authority for EHB design should exist at the insurer level under any circumstances. As an important part of the health system, insurers should, however, have their suggestions reviewed through open and transparent comment processes.

HHS also contemplates allowing insurers to make substitutions in benefits so long as they are "substantially equal" to the benefits of the benchmark plan as modified to meet the ten coverage categories. We strongly encourage against allowing this additional flexibility, as it will likely result in a cost-driven calculation by the insurer resulting in restrictive benefit design features that limit services that Congress specifically intended to cover. This should not be allowed. To the extent that HHS allows insurers to have any flexibility in benefit design and the scope of EHB standards, there must be a higher level of scrutiny to ensure that vital services are not eliminated for those populations relying on them. The financial calculations behind such benefit design and coverage schemes must be strictly scrutinized to ensure that the health and well-being of individuals is not being sacrificed for the sake of cost savings.

The Need for Strong Federal EHB Standards

A clear robust federal EHB policy will make administration of Exchanges and other markets much easier. Vague federal standards will lead to a host of problematic consequences – different benefits packages, confused consumers, confused payors, inefficient and unaccounted for use of public funds, and significant administrative costs. Vague and varying standards also undermine

basic reform objectives of the ACA, such as developing a simple and navigable insurance market for consumers, promoting health care systems that are unified as opposed to siloed, and ensuring widespread and comprehensive access to coverage for low income and vulnerable populations. As Medicaid history has sometimes proven, loose federal standards will also lead to local abuses calling out for federal oversight, and more importantly, it can lead to serious health consequences for participants. Moreover, avoiding these serious health consequences for participants would correspond to a strategy identified in the *HHS Action Plan to Reduce Racial and Ethnical Health Disparities*. The *Action Plan* requires HHS to evaluate relevant program actions within its lead agencies to determine if these activities have improved health outcomes for disparity populations.[8] Therefore, HHS must ensure that EHB standards reduce or eliminate health disparities for all impacted populations, instead of contribute to the factors that cause them.

Varying EHB standards as proposed by the Bulletin will be bad for individual health and are likely to result in individuals having different benefits depending on where they live rather than on their medical needs. There may be reasons to accommodate regional or local health interests, but a federal EHB standard should set a national floor and oversee the regional differences. That floor must represent the minimum package of benefits that individuals need to meet all of their health care needs. Regional or local considerations, by states and/or plans, should be relevant to decisions about providing *additional* coverage. The Federal EHB standard should set a strong national floor, but it is not a ceiling. States and plans can be free to use their judgment about ways to expand benefits packages to improve upon the national standard or take into account local health needs. This is explicitly contemplated by the ACA, which allows states to add on to the federally defined EHB.[9] At minimum, however, a *firm and comprehensive federal EHB standard must be the starting point.*

In addition, allowing state or local discretion based on ~~–a~~ctuarial equivalence" will create an environment that can be exploited as a proxy for insurance rating. This is troublesome for vulnerable populations who are often the victims of medical underwriting and can also lead to systemic failure, encouraging adverse selection and leading to risk pool imbalance. One of the most important structural objectives of the ACA is to stabilize insurance markets by expanding and evening risk pools. Without a strong federal EHB minimum standard, this objective will be undermined.

Another reason HHS must maintain sole authority in defining the EHBs is to ensure that insurance plans do not maintain harmful refusal clauses or allow denials of care that are against accepted medical guidelines.[10] Insurers should not be allowed to justify refusals and denials of care based on ideological and political justifications that have no basis in scientific evidence, good medical practice, or patient needs. Instead, HHS must ensure that the EHB package

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[8] U.S. DEP'T OF HEALTH & HUMAN SERVICES, HHS ACTION PLAN TO REDUCE RACIAL AND ETHNIC HEALTH DISPARITIES 33-34 (2011).

[9] ACA § 1311(d)(3)(B). *See also* § 1302(b)(5).

[10] *See generally* NATIONAL HEALTH LAW PROGRAM, HEALTH CARE REFUSALS: UNDERMINING QUALITY CARE FOR WOMEN, (2010), http://www.healthlaw.org/images/stories/Health_Care_Refusals_Undermining_Quality_Care_for_Women.pdf .

maintains the essential principles of modern health care delivery in terms of patient centeredness, and prevention.

Yet another principle that requires a strong federal standard is the need to remove language barriers that impede access to health care, compromise quality of care, and increase the risk of adverse health outcomes among limited English proficiency (LEP) patients.[11] HHS must set a federal standard that requires the provision of language access in conjunction with all EHBs to ensure that all people can access health care in a linguistically and culturally appropriate environment.

Finally, the Affordable Care Act grants HHS with clear authority to ensure that insurance plans in the Exchanges and other markets do not discriminate against participants based on health status or through exclusion from participation in or denials of benefits in health programs and activities.[12]

❖ ***Recommended Regulatory Approach***

- HHS should create one uniform and prescriptive national EHB standard which serves as a national floor.
- States should not be allowed to modify the EHB minimums, although they should be allowed to expand upon the minimums. If HHS allows state-level implementation of the EHB standard (which we recommend against and consider to be outside of HHS's legal authority under the ACA), we recommend that state flexibility be tightly limited and carefully monitored and regulated.
- We categorically oppose even further sub-delegation of EHB design to insurers. We believe this has no advantages and is riddled with dangers.
- HHS should not include insurer refusal clauses that would allow insurers to refuse to cover any services required under the EHB package.
- HHS should require the provision of language services for LEP patients in connection with all EHB.

3. No Benchmarking or Other Flexibility to States or Health Plans

The ACA sets out the criteria that the Secretary must use in defining the EHB package. The ACA requires that Secretary must define the EHB package to match the scope of benefits provided under a typical employer plan, as determined by the Secretary, and that it shall also include at least ten specific categories of services listed in the ACA.

As described earlier, we recommend that the EHB standard should be a prescriptive and uniform national benefits standard. Anything less will fail to meet the needs of the vulnerable

[11] Chandrika Divi, et. al., The Commonwealth Fund, *Language Proficiency and Adverse Effects in U.S. Hospitals: A Pilot Study*, 19 Int'l J. Quality U.S. Health Care 60 (2007).
[12] ACA § 2704. *Id.* at § 1557.

populations that will depend on the EHB definition and will create inefficiencies between and within states. Instead of creating a clear EHB standard as the ACA requires, the Bulletin creates a benchmarking framework for states and insurers to develop implement EHB standards. **The Bulletin's benchmarking framework should be abandoned because it does not satisfy the requirements of the ACA, and it represents poor policy. NHeLP strongly opposes the use of benchmarks. Out of concern that HHS will continue to pursue a benchmarking framework, we provide comments on steps HHS can take to ensure that benchmarking is less harmful to consumers. Our willingness to provide comments on benchmarking does not signal our support for their use under any circumstances, or cure the negative impact they will have on the health of consumers.**

To the extent HHS pursues a benchmarking framework, it is crucial that the standard minimize the problematic qualities of benchmarks. We recommend several changes to the Bulletin to bring it into compliance with the ACA and improve it as a matter of health policy. As discussed in Section 2 above, HHS does not have authority under the ACA to delegate so many inadvisable ~~"f~~lexibilities" to states and insurers.

Benchmarking should always be subject to a firm national EHB standard

Ultimately, the EHB standard must meet the needs of the insured population that will depend on that standard. As we have explained earlier, that population is largely comprised of individuals who will be lower-income and vulnerable, and living in a correspondingly worse health status. Therefore, the EHB standard should be based on a uniform and prescriptive national set of benefits designed to meet these needs. Any use of benchmarks should be something that is overlaid on top of this core national EHB benefits. We understand the need to allow state flexibility, both to allow for state variation generally and to allow for state inclusion of relevant mandates; however, we do not believe this flexibility should ever lessen the strong national EHB standard we recommend. We recommend that HHS require states to implement a uniform national benefits standard, which can then be supplemented but not reduced by adding services from one or more of the appropriate benchmarks.

If there is no national standard (not recommended), HHS should use Medicaid benchmarking

If HHS does not adopt a uniform national core set of EHB services, the result would be an inferior policy. However, in that case, we would recommend that the benchmarking framework be modeled on the Medicaid benchmarking authority in section 1937 of the Social Security Act. The Medicaid benchmark authority refers to three coverage levels (state employees, federal employees, and largest commercial plans) offering reliable standards for consumers who need services on which to model the EHB benchmarks.[13] In matching to Medicaid benchmarks we would advise against reliance on ~~"S~~ecretary approved benchmarks" or ~~"b~~enchmark equivalents" because in practice these could lead to 50 different state EHB standards. We also suggest that the state employee option be interpreted as the largest such option in the state. While using the

[13] § 1937(b)(1).

three core Medicaid benchmark standards is inferior to what HHS could do if it followed the ACA's command to create a prescriptive EHB standard, these Medicaid benchmarks do at least ensure there will be a strong minimum benchmark level.

These Medicaid benchmarks would also create uniformity between the Exchange (EHB) and Medicaid Expansion populations. If each of these populations has coverage based on the Medicaid benchmark standards, the programs will be easier for consumers to navigate, for states and insurers to operate, and for HHS, CMS and CCIIO to regulate. Again, we note the vulnerable nature of the populations that will rely on the EHB standard, and this was in large part the population the Medicaid benchmarks were designed to serve. It is because of this that we recommend, in the strongest terms possible, that under no circumstances could or should the Medicaid benchmarks themselves be altered to allow for more flexibility.

