Biotechnology Industry Organization

December 21, 2012

Kathleen Sebelius, Secretary
Department of Health and Human Services
Hubert H. Humphrey Building
Room 445–G
200 Independence Avenue SW.
Washington, DC 20201

Re: CMS–9880–P; Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation

Dear Secretary Sebelius:

The Biotechnology Industry Organization (BIO) is pleased to submit the following comments on the Department of Health and Human Services' (HHS) proposed rule on the essential health benefit (EHB) provisions and actuarial value provisions of the Patient Protection and Affordable Care Act (PPACA).[1]

BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO's members develop medical products and technologies to treat patients afflicted with serious diseases, to delay the onset of these diseases, or to prevent them in the first place. In that way, our member's novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, including productivity and quality of life, but also have reduced health care expenditures due to fewer physician office visits, hospitalizations, and surgical interventions.

BIO firmly believes that to fulfill the goals of PPACA the EHB coverage standard must ensure meaningful coverage for patients enrolled in non-grandfathered health plans sold in the individual and small-group markets both inside and outside of the American Health Benefit Exchanges ("Exchanges"). Essential health benefits should guarantee that individuals have access to preventive services, medically necessary treatments, clinically appropriate treatments, and innovative treatments—all at affordable costs.

We support the decision of the Centers for Medicare and Medicaid Services (CMS) to move forward with the approach outlined in the EHB Bulletin, granting states flexibility to select a base-benchmark plan that serves as the basis for the definition of EHB in that state.[2] BIO believes this flexibility will facilitate competition among health plans within the states, thus contributing to greater patient choice. However, we have concerns that the proposed approach to essential health benefits leaves enrollees vulnerable in critical ways, and therefore we urge CMS to consider the following comments, discussed in more detail below.

[1] Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation, 77 Fed. Reg. 70,644 (Nov. 26, 2012) (to be codified at 45 C.F.R. pts. 147, 155, 156).
[2] Center for Consumer Information and Insurance Oversight, Essential Health Benefits Bulletin (Dec. 16, 2011).

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- Because the United States Pharmacopeia (USP) Medicare Model Guidelines (MMG) classification system was originally created for use with Medicare Part D, the categories and classes may not adequately represent the range of drugs that a typical employer-based plan covers, particularly with regard to physician-administered drugs that are typically covered as part of a medical benefit and with respect to new and innovative therapies.
- The proposed rule does not appear to ensure that patients have timely access to new and innovative therapies; therefore, BIO recommends the regular updating of the state-based EHB prescription drug benefit category and the availability of appeals and exceptions processes.
- Specialty tiers discriminate against the most vulnerable patients and should not be permitted.
- Meaningful oversight and enforcement of PPACA's prohibition of discrimination is critical for meeting the needs of vulnerable patient populations.
- CMS should provide detailed guidance to Exchanges and plans regarding acceptable and unacceptable utilization management techniques.
- Additional protections should be established to ensure adequate provider networks.
- CMS should ensure the incorporation of the 2008 Mental Health Parity Act, as required by Congress, in state EHB benchmarks.

I. The existing USP classification system has deficiencies that limit its utility in ensuring coverage that reflects a typical employer plan.

The proposed rule offers an approach for defining the prescription drug EHB requirement that is a welcome improvement over the one drug per category and class minimum proposed in the EHB Bulletin. The new proposed EHB drug coverage standard would require plans to cover "at least the greater of: (i) One drug in every United States Pharmacopeia (USP) category and class; or (ii) The same number of prescription drugs in each category and class as the EHB-benchmark plan."[3]

BIO supports requiring plans to include in their formularies at least the "greater of" one drug per category and class of drugs, or the same number of drugs in each category and class as the EHB-benchmark plan. However, BIO believes that additional safeguards are needed to ensure enrollees have access to prescription drug benefits equal in scope to a typical employer plan. The previously proposed one drug per class minimum would have set a floor for prescription drug benefits far below the level of benefits currently provided in a typical employer plan. A recent analysis by Avalere Health, which examined the prescription drug coverage of EHB benchmark plans selected in eight states, found that those states-selected benchmark plans included on their formularies a significant number of drugs in each class. In addition, the benchmark plans included an average of 62 percent of the drugs available in each class.[4] BIO agrees with CMS's proposal, and believes adopting an approach that uses a "greater of" floor will better ensure that those plans that are required to cover

[3] 77 Fed. Reg. at 70,670.
[4] Avalere Health LLC, Drug Coverage in Essential Health Benefits Benchmark Plans: Formulary Analysis (Oct. 2012), *available at* http://www.avalerehealth.net/news/2012-10-01_EHB_Formulary_Analysis/EHB_Formulary_Analysis.pdf

EHB offer prescription drug benefits comparable in scope to a typical employer plan, as required by PPACA.[5]

A. Submission of formularies using a consistent classification system should facilitate oversight of plans' prescription drug benefits.

BIO appreciates the effort CMS has made to enable comparison and oversight of plan formularies by requiring plans to report their drug lists to their respective oversight body (the Exchange, the State, or the Office of Personnel