Small Group Option Should Be Eliminated

We recommend that benchmarking should never be based on ~~"s~~small" group coverage if a core national standard is not used. Small group insureds are not typical; most employees have large group coverage. Linking the EHB standard to small group coverage is poor policy in that it will provide a *large* population with coverage based on the standards that are used for *small* insurance pools. It makes no sense to reform health care by broadening and stabilizing risk pools, and then turn around and use benefits standards based on dysfunctional risk pools. Large employers are very sensitive to both price and health needs and carefully negotiate their benefits to achieve a balanced policy. Smaller employers, due to bargaining power, are generally faced with worse policies. This is a systemic flaw that health care reform was intended to redress; pegging a national standard to the lower small employer coverage level just perpetuates a flaw in the health insurance market.

We believe it would be an unwise national policy to set a low standard for a large EHB population (millions of individuals nationwide) based solely on the weak bargaining position of small employers. Large employers quite deliberately consider cost and need in designing their coverage packages, pooling insured lives and negotiating fair prices and benefits, and this is what the EHB standard should imitate. This is what the Medicaid benchmark imitates with the ~~"l~~largest commercial employer" option, which is based on number of insured lives as a measure of typicality.

Relying on small group coverage is not only illogical, it would also lead to weaker benefits packages that would harm vulnerable individuals. The IOM acknowledges that small employer plans are more likely than large employer plans to utilize restrictive benefit design features as a way to control costs. Such features include limited provider networks, aggressive medical management, and heavy cost-sharing. These benefit design features can create unnecessary disruptions in care, and serve as a barrier for those unable to navigate the complex rules or meet the out-of-pocket expenses. The critical point is that these barriers prevent individuals from accessing services, even services they desperately need.

For example, high cost-sharing in the form of co-payments can limit access to care based on price-sensitivity, not based on need. This is especially true for the low-income individuals who will be enrolled in plans utilizing the EHB standard – enrollees in the Medicaid expansion, Basic Health plans, and Exchanges.

Excessive Flexibility Should Be Reduced

Not only does the Bulletin allow benchmarking to small employers, but it also allows states or insurers to pick and choose among three plans for each of the benchmarks (except the largest commercial HMO). We believe this flexibility serves very little purpose and puts individuals at unnecessary risk. States (or insurers) already have the flexibility to choose among benchmarks; the additional flexibility to choose between 3 plans within each benchmark opens the door to greater flexibility which can be used to harm individuals. This may be particularly true in rural or smaller market areas where there may be an enormous difference between the largest and third largest plan. In fact, preliminary data review by NHeLP indicates that even the three largest federal employee plans are positioned very differently.[14] We note that the EHB standard is a floor – not a ceiling – so states already have the authority to offer more coverage. This added flexibility, therefore, will only serve to allow for weaker coverage packages and increase the possibility that insurers will be able to use benefit design as a proxy for impermissible medical underwriting. Unless there is a core national EHB standard of benefits, this flexibility should not be allowed.

Substitution of Benefits Should Not Be Allowed, Under Any Circumstances

The Bulletin suggests problematic authority for ‗substitution' of benefits. This is suggested within the context of a particular benefit category, and even between benefit categories. This authority completely undercuts the letter and intent of the ACA to ensure coverage in key areas, and adequate overall coverage. Again, since the EHB standard is a floor and not a ceiling, coverage can always be added. Allowing states or insurers to substitute services creates dangerous potential for even further weakening of benefits or insurance rating through benefit design.

❖ ***Recommended Regulatory Approach***

- HHS should define the EHB based on a prescriptive national standard of benefits.
- HHS could use benchmarks as a reference for states to add to but not reduce the national standard of benefits.
- If there is no core set of mandatory national benefits (an approach we oppose), then the option to benchmark to small group plans or to choose from three plans of any type should be eliminated. Under these circumstances the benchmarks should all be

[14] NHeLP understands that the largest federal employee plan, the BCBS Service Benefit Plan, has over 2.5 million enrollees, while the third largest is the Mail Handlers Benefit Plan with less than 175,000 enrollees. Our inability to provide further citation to these numbers is a reflection of the difficulty advocate face in identifying and assessing these plans.

strong options, and the Medicaid benchmarking standards (without the Secretary approved benchmark option) should be the model HHS adopts.
- Insurers should have no role in setting or altering the EHB standard, under any conditions.

4. Require Comprehensive Coverage of All Ten Statutory Categories Of Services

The ACA defines the EHB package as the coverage offered by a typical employer plus ten additional categories of coverage ("Ten Categories"). The Bulletin correctly recognizes the need to supplement benefit packages that offer no coverage in one of the Ten Categories. However, we believe the proposed solution, filling in gaps by reference to other benchmarks, violates the letter and intent of the ACA and is also bad policy. We recommend the Bulletin be strengthened to require all EHB packages to include *substantial* coverage in *all* Ten Categories; substantial coverage should be determined by the Secretary and established as the amount needed to meet the needs of the covered population.

As an initial matter, the policy of the Bulletin to fill in coverage where a category is "missing" seems difficult to apply. Does this mean a benchmark offering only one minimal habilitative service would be compliant and not need to be "filled in?" Ultimately, the problem is that the Bulletin scheme fails to ensure what the statute requires: coverage of the Ten Categories. After all, relying on another benchmark to fill-in the benefit only begs the question of whether any plan is actually providing meaningful coverage as required by the ACA.

The Language of the ACA

The *Rules of Statutory Construction* indicate clear Congressional intent in the ACA. In defining the EHB, the ACA reads[15]:

> Subject to [a requirement to cover services in equal scope as provided under typical employer coverage], the *Secretary shall define* the essential health benefits, except that such benefits shall include at least the following general categories and the items and services covered within the categories:
>
> (A) Ambulatory patient services.
> (B) Emergency services.
> (C) Hospitalization.
> (D) Maternity and newborn care.
> (E) Mental health and substance use disorder services, including behavioral health treatment.
> (F) Prescription drugs.
> (G) Rehabilitative and habilitative services and devices.
> (H) Laboratory services.
> (I) Preventive and wellness services and chronic disease management.

[15] ACA § 1302(b)(1) (emphasis added).

(J) Pediatric services, including oral and vision care.

According to the basic rules of statutory interpretation, the ACA should be read in the simplest way which gives meaning to all of its parts, reduces redundancies and contradictions, and accords with the statute's intent.[16] Applying these rules, the appropriate way to interpret the EHB provision is that it applies the requirement for typical employer equivalence only to the general definition of EHB by the Secretary and separately requires the EHB to additionally cover services in each of the Ten Categories.[17] In other words, the Secretary must design an EHB package equivalent to a typical employer plan plus ten additional categories.

Each of the Ten Categories is a non-redundant addition to supplement typical employer coverage. Furthermore, "plus ten" means that provisions including services like habilitative service now take on meaning. The "plus ten" reading matches the language of the law and is the only way to give meaning to all of the provisions. This interpretation is what statutory interpretation requires, as a matter of law.

Furthermore, "plus ten" is also the interpretation which best comports with legislative intent. One of the fundamental underlying principles in the ACA, reflected in countless ACA provisions, is that by investing in critical services we will transform health care coverage and reduce long term spending. It would make no sense for the ACA to, with regard to the EHB standard, list the critical services and then suggest they be covered only to the minimal extent already covered. It is no coincidence that the "plus ten" categories include critical gap services like preventive and wellness services and chronic disease management, maternity and newborn care, pediatric services, etc., and it is the ACA's intent to invest in these services beyond current minimum norms.

The statute should not be read to apply the first clause requiring equivalence with typical employer coverage to both the general definition by the Secretary and to all of the required ten Categories. Such a reading of the statute would violate the rules of statutory construction and make it impossible to make sense of the statute for at least two clear reasons:

1) Redundancy. Each phrase of a statute needs to be given its full meaning, and the statute cannot be read to make provisions redundant.[18] The statute requires the Secretary to *generally* design an EHB package equivalent to typical employer coverage. It is entirely redundant for the statute to then list ten *specific* areas of coverage if those areas are interpreted to only be covered to the extent covered under typical employer coverage. Coverage of the specific areas would already be required by the general requirement. Therefore, if the list of Ten Categories is to serve any purpose or make any sense, it must be the case that it was not intended to be limited by the typical employer requirement.

[16] *See United States v. DBB, Inc.*, 180 F.3d 1277, 1285 (11th Cir. 1999); *Morante-Navarro v. T & Y Pine Straw, Inc.*, 350 F.3d 1163, 1167-68 (11th Cir. 2003).
[17] The simplicity of this approach is confirmed by the layout of the statute. The first clause requiring "typicality" should apply to the second clause. The third clause was placed last and begins with "except" because it was meant to stand alone, and modify both of the first two clauses.
[18] *United States v. DBB, Inc., supra* note 15, at 1285.

2) Meaningless provisions. The rules of statutory construction require that provisions of a statute not be rendered meaningless.[19] Numerous of the Ten Categories listed (for example, mental health and substance abuse disorders and rehabilitative and habilitative services and devices) are services categories which receive virtually no coverage in typical employer coverage. It would make no sense for the ACA to create a requirement to cover a specific service ~~–in~~ the same scope as a typical employer" when that coverage is nearly nonexistent. For the inclusion of a service like habilitative services to make any sense, therefore, each of the categories cannot be subject to the typical employer requirement.

❖ ***Recommended Regulatory Approach***

- The Bulletin should be made consistent with the clear statutory language and thus amended to require that in all Ten Categories the EHB standard must provide substantial coverage, with substantial coverage defined as the level of coverage needed to meet the needs of the covered population. This means that a benchmark (we oppose reliance on benchmarks) should be supplemented if it is offering no coverage or less than substantial coverage in one of the ten categories.

5. Minimize Use of Utilization Management

The Bulletin suggests that the regulatory approach will grant states and insurers extensive flexibility to reference and modify benchmarks. While any ~~–t~~ypical" employer plan would be expected to employ utilization management techniques, the framework created by the Bulletin makes it likely that there will be abnormally heavy use of utilization management. This is likely to be true for a number of reasons. Most notably, the Bulletin allows benchmarking to small group plans, which rely heavily on utilization management.[20] Furthermore, the general flexibility suggested to allow insurers to modify benchmark designs will lead to further increase of utilization management. The net result for the low-income individuals who will be the largest population relying on the EHB standard will be more barriers to care which worsen their health.

Utilization management techniques are not all inherently problematic. For example, a medication management review to evaluate prescription contraindications can be helpful. However, the reality is that the majority of utilization management conducted by insurers today is used to drive down utilization, not to improve care, much to the detriment of consumers. For vulnerable individuals, who lack the extra money to pay out-of-pocket for needed care, the result is predictable: they go without care. Some forms of utilization management, such as copays, may in fact never serve any valid clinical purpose.

[19] *id.*
[20] *See* Alan Spiro, *Utilization Management in the Small Group Insurance Market*, 4 AMER. J. MED. QUALITY 43-46 (1989)

The Bulletin does not specify any criteria focusing utilization management for the EHB on improving quality. Because the Bulletin does not provide these details, and there is instead flexibility granted to small group plans and insurers to modify benefits, NHeLP is concerned that utilization management strategies would solely reflect the cost control goals of insurers. This would not only restrict coverage and scope of services, but access to them as well. Such an approach would be detrimental to low-income and medically-underserved communities who are more likely to be experiencing poor health status and health disparities.[21] Moreover, cost control utilization management strategies serve to inhibit deference to health providers as clinical managers, and typically results in negative health outcomes for low-income patients.

Utilization management strategies applied to the EHB should be limited to evidence based criteria with the sole objective of allowing health providers to improve the quality of services offered to their patients. Utilization management criteria should be documented and publicly available, to ensure that decisions are made based on sound clinical practice. The standards should be based on medical criteria (such as guidelines of the major relevant professional academies or provider associations, for example, the American Academy of Pediatrics, American Congress of Obstetrics and Gynecologists, etc.). Ultimately, a coverage limit should only be allowed if it is based on medical evidence and is not detrimental to the health care needs of enrollees.

In those 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 an EHB 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 drug, without additional cost or delay to the individual.[22] This position is currently reflected in the Medicaid Act's policies and should also be applied to EHBs.

Utilization Management Can Negatively Impact the Health of Low-Income Communities

It is widely recognized that low-income populations have a poorer health status, with more chronic health problems and work limitations because of their health than more affluent

[21] Leighton Ku and Victoria Wachino, *The Effect of Increased Cost-sharing in Medicaid: A Summary of Research Findings* (July 7, 2005), http://www.ideainfanttoddler.org/pdf/apph.pdf.; LEIGHTON KU ET AL., CTR. ON BUDGET & POLICY PRIORITIES, THE EFFECTS OF COPAYMENTS ON THE USE OF MEDICAL SERVICES AND PRESCRIPTION DRUGS IN UTAH'S MEDICAID PROGRAM (2004), http://www.cbpp.org/files/11-2-04health.pdf

[22] 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)).

populations.[23] Low-income communities also face additional barriers when attempting to access high quality sources of health care. In addition, about half of poor and near-poor adults are from minority racial or ethnic groups with an estimated 20% of poor adults living in homes where English is not the spoken language compared to only 8% of adults with incomes of at least 200% of poverty.[24]

To improve health status and reduce mortality and long-term disability rates of underserved populations, it becomes critical that they obtain effective medical treatment and interventions in a timely fashion. Efforts from health insurers to use utilization management strategies to restrict access to services and control health costs can exacerbate health disparities for low-income populations.

The approach often used by health insurers to control utilization tends to focus on coverage for services that are expensive or indicate some variation in use.[25] As a result, low-income individuals with disabilities or chronic health issues are more likely to be negatively impacted by these coverage limitation strategies. For example, prior authorization requirements and restrictive drug formularies can create unnecessary delays in low-income patients obtaining access to specialty care treatment and prescription drugs. This is a particular concern for those individuals with disabilities, such as certain forms of cancer and HIV/AIDS. Similarly, restrictive or excluded coverage in EHB plans for pediatric dental care may prohibit access to specialty dental providers (e.g., orthodontists), as well as mid-level dental providers and other non dentists (e.g., hygienists and medical providers) who can provide limited oral health services (such as fluoride varnish) for low-income children experiencing oral health disparities.

Health providers have criticized utilization review generally as a strategy that over-standardizes diagnostic and treatment options and impedes their ability to practice medicine.[26] This concern underscores the need for utilization management techniques to serve only as a tool for providers in delivering quality health services to low-income populations, instead of for cost containment or coverage limitation purposes. The Bulletin and subsequent EHB guidance should reflect this policy.

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[23] HOLLY MEAD ET AL., RACIAL AND ETHNIC HEALTH DISPARITIES IN U.S. HEALTH CARE: A CHART BOOK 19 (2008). These include, but are not limited to higher incidence and mortality rates of hypertension, stroke, heart disease, mental illnesses and substance use, diabetes, and asthma.

[24] Kaiser Family Foundation – Kaiser Commission on Medicaid and the Uninsured, *Low Income Adults under Age 65: Many Are Poor, Sick, and Uninsured* (June 2009), http://www.kff.org/healthreform/upload/7914.pdf.

[25] Terry Golash, MD, *Basic Principles and Practices of Utilization Management*, 4 SEMINARS IN MED. PRAC. 5, 8 (March 2001).

[26] *Id.* at 13. *See also* American Academy of Child & Adolescent Psychiatry, *Policy Statements: Issues in Utilization Management* (June 1990), http://www.aacap.org/cs/root/policy_statements/issues_in_utilization_management. —From a clinician's point of view, many utilization management reviewers are intruding into clinical practice in a way that has a negative effect on quality of care. . .by compromising confidentiality, and by inappropriately mixing fiscal and medical treatment concerns. . . ." *Id.*

Medical Necessity Requirements

While not directly addressed by the Bulletin, it is critical that the EHB reflect an appropriate standard for defining medical necessity. Medical necessity is a management tool which will be one of the core determinants of whether a service should be covered and/or is accessible to an individual. All too often, however, medical necessity is defined by rigid or narrow criteria which prevent individuals from accessing medical treatments which they need.

Medical necessity should generally defer to the clinical judgment of the treating physician or treatment team. The major advantage of this view is that it reduces the likelihood that determinations of insurance coverage will be solely cost-based or administratively burdensome. This approach is particularly applicable since Exchanges, Medicaid benchmarks, etc., will rely heavily on managed care delivery systems. Because one of the primary responsibilities of managed care delivery systems is to contract with a highly qualified network of health providers, proper selection of networks establishes the foundation for allowing deference to the clinical decisions of network providers and minimized utilization review.

Accordingly, NHeLP recommends that the decisions of the treating provider should be given great weight and deference. When decisions are reviewed, the purpose of the review should be to determine:

- Whether the treatment accords with professional standards of practice (these standards should be considered a baseline of professionally agreed-upon practices, generally based on large quantities of evidence from empirical studies (i.e., evidence based), but where such evidence is lacking due to the condition or unique nature of a patient‘s needs or illness, the standards should be based on a clinician‘s experience in practice;
- Whether it will be delivered in the safest and least intrusive manner and least restrictive setting;
- Whether there are equally effective treatments, services, and care that are actually available and accessible to the enrollee.

We also encourage an explicit understanding of medical necessity for children living at or below 400% FPL and children with special health needs that is defined using the Early and Periodic Screening, Diagnostic and Treatment services (EPSDT) standard. This standard focuses on whether the care and/or treatment are necessary to correct or ameliorate physical and mental illnesses. Medical necessity should also include treatments which maximize, maintain, or reduce the degeneration of functional status.

Formularies

The Bulletin suggests modeling flexibility around drug benefits after the Medicare Part D system, however, it recommends requiring coverage of *one* drug per class where Medicare requires coverage of *two* drugs per class. At a minimum, HHS should require coverage of two drugs per class as is the Medicare norm. If HHS maintains this formulary structure, we recommend that HHS carefully design the drug classes to promote uniformity and maximize

coverage of sub-classes. As with all utilization management techniques, HHS should ensure a simple and accessible exceptions process is required.

❖ ***Recommended Regulatory Approach***

- The Bulletin should not allow benchmarking to small group plans or other flexibility which will subject low-income and underserved enrollees to heavy utilization management.
- Use of utilization management should be minimal.
- Utilization management techniques that are used must be based on documented evidence-based criteria or standards.
- In all cases, plans using the EHB standard should have a clear and simple exceptions process for patients or their providers to initiate expedited exceptions to any utilization management requirements. Plans should defer to the clinical opinion of treating physicians with whom they contract.
- Medical necessity determinations should also defer to the clinical judgment of treating physicians. Any review of this judgment should be subject to clear requirements (described above).
- Medical necessity should be broadly understood to include both physical and mental illnesses, promotion of functional status, and emphasis on the least restrictive setting for patient care.
- Formularies should be required to include at least two drugs in each class, and classes should be carefully designed.

6. Broadly Include State Benefit Mandates

The Bulletin indicates that state laws regarding required coverage of benefits vary widely in number, scope and topic so that generalizing about mandates and their impact on typical employer plans is difficult.[27] This also makes it challenging to assess the impact of HHS' proposal for State Mandates.

Section 1311(d)(3)(B) of the ACA requires states to defray the cost of any benefits required by the state which are not included in the EHBs. In the Bulletin, HHS suggests a transition plan for 2014 and 2015. For those two years, if a state chooses a benchmark subject to state mandates, then the mandates will be included in the state's EHB package, and the state will not have to cover the cost. But if a state selects a benchmark that does not include some of the mandates then the state will have to pay the cost of those mandates. According to the Bulletin, HHS will reevaluate this system in 2016 and will develop an approach that may exclude some state benefit mandates from inclusion in the state EHB package.

[27] *Essential Health Benefits Bulletin,* CCIIO, December 16, 2011, pg. 7.

We urge HHS to consider the important value of many existing mandates. Failure to include state mandates in the EHB definition will mean that, ultimately, states will have an incentive to drop mandates. Many of these mandates provide valuable coverage to individuals.

Value of state mandates

The IOM recognized that state mandates are market interventions aimed at meeting critical health policy goals recognized by a state legislature. The aim of state mandates is to improve population health while requiring that the risk of loss be shared within the insured community.[28] Mandates also play a critical role in helping states address gender, racial, and disease disparities. An EHB standard which ignores state efforts to improve insurance coverage will undermine those efforts and put states and insurers in an untenable financial situation.

While we recognize the IOM has raised an important question regarding whether state mandates are usually well-grounded in evidence-based medicine, we consider that many state mandates *are* evidence-based, and many of those that are not, are in keeping with modern clinical practice and otherwise valuable. The lack of clear evaluative criteria for evidence-based standards or best clinical practice makes it hard to accept the IOM's evaluation on this issue. Numerous populations which are often ignored by mainstream health insurance – such as children with autism or low-income women – depend upon state mandates to receive critical services.

We note that while mandates differ between states, there are many important types of mandates protecting health care services/treatments and health providers whose services should be covered by health plans.[29] We believe that the cost of including these mandates in the EHB will be lessened by the fact that many of the mandates will be included within the ten required EHB categories or in benchmark coverage (if HHS implements a benchmarking framework, which we have recommended against). There will, however, be a subset of the mandates which are not included. For example, certain services do not appear to fall within any of the ten categories (e.g., chemotherapy, renal dialysis, mastectomies, organ transplants) and many are not generally included in the benchmarks.[30] It is also unclear how services rendered in skilled nursing facilities, home health, and hospice settings will fit into these categories or be covered by benchmarks.[31] We note also that because the EHB standard will be the only minimum requirement for critical preventive services for some EHB-covered populations (i.e., the PHSA section 2713 requirements are not explicitly applied to the Basic Health Plan or the Medicaid benchmarks), state mandates may be all the more important to ensure access to basic preventive services such as contraceptive services and supplies. In addition, as noted below, we recommend that coverage of all of the preventive services in Section 2713 of the ACA be required as part of the EHB ~~"p~~reventive and wellness services and chronic disease management" category. Regardless of the ten categories or benchmarks, it is crucial that the EHB definitions be adjustable to include valuable mandates.

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[28] *See* IOM Report at 4-16.
[29] State Health Insurance Mandates and the ACA Essential Health Benefits Provisions, NCSL, Updated December 16, 2011, pg. 5.
[30] *Essential Health Benefits White Paper,* National Health Council, September 2010, pg. 13.
[31] *id.*

HHS Bulletin jeopardizes state mandates

Since the ACA makes states responsible for any services required above and beyond the EHB requirements, states are financially liable for mandates if they are not included in the EHB definition. This creates a dangerous incentive for states to drop existing mandates.[32] Put another way, this position punishes states that have taken steps to address the inequities in insurance market coverage and makes it likely mandates will be dropped after 2015. This would have a negative impact on all of the populations dependent on mandates for coverage.

Recognizing this, the Bulletin creates a two year grace period whereby states can (with key exceptions discussed later) continue to require coverage for state mandates without incurring any costs. However, this grace period only delays the inevitable conflict and does not change the fact that states will have an economic incentive to drop the mandates two years later. We recommend the policy be altered to ensure on-going and enduring inclusion of valuable state mandates. Otherwise, we hope it is HHS' intent to use the two year transition period to include mandates in the EHB definition.

Mandate evaluation, inclusion and review

There should be a process for determining which existing state mandates are added to the EHB package. HHS should identify these mandates and ensure that coverage provided in the EHB is sufficient to avoid disruptions in care. We urge HHS to include in the EHB package those mandates which occur with high frequency among states, as well as those grounded in a strong evidence base. That said, a weak evidence basis should not be sufficient to reject a mandate. The science of evidence based standards is in its infancy, and many mandates may be in place precisely because the treatment or service has a successful track record in improving or maintaining health despite a missing or weak evidence base. Given the importance of services covered through state mandates to individuals in states, HHS' evaluative process should be transparent and include stakeholder input.

At least 30 states have a mandate review requirement which restricts the adoption of new mandates and is intended to analyze and in some cases justify the medical efficacy and cost-effectiveness of the mandate.[33] For example, the California Health Benefits Review Program (CHBRP) analyzes mandates by looking at

> ~~(~~a) the impact on the health of the community, including the reduction of communicable disease and the benefits of prevention such as those provided by childhood immunizations and prenatal care, (b) the impact on

[32] We note as an example that this has occurred in the context of federal mandates, which only require that *if* a health plan offers the benefit, it must comply with minimum requirements. Therefore, some health plans have opted to exclude the benefit category entirely in order to avoid the requirement associated with the mandate (e.g. excluding coverage for mental health). See *Essential Health Benefits White Paper,* National Health Council, September 2010, pg. 2.

[33] State Health Insurance Mandates and the ACA Essential Health Benefits Provisions, NCSL, Updated December 16, 2011, pg. 2.

> the health of the community, including diseases, and conditions where gender and racial disparities in outcomes are established in peer-reviewed scientific and medical literature, and (c) the extent to which the proposed service reduces premature death and the economic loss associated with disease."[34]

HHS should consider using a similar review process when determining which state mandates will be included in the EHB package.

Bulletin's proposed mandate framework will harm benchmark selection

If benchmarks are to be used (see above for our strong objections), then state mandates and the process for including such mandates should be applied to all benchmark selections. Including state mandates in all benchmark selections would eliminate the negative incentives created by the Bulletin policy.

❖ ***Recommended Regulatory Approach***

- HHS should develop a process to evaluate existing state mandates and include valuable mandates in the EHB package on a permanent, not temporary, basis in a timely manner before states begin repealing mandates.
- HHS should not include mandates in a way which favors some benchmark options.

7. Implement High Standards For Preventive Services and Children's Health

In setting existing private market plans that serve higher-income, historically insured and healthier populations as the standard for scope and content of coverage, the Bulletin does not meaningfully recognize that the EHB package will be the primary, if not only, source of health coverage for millions of lower-income and underserved individuals that have higher and different needs than those of historically privately insured consumers. To strengthen the Bulletin to meet the needs of medically vulnerable individuals, HHS should look to existing models or standards that better serve these populations and take their particular needs into account. In particular, HHS should look to Medicaid's Early and Periodic Screening, Diagnostic and Treatment (EPSDT) program to strengthen the Bulletin and form the foundation for a distinct EHB standard for children. With regard to preventive services, HHS should take a more prescriptive approach that includes comprehensive preventive services as required by section 1302 of the ACA, and to this end include the evidence-based standards and services required in section 2713 of the Public Health Services Act (PSHA).

[34] CHBRP looks at mandates with a public health/health improvement framework rather than a strict cost-effective framework, and also considers racial/gender health disparity outcomes. Information about CHBRP available at: www.ncbi.nlm.nih.gov/pmc/articles/PMC1713219.

Children's Coverage.

Ensuring a robust and comprehensive EHB package is critically important for children, especially those who are lower-income and/or have special health care needs. Because the private insurance market has not historically provided benefits sufficient to meet children's health needs (as it is geared more towards the needs of employers), HHS must aggressively define the EHB package for children and cannot rely on the sufficiency of the existing benchmark options outlined in the Bulletin. HHS should look to Medicaid's Early and Periodic Screening, Diagnostic and Treatment (EPSDT) program to strengthen the Bulletin and form the foundation for the EHB package for children.[35] While we recognize that the CHIP program has helped children and is referenced in the Bulletin, it should not be the benefit model for lower-income children because it offers inadequate coverage; Medicaid's EPSDT standard for low-income children's benefits is the only one that meets the needs of these vulnerable children.

Because it will serve millions of families living in or near poverty, the EHB standard will be relevant to many low-income children. It is well established that low-income children are more likely to have poor health than other children.[36] Low-income children have a higher prevalence of special health care needs and conditions such as obesity, asthma, and attention deficit hyperactivity disorder.[37] Low-income children are also at greater risk for extreme prematurity, oral health problems, elevated blood lead levels, and behavioral health problems, all of which can cause long-term disabilities and limitations.[38] Moreover, children's health care needs are different from adults', making it unlikely that children will be well served by a standard designed primarily to meet the lesser health needs of higher-income adult populations. The scope and content of the EHB package must therefore be specifically tailored to offer the necessary preventive screenings, developmental services, and treatments that each child requires to be as healthy and functional as possible.

Private insurance plans – like the benchmark plans proposed in the Bulletin – have historically failed to cover services that are critical for children's health. A study in the *New England Journal of Medicine* found that children in private plans are twice as likely to be *under*insured as

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[35] *See* AMERICAN PUBLIC HEALTH ASSOCIATION, MEDICAID, PREVENTION AND PUBLIC HEALTH: INVEST TODAY FOR A HEALTHIER TOMORROW (2005), at http://www.apha.org/NR/rdonlyres/675F96CD-7701-4049-89BD-D96625A6A3BE/0/MedicaidReport.pdf. The EPSDT Program provides comprehensive preventive health services, screenings, treatment, and follow-up care for children enrolled in Medicaid under age 21.

[36] *See, e.g.,* Leighton Ku et al., Center on Budget and Policy Priorities, Improving Children's Health: A Chartbook About the Roles of Medicaid and SCHIP (2d ed. 2007).

[37] *See, e.g.,* Sara Rosenbaum & Paul H. Wise, *Crossing the Medicaid-Private Insurance Divide: The Case of EPSDT*, 26 HEALTH AFFAIRS, 382-93 (2007); C. Bethel et al, *National, State and Local Disparities in Childhood Obesity,* 29 HEALTH AFFAIRS, 347-56 (2010).

[38] *See, e.g.,* The George Washington University, Comparing EPSDT and Commercial Insurance Benefits (September 2005); Clarisa Ramirez, *Toothaches more likely in minority, poor, special needs children, study finds*, Medill Reports Chicago, Nov. 4, 2010.

their counterparts in public programs.[39] This is due in large part to the overall lack of emphasis on preventive care. Additionally, private insurers commonly employ a narrow definition of medical necessity, limited to services that diagnose or treat illnesses and are needed to restore normal functioning.[40] Only limited rehabilitative services are covered, and habilitation services are not typically included at all. Oral and vision care coverage is also unusual. Such narrow definitions too often serve as a blunt tool used to draw sharp lines that deny the type of care that vulnerable children need to stay healthy and thrive.

For the reasons outlined above, HHS should take a prescriptive, rather than flexible, approach in setting the standard for children's health care. Medicaid's pediatric standard of coverage, EPSDT, should serve as the model for the scope and breadth of EHBs for children, including vision/oral care. EPSDT was developed specifically to meet the physical, emotional, and developmental needs of low-income children. EPSDT covers, for all children under the age of 21: medical screens according to a periodicity schedule (including a comprehensive health and developmental history), a physical exam, immunizations, lab tests, and health education; vision, hearing, and dental services; and the necessary treatments and services (consistent with the scope of benefits under the Medicaid Act, 42 U.S.C. 1396(d)(a)) to correct or ameliorate physical and mental illnesses.[41] Using EPSDT as a model for essential pediatric benefits will ensure that plans are required to provide not only frequent screening and preventive measures, but also comprehensive treatment to correct or ameliorate physical and mental conditions, including chronic diseases and developmental conditions.

Additionally, as detailed in section six above, NHeLP is concerned about the future of state mandates. Because there are many state laws that currently mandate the coverage of services of importance to children, a failure to permanently incorporate those services into the EHB standard is likely to result in a dilution of covered services on which many children currently rely. In particular, as HHS highlights in the Bulletin, coverage of ABA therapy for autism is currently mandated in 29 states, meaning that privately insured children in a majority of states currently have access to this important clinically proven therapy.[42] This is a primary example of a mandate that occurs with high frequency and should therefore be included in the EHB standard so as to avoid widespread disruptions in care and untenable positions for states that have made informed policy judgments in response to children's health needs and should not face financial repercussions for doing so.

- ***Recommended Regulatory Approach***

  - HHS should take a prescriptive, rather than flexible, approach in setting the standard for children's health care.

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[39] Michael D. Kogan et al., *Underinsurance among Children in the United States*, 363 New Eng. J. Med. 2010, 841-851, 845 (2010).
[40] *See, e.g.,* Rosenbaum & Wise, *supra* note 25, at 387-91.
[41] 42 U.S.C. §§ 1396a(a)(10)(A), 1396a(a)(43), 1396d(a)(4)(B), 1396d(r). For further explanation, *see, e.g.,* National Health Law Program, Towards a Healthy Future: Medicaid Early and Periodic Screening, Diagnostic and Treatment Services for Poor Children and Youth (2005).
[42] U.S DEP'T OF HEALTH & HUMAN SERVICES, ESSENTIAL HEALTH BENEFITS BULLETIN 7 (2011).

- Medicaid's pediatric standard of coverage, EPSDT, should serve as the model for the scope and breadth of EHBs for children, including vision/oral care. This includes EPSDT's broader medical necessity definition, which is critical to ensuring healthy childhood development.
- Valuable state mandates securing access to critical services for children should be included in the EHB definition.

Coverage of preventive health services

The EHB package is specifically intended to remedy and close existing gaps in private health care coverage. For this reason, "preventive and wellness services and chronic disease management" were included in the list of ten categories of additional coverage in Section 1302 of the ACA. Yet, in pinning preventive coverage in the EHB to the level of coverage already offered in a benchmark, HHS is upholding the very model that the ACA acknowledged as deficient. This approach maintains the focus on reactionary and acute care and contradicts the intent of the ACA to transform the way individuals receive health care through a focus on preventive services and treatment of chronic conditions – services that will improve long-term health and improve overall quality of life.

The flexibility provided to states and insurers in the Bulletin is likely to lead to EHB packages that will fail to secure the health of low-income and vulnerable communities who will not have the resources to otherwise access critical preventive services that remain uncovered. Failure to provide the robust and comprehensive preventive benefits that this population needs will lead to unnecessary emergency room visits, unnecessary hospitalizations, unplanned and high-risk pregnancies, and costly mismanagement of chronic illness. It will also lead to millions of people living in poorer health and lower functional status, exacerbating existing health disparities among low-income individuals, many of whom are also people of color.

Incorporation of PHSA Section 2713

We strongly encourage future EHB guidance to be more prescriptive and aggressive in setting out robust and comprehensive preventive care requirements that stretch beyond what has historically been provided in private market coverage, as is required under section 1302 of the ACA. One obvious step to achieve this, which also would improve systemic coordination of benefits, is for the Bulletin to explicitly reference and incorporate section 2713 of the PHSA into the core EHB requirements. Section 2713 requires coverage of four categories of recommended preventive health services, all of which are evidence-based and critical for securing the health of women, children, low-income individuals, and other vulnerable populations.

Some analysts have mistakenly concluded that there is no problem regarding section 2713, since section 2713 protections will apply to many health insurance plans regardless of the EHB standard. However, dependence on the applicability of section 2713 is insufficient and has the potential to leave many without critical services and protections. Important consumer protections under the ACA, such as lifetime and annual limits, are attached exclusively to services encompassed by the EHB standard and do not extend to benefits outside that standard.

Further, section 2713 does not independently apply to many low-income populations. None of the section 2713 requirements explicitly extend to the Basic Health Plan or Medicaid benchmark coverage.[43] Enrollees in these public insurance plans will depend on the EHB standard for requirements regarding the scope of preventive health services. If the services that are necessary and required under section 2713 are not included within the EHB standard, the neediest enrollees will go without the robust service requirements that higher income populations will receive, or will have to pay copayments that higher income populations do not have to pay. HHS must prevent this perverse result by incorporating the requirements of section 2713 into the requirements for all EHB plans.

Benchmarking to grandfathered or outdated plans should be prohibited

In the absence of further action to include section 2713 in the EHB requirements, the approach outlined in the Bulletin will allow states the flexibility to choose a benchmark plan that is not subject to section 2713 requirements. Nothing in the Bulletin explicitly prohibits a state from selecting a plan with grandfathered status as the standard for its state EHB package. Because grandfathered plans are explicitly exempt from section 2713 requirements, this flexibility will allow states to select EHB benchmarks that do not offer the robust preventive health benefits contemplated by the ACA. HHS should explicitly preclude states from any flexibility to use grandfathered plans to set their EHB standards.

Additionally, the flexibility contained in the Bulletin could conceivably allow a state to define its EHB package through a benchmark plan *as it existed at the particular point in time when it was selected*. Because issuers are not required to meet the coverage requirements under section 2713(a)(4) relating specifically to women's preventive services and contained in the Women's Preventive Services Guidelines until August 1, 2012 at the earliest and potentially later, state EHB standards based on the static contents of a benchmark plan before that date are not guaranteed to include these critical services for women even if the benchmark selected does not have grandfathered status. HHS should explicitly preclude states from selecting plans that do not yet meet the women's preventive services requirements under section 2713(a)(4).

Finally, the critical reproductive services required under section 2713(a)(4) for women (discussed further in the next section) should extend to men, where appropriate. Reproductive health is integral to both women's and men's health, and men should also be able to gain access to annual counseling and screening for STIs and HIV/AIDS, as well as all FDA-approved contraceptive methods (e.g., condoms), sterilization procedures, and family planning education and counseling.

[43] §§ 2713(a)(1) and (a)(2) are applied to Medicaid state plan services (at 1905(a)(13)) through ACA § 4106, however, Medicaid state plan services at 1905(a)(13) are not applicable to Medicaid benchmark coverage, which relies on the coverage rules at § 1937. Meanwhile, §§ 2713(a)(3) and (a)(4) are not applied to Medicaid coverage in § 4106 or any other provision.

❖ ***Recommended Regulatory Approach***

- The Bulletin should require comprehensive coverage in each of the ten statutorily mandated areas, including ~~"~~preventive and wellness services and chronic disease management." This must be coverage above and beyond what is already in a benchmark.
- The Bulletin should require a strong prescriptive preventive health benefit, not subject to reduction through benchmarking schemes or state and insurer flexibility.
- The Bulletin should incorporate section 2713 of the PHSA into the core EHB requirements.
- To the extent that HHS allows some flexibility, HHS should explicitly prohibit states from selecting grandfathered plans or plans that do not include all section 2713 services or including plans that do not yet meet the women's preventive services requirements under section 2713(a)(4) as the benchmarks for EHB standards, or otherwise modifying those requirements.
- NHeLP recommends that the EHB guidance be strengthened to specifically require a full range of reproductive health services and extend the reproductive services required under section 2713(a)(4) to men, where appropriate.

8. Prevent Discrimination and Reduce Disparities

ACA requirements

The Affordable Care Act contains numerous provisions that prohibit discrimination in the creation of the Essential Health Benefits package. The Bulletin fails to comply with these requirements by allowing for a weaker, flexible benefit that will discriminate against numerous vulnerable populations.

Section 1302 of the ACA creates the EHB requirement. This provision places specific requirements on the Secretary prohibiting discrimination and requiring special consideration for vulnerable communities. First, there is an explicit prohibition on design benefits and making other decisions ~~"~~in ways that discriminate against individuals because of their age, disability, or expected length of life." Second, there is a specific requirement to take into consideration the needs of diverse populations, including ~~"~~women, children, [and] persons with disabilities." Finally, there is a requirement that the EHB 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." All of these statutory provisions bar discrimination and require special considerations for diverse populations with respect to the EHB package.

The ACA also contains a general nondiscrimination provision, section 1557, which prohibits discrimination based on race, ethnicity, national origin, age, disability, functional status, or gender by any ACA provision. This provision provides an independent and additional prohibition on discrimination in the EHB package, because the EHB will be offered in the

Exchanges which receive federal funds and because the Exchanges and qualified health plans are regulated by the federal government.

In sum, the ACA has both specific and general requirements which prohibit the development of an EHB standard which intentionally or in effect discriminates against vulnerable populations. The EHB standard proposed in the Bulletin would result in discrimination against numerous protected populations in violation of the ACA requirements.

As described in previous sections, the Bulletin creates an EHB standard that provides for inadequate coverage for lower income vulnerable populations. These vulnerable low income populations are disproportionately composed of the very populations the ACA's anti-discrimination provisions are trying to protect – racial and ethnic minorities, women, and individuals with disabilities. The implementation of the EHB standard described in the Bulletin will in practice discriminate against legally protected populations.

Excessive flexibility will lead to discriminatory adverse selection

The EHB design proposed in the Bulletin will also discriminate against vulnerable groups because the extreme flexibility allowed to states and insurers will facilitate insurance rating practices whereby sick populations or those who have historically not had insurance and need more initial services will be avoided. The ACA's intent to ban explicit pre-existing condition exclusions will be threatened by the ability of insurers to use benefit design as a proxy for health status. This of course defeats the goal of the ACA to stabilize health costs by balancing risk pools better. Ultimately, vulnerable populations associated with costs – such as the elderly, individuals with a disability, LEP patients, or women – may be discriminated against with the proposed EHB standard.

❖ ***Recommended Regulatory Approach***

- The Bulletin should require the EHB to include a prescriptive definition of benefits which meets the needs of diverse populations to comply with the statutory requirements prohibiting discrimination. This requires upfront and on-going disparities analysis to evaluate amendments to the EHB and address the specific needs of vulnerable populations.
- The Bulletin should not allow for extreme state flexibility and should not introduce issuer flexibility. There should be no provisions for benefit ―substitutions," as these will have a discriminatory impact.
- If any flexibility is allowed, HHS must conduct additional monitoring and enforcement to ensure that vulnerable populations are not discriminated against in benefit design, including through design that promotes adverse selection.

Discrimination against women

The standard proposed by the Bulletin fails to require that the health needs of low-income women be taken into account. Because women, particularly women of color, experience higher

rates of poverty and lower wages than men, they are more likely to experience chronic health conditions associated with poverty and less likely to overcome barriers to health care.[44] Additionally, low-income women are the least likely to have the resources to obtain reliable methods of family planning and most likely to experience unintended pregnancies.[45]

A failure to mandate coverage of robust preventive and reproductive benefits will force many women to go without needed health care and enter the health system at more advanced stages of illness, requiring more invasive and expensive treatments and interventions. Perhaps no example in all of health care has been better established than the heavy expenses associated with failing to provide women with robust family planning services and supplies.[46] Women will therefore be inequitably harmed by the approach proposed in the Bulletin, which sets benchmark plans that are designed to cover higher income, historically insured, and healthier populations, as the standard of coverage for all.

Women have special health needs and are typically underinsured in the private market

The failure to require a strong national EHB standard that guarantees robust and comprehensive coverage will lead to discrimination against women because women are high utilizers of health care overall. In addition to being disproportionately poor and lower-income, women live longer, bear a higher historical burden of chronic disease and disability, and have many reproductive and gender-specific needs and conditions. While the benchmark plans likely to result under the Bulletin's broad requirements may provide sufficient coverage for most healthy men, the failure to create a generous EHB standard designed to specifically provide for women's health needs will mean that women are less likely to receive meaningfully comprehensive or sufficient coverage and more likely to remain underinsured. Additionally, the Bulletin allows insurers the flexibility to design coverage that generally disfavors women because of their heightened and more expensive health needs.

Women have specific and critical – indeed, *essential* – health needs that are unique and less likely to be covered by insurers in the absence of explicit coverage requirements. The historic exclusion or insufficient inclusion of critical women's health services in private market health plans means that the proposed benchmarking scheme is likely to perpetuate historic gender

[44] Nat'l Women's Law Ctr, POVERTY AMONG WOMEN AND FAMILIES, 2000-2010: EXTREME POVERTY REACHES RECORD LEVELS AS CONGRESS FACES CRITICAL CHOICES (2011), http://www.nwlc.org/sites/default/files/pdfs/povertyamongwomenandfamiliesin2010.pdf (last visited Jan. 12, 2012).

[45] Lawrence B. Finer & Mia R. Zolna, Guttmacher Institute, *Unintended pregnancy in the United States: incidence and disparities, 2006* 8, 11-12 (2011), http://www.guttmacher.org/pubs/journals/j.contraception.2011.07.13.pdf .

[46] *See, e.g.,* Adam Sonfield, Kathryn Kost, Rachel Benson Gold & Lawrence B. Finer, Guttmacher Institute, *The Public Costs of Births Resulting from Unintended Pregnancies: National and State-Level Estimates*, 43(2) Persp. on Sexual & Reprod. Health 94 (2011), https://www.guttmacher.org/pubs/psrh/full/4309411.pdf.

inequities in health coverage.[47] According to the Guttmacher Institute, 28 states require insurers to cover FDA-approved contraceptives.[48] These contraceptive equity laws arose specifically because insurers were not covering contraceptives even though they were covering other prescription products. In 1998, before the first state contraceptive mandate was enacted, 97% of indemnity plans covered prescriptions, but only 33% covered prescription contraceptives.[49] The Bulletin allows a level of flexibility within the ten required categories of coverage that will permit insurers to design benefit packages that technically meet the anemic EHB requirements while failing to provide the scope of services that are required to secure and protect women's health. Requiring the EHB standard to cover categories of services of particular importance to women, such as maternity and preventive services, *only to the extent already covered* by an existing commercial plan, is likely to lead to inadequate and substandard coverage for women.

Women's health services should be prescriptively required

To be substantial and comprehensive, coverage must consider and address the health needs of women, likely surpassing the scope of benefits offered through many of the existing benchmark options listed in the Bulletin. For example, to ensure a meaningful maternity benefit, it is not enough for plans to offer coverage of basic prenatal, labor and delivery care; HHS should require a prescriptive set of benefits that require plans to offer *comprehensive and robust* maternity care that specifically includes preconception care, pregnancy-related counseling, permissibly covered abortion services, postpartum services, screening for domestic violence, family planning services and supplies, breastfeeding support, enhanced coverage for high-risk pregnancies, and services for other conditions which may complicate pregnancy.[50]

The EHB policy must also require *comprehensive and robust* prescription coverage so that women's full prescription needs are met. A full range of prescription contraceptive drugs and devices must be offered by each plan so that each woman can access the particular method of family planning that is best suited to meet her health needs and overcome potential barriers to use such as domestic violence, ease of pharmacy access and contraindications. HHS should clarify that a plan's failure to provide robust gender-specific benefits in an EHB package would

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[47] Sheila D. Rustgi, Michelle M. Doty & Sara R. Collins, The Commonwealth Fund, *Women at Risk: Why Many Women are Forgoing Needed Health Care* 3-4 (2009), http://www.commonwealthfund.org/~/media/Files/Publications/Issue%20Brief/2009/May/Women%20at%20Risk/PDF_1262_Rustgi_women_at_risk_issue_brief_Final.pdf. *See also* Rachel B. Gold, *The Need for and Cost of Mandating Private Insurance Coverage of Contraception*, The Guttmacher Report on Pub. Policy 5 (Aug. 1998), http://www.guttmacher.org/pubs/tgr/01/4/gr010405.pdf.

[48] Guttmacher Institute, State Policies in Brief as of January 1, 2012, Insurance Coverage of Contraceptives, (Jan. 1, 2012) accessed Jan. 15, 2012 http://www.guttmacher.org/statecenter/spibs/spib_ICC.pdf.

[49] Rachel Benson Gold, The Need for and Cost of Mandating Private Insurance Coverage of Contraception, Guttmacher Report on Public Policy, Guttmacher Institute, (Aug. 1998).

[50] *See* AMNESTY INTERNATIONAL, DEADLY DELIVERY: THE MATERNAL HEALTH CARE CRISIS IN THE U.S.A., (2010), at http://www.amnestyusa.org/sites/default/files/pdfs/deadlydelivery.pdf. African American women are nearly four times as likely to die from pregnancy-related complications than white women in the U.S. The authors describe solutions to address this public health emergency.

necessarily constitute impermissible gender-based discrimination. In fact, the Equal Employment Opportunity Commission (EEOC) has determined that in the employment context, failure to provide contraceptive coverage in an otherwise comprehensive prescription drug plan constitutes gender-based discrimination. Under the EEOC analysis, the failure of HHS to require contraceptive coverage in the EHB will also discriminate against women.[51] As mentioned earlier, to the extent HHS adopts a formulary policy like the Medicare model suggested in the Bulletin, it should at least cover two drugs in every class (like Medicare) and "classes" must be carefully designed to ensure broad coverage. For example, covering only one or two drugs in a broad "contraception" category would fail the countless women who might only be able to successfully use "long acting reversible contraception" (a class which would include an IUD) as opposed to an oral contraceptive (a class which would include birth control pills) for numerous reasons, such as a woman's particular medical condition or a personal experience such as domestic abuse.

In considering which reproductive health services must be included within EHB packages, the following principles should be considered:

- Preventive and promotive health care services must be considered essential aspects of a benefits package, including for the prevention of unwanted pregnancy and the prevention of sexually transmitted infections. The services should encourage and promote participatory decision-making on the part of the enrollee seeking care.
- In the reproductive health context, it is the patient who must make the ultimate informed decision regarding which treatments and services are appropriate. Enrollees seeking reproductive health care must have access to all necessary information to make informed decisions regarding their health needs. Benefits should never be restricted based on considerations outside of evidence-based or clinically proven medical standards.
- Reproductive health services must respect the decisions and needs of enrollees, particularly those marginalized by society as a result of low income, racial or ethnic discrimination, language barriers, disability, sexual orientation or gender identity, or low level of literacy. The EHB package must ensure that enrollees are guaranteed confidentiality and privacy in the health care context, and that they are provided with necessary and understandable information to help them make well-informed decisions.

EHB must specifically include the Women's Health Amendment

Earlier, in our discussion on preventive services generally, we recommended the incorporation of PHSA Section 2713 into the EHB definition. This is particularly important because section 2713(a)(4), the Women's Health Amendment, is necessary to secure vital services for women. Failure to incorporate the Women's Health Amendment into the EHB standard would lead to discrimination against women.

[51] U.S. Equal Emp't Opportunity Comm'n, Decision on Coverage of Contraception (Dec. 14, 2000), *available at* http://www.eeoc.gov/policy/docs/decision-contraception.html.

As the Institute of Medicine acknowledged in its report, *Clinical Preventive Services for Women: Closing the Gaps*, the commitment to prevention in the ACA represents a ~~"~~profound shift from a reactive system that primarily responds to acute problems and urgent needs to one that helps foster optimal health and well-being."[52] This shift will prove particularly important for women who have more preventive health needs overall and are historically more likely to forgo necessary preventive care due to insufficient coverage and cost.[53]

Congress passed the Women's Health Amendment, the IOM carefully considered and issued evidence-based recommendations, and HHS adopted the *Women's Preventive Services: Required Health Plan Coverage Guidelines* to ensure women's access to necessary preventive health care and to redress prevailing inequities in women's health care access. These new requirements acknowledge that the scope of preventive services traditionally covered by the private group and individual markets do not meet women's complex preventive health needs absent such directives. Through the implementation of section 2713(a)(4), HHS has acknowledged that women must have access to coverage which includes necessary preventive services such as: screenings for gestational diabetes, domestic violence, HIV and other sexually transmitted diseases; lactation support and counseling by trained providers and the rental of breastfeeding and lactation equipment; well-woman visits; and the full spectrum of FDA-approved contraceptive options.

As noted above, NHeLP recommends that HHS prohibit plans from selecting as benchmarks grandfathered plans that do not meet the women's health preventive services requirements of section 2713(a)(4).

❖ ***Recommended Regulatory Approach***

- The Bulletin should be strengthened to require coverage of preventive services that take women's preventive health needs into account.
- HHS must explicitly incorporate section 2713 of the ACA into the core EHB requirements, including the Women's Health Amendment at section 2713(a)(4).

Discrimination on the bases of a Mental Health, Behavioral Health, or Substance Abuse conditions should not be allowed

The EHB populations will be largely low income and have disproportionately high incidence of mental health, behavioral health and substance abuse conditions (~~"~~MH/BH/SA"). Further, the historic failure of health care packages to provide services for these conditions has trapped many individuals in a cycle of medical underinsurance, gaps in treatment, decreased function,

[52] INSTITUTE OF MEDICINE, CLINICAL PREVENTIVE SERVICES FOR WOMEN: CLOSING THE GAPS, Report Brief 1 (2011).
[53] Sheila D. Rustgi, Michelle M. Doty & Sara R. Collins, The Commonwealth Fund, *Women at Risk: Why Many Women are Forgoing Needed Health Care* 3-4 (2009), http://www.commonwealthfund.org/~/media/Files/Publications/Issue%20Brief/2009/May/Women%20at%20Risk/PDF_1262_Rustgi_women_at_risk_issue_brief_Final.pdf.

socioeconomic depression, and social stigma.[54] Although the ACA prohibits discrimination on the basis of disability, the EHB standard proposed in the Bulletin may well discriminate against individuals with MH/BH/SA conditions.

Numerous aspects of the Bulletin raise concerns. As an initial matter, the historic exclusion of MH/BH/SA services in private market health coverage means that any ―benchmarking" scheme would likely perpetuate that inadequate and substandard discriminatory coverage (and is yet another reason why we strongly oppose benchmarking). The EHB policy must require robust *additional* coverage of MH/BH/SA services. Anything less than a prescriptive coverage requirement is likely to discriminate against individuals with MH/BH/SA based on their disabilities. Similar concerns arise from the Bulletin's provisions that allow states and insurers to set the benefit package. The Bulletin's sole reliance on parity requirements is not sufficient since parity only requires comparable coverage of physical health and MH/BH/SA benefits but does not require that MH/BH/SA benefits be covered nor be adequate in the first place; as a practical matter, parity has also proven difficult to enforce.

While the Bulletin's reliance on parity is inadequate, the discriminatory effects of the Bulletin policy are also likely to undercut efforts to obtain parity of health coverage. The reliance on benchmarking to determine the coverage of screening, diagnosis and treatment for MH/BH/SA conditions in the EHB standard will represent a significant setback for individuals with disabilities. Specifically, the failure by private market health plans to diagnose and treat MH/BH/SA conditions will continue to be prevalent and will lead to millions of dollars in wasted health care spending where it, for example, focuses on a physical health comorbidity and where the treatment fails to achieve results due to the underlying, untreated MH/BH/SA condition. Co-occurrence of physical and mental health disorders are common in the low-income and vulnerable Exchange, Basic Health and Medicaid Expansion populations. Failure to comprehensively cover screening, assessment and treatment of MH/BH/SA conditions will undermine the ACA goal of promoting patient-centered care and better coordinated medical care, and will discriminate based on disability.

To maximize effectiveness of health care coverage and avoid discrimination, a wide array of MH/BH/SA benefits should be available based on acuity, disability, and patient preferences and engagement. For example, the Substance Abuse and Mental Health Services Administration (SAMHSA) supported care continuum includes the following services which are essential to people with MH/BH/SA conditions:

- Health Homes
- Prevention and Wellness Services
- Engagement Services
- Outpatient and Medication Assisted Treatment
- Community Supports and Recovery Services
- Intensive (Community) Support Services
- Other Living Supports
- Acute Intensive Services

[54] *See* ―Mental health care—the economic imperative," *The Lancet,* 378, 1440 (2011).

A final critical aspect of EHB design for individuals with MH/BH/SA conditions is the inclusion of rehabilitative and habilitative services and devices, appropriate pain management, and chronic disease management within the EHB package. These categories of benefits are critical to the ability of the health coverage system to meet the needs of people with MH/BH/SA disabilities and chronic conditions. The Bulletin's approach to ensuring habilitative coverage is to require coverage to the same extent as rehabilitative coverage is required under a chosen benchmark. Aside from the obvious point, that there is no assurance that the benchmark will have adequate coverage of the rehabilitative benefit in the first instance, this policy is also flawed because it is an inappropriate comparison. 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 covered, as required by the ACA, in the scope necessary to meet the needs of the covered population.

See recommended regulatory approach at the end of the next subsection.

Individuals with disabilities and/or functional impairments

The Bulletin fails to ensure that home supports and services will be available to meet the needs of individuals with disabilities, and therefore impermissibly discriminates based on disability. Multiple aspects of the Bulletin policy will harm individuals with disabilities. A weak and non-prescriptive EHB standard will disfavor individuals with disabilities who have greater or more intensive services needs. Extreme flexibility will allow for the creation of weak EHB packages, and more generally allow for insurers to use the benefit design to adversely select against individuals with disabilities by excluding the services they are likely to need. And finally, allowing insurers to benchmark to existing plans, without a strong requirement for additional services in the ten areas identified by the ACA, will only perpetuate the current imbalances in the insurance market which discriminate against individuals with disabilities. Taken together, these policies will result in populations with disabilities receiving fewer services and ultimately exacerbate related health care disparities.

Low-income individuals with disabilities who have no coverage for needed home supports and services will be forced to be institutionalized as they are required to rely on public financing for the coverage of costly institutionalizations. To ~~"b~~end the cost curve," the EHB standard should include broad coverage of home supports and related services.

Ultimately, a relatively inexpensive set of home support services, along with robust coverage of habilitative and rehabilitative services and supplies, is necessary to be in compliance with both ACA and ADA law. Robust coverage would also prevent countless unnecessary institutionalizations and maximize the functional status, independence, and quality of life of enrollees.

❖ ***Recommended Regulatory Approach***

- The Bulletin should not allow state or insurer flexibility to go below a national EHB floor or allow flexibility that will discriminate against individuals with disabilities, functional limitations, or MH/BH/SA conditions or otherwise undermine efforts to achieve true parity in benefits.
- When flexibility is allowed, HHS should conduct additional monitoring and enforcement to ensure that the benefit design does not discriminate against individuals with disabilities, functional limitations, or MH/BH/SA conditions nor promote adverse selection.
- The Bulletin should require comprehensive coverage in all ten service areas mandated by section 1302 to ensure the EHB standard does not discriminate against individuals with disabilities, functional limitations, or MH/BH/SA conditions.
- The Bulletin should be strengthened to include prescriptive preventive services requirements that take the health needs of individuals with disabilities, functional limitations, or MH/BH/SA conditions into account.
- The EHB standard should require that medical necessity be defined to include both physical and mental illnesses, including the maintenance of maximum functional capacity.

9. Require a Transparent and Inclusive Process for Developing EHB Standards

NHeLP would like to express serious concern with the process underway to implement the EHB standard and its failure to adequately allow for consumer input. While the IOM process included consumer testimony, the IOM report largely ignored consumer concerns. Although HHS held EHB listening sessions to include consumer stakeholders, HHS has chiefly implemented the recommendation for a ~~"~~more general guidance, allowing for greater flexibility" suggested by ~~"~~health insurance issuers and employers."[55]

Presently, in development of a formal policy on the EHB standard, HHS has circumvented the consumers' ability to provide meaningful input because the deference to states leaves significant issues undetermined. Ultimately, the Bulletin is a policy which completely alters the statutory framework for the EHB standard. HHS has essentially used a sub-regulatory process to convert an ACA national standard into a state-based standard, or maybe even an insurer-based standard.

Although HHS has allowed for a 45-day comment period, this provides consumer stakeholders little recourse to provide meaningful feedback. This is true for numerous reasons, including most notably:

- The benchmarking standard proposed in the Bulletin is itself only a method for referencing to another standard, which itself is totally unknown. By the Bulletin's framework, each state could select from any one of ten ~~"~~benchmarks" (most of them

[55] *Essential Health Benefits Bulletin,* CCIIO, December 16, 2011, pg. 7.

being state specific) to set its EHB standard. Consumer advocates have no easy way to identify which plans would be among the ten. And, even if they *could* identify the ten plans, they would have no easy way of knowing the coverage package of each plan.

- There is no explanation given as to the process by which states will choose the standard. Who chooses the standard? Using what criteria? By what process? How are consumer consulted? Consumers have no way of assessing how the EHB standard would be implemented in their states.

Without any of the relevant information, such as what the plans might be, what they would include, and how they would be selected, consumers have virtually no way to provide specific and meaningful comments. HHS has not provided any significant analysis or resources for consumers to understand how the Bulletin's EHB standard would impact their health care in their state.

We recommend that HHS must meaningfully include consumer stakeholder input. As an initial matter, we believe that the Bulletin's EHB policy establishes a rule of general applicability. As such, the policy must ultimately be promulgated through regulation as required under the Administrative Procedures Act (and we recognize this may be HHS' intent), including a long notice and comment period.[56]

Additionally, NHeLP recommends that HHS supplement its regulation with the resources consumers would need to properly evaluate the proposed rule, such as means to identify the benchmark plans and the coverage the plans provide. Ideally, HHS would also conduct its own analysis and make available the results of that analysis. We recognize that gathering all of this information is a significant endeavor for HHS, but we urge HHS to realize that obtaining this information is supremely more difficult consumers. We also encourage HHS to consider the complexity of the proposed standard. The resulting difficulty in conducting this analysis is direct evidence of the fact that this standard will be extremely difficult and labor-intensive to monitor (as HHS is required to do under law).

Finally HHS must ensure that consumers are included in the state process to select a benchmark, including as stakeholder representatives on committees or similar bodies that select the benchmark and require a broader meaningful notice and comment process at the state level. This should include a requirement for states to provide consumers with names and coverage summaries for the benchmark plans under consideration.

❖ ***Recommended Regulatory Approach***

- HHS should issue a regulation with specific details provided and provide for a full opportunity for notice and comment.
- If HHS pursues a benchmarking framework, it must provide consumer stakeholders with adequate resources and analysis to evaluate the proposal.

[56] *See* Administrative Procedures Act at 5 U.S.C. §§ 500 et seq.

- HHS must require the state benchmark selection process to include consumer stakeholder participation.

10. Review and Update of Essential Health Benefits

The Bulletin only briefly addresses the on-going review and update of the EHB. The Bulletin states that HHS will assess the following factors: whether enrollees have difficulties with access due to coverage or cost, changes in medical evidence or scientific advancement, market changes not reflected in the benchmarks and the affordability of coverage. While the Bulletin invites comments, it does not provide any information on how such information will be collected and assessed. We believe that a process must be established in order to comport with the requirements of the ACA.

The Language of the ACA

The ACA requires the Secretary of HHS to periodically review the EHB and provide a publicly available report to Congress that includes an assessment: (1) of whether enrollees are experiencing barriers to needed services, (2) of whether services should be modified or updated to account for changes in medical evidence or scientific advancement, (3) addressing gaps in access, and (4) of whether existing benefits need to be expanded or reduced and the impact on cost.[57]

We believe that meaningful compliance with this requirement as well as nondiscrimination requirements addressed earlier includes providing further detail on how these assessments will be made to allow public comment on the proposed process. Further, the Institute of Medicine recommended ~~–e~~reating a framework and infrastructure for collecting data and analyzing implementation of the initial EHB." We recommend that such framework and infrastructure be addressed in the Bulletin and future regulations.

HHS *must* explain, in the Bulletin and regulation, how it will monitor and evaluate the EHB standard's impact on consumers and how adjustments to the standard will be implemented based on the evaluation. This is not only a statutory requirement, but also a fundamental policy requirement.

❖ ***Recommended Regulatory Approach***

The Bulletin should be amended to set forth the framework for reviewing and updating essential health benefits, rather than simply listing the assessments that will be made. This process should include the following:

[57] ACA § 1302(b)(4).

Identifying barriers and gaps in access to care

- Benefits packages should be regularly reviewed to ensure that certain populations or specific diseases or conditions are not adversely affected by the services or level of coverage offered and that covered benefits reflect the standard of care and current clinical approaches.
- The process for review of the EHB packages must be transparent, with mechanisms in place to allow for regular and meaningful public review and comment. Once benefits are established, there should be ongoing mechanisms available to track access to health services and potential obstacles in accessing services due to coverage limitations or cost.
- Plans should be expected to report all denials of coverage and consumer complaints; HHS should have a system in place for monitoring these reports as well as the outcomes (appeals/overrides) to provide early warnings of what types of problems consumers are encountering.
- A system of regular, standardized surveys should be used with both quantitative rating and qualitative experience reporting to assist in determining whether enrollees are facing difficulty in accessing coverage due to cost, unlawful practices, or other barriers.[58]
- Current and innovative survey and reporting methods and designs should be utilized to ensure that information received is based on sound protocols and guidelines. Surveys must be tested with a variety of audiences, including low-income, LEP and vulnerable populations to ensure that comprehension and usability is maximized and the surveys are meaningful. All major stakeholders, including clinicians, administrators, and consumers should have an opportunity to provide feedback via the surveys.
- All information collected and reported should be made publicly available, with opportunities to provide comment, and no charge should be required to access this information.

Updating benefits package

- The Secretary of HHS should create a separate and independent advisory council to assist in reviewing and determining whether the EHB package meets the general and nondiscrimination requirements specified in the ACA. Patient and Consumer representatives must be adequately represented on the council. There should be flexibility available to HHS and the advisory council to make recommendations as to how benefits can be modified to address identified gaps in

[58] For example, the Federal Employee Health Benefits program can be an instructive model in this context. This program conducts an annual survey of a random sample of plan members to assess satisfaction with plans. The indicators used include: overall plan satisfaction, getting needed care, speed of getting care, provider communication, customer service, claims processing, and plan information on costs. This information is publicly available to members so they can compare results across plans (generally surveys are only available for those plans with more than 500 subscribers).

access. Further, the council should have the authority to monitor changes and developments in medical evidence, and update the benefits package to reflect those changes in a timely manner.

- There should also be a public notice and comment process to address updates.

Conclusion

In conclusion, we urge HHS to define the EHB package in a way that establishes strong federal standards to promote comprehensive and robust coverage based on the needs of the low-income and underserved communities that will rely on this standard. We believe this is consistent with the legal requirements and underlying intent of the ACA. If you have any questions or need any further information, please contact Leonardo Cuello (202-289-7661), Staff Attorney at the National Health Law Program.

Sincerely,

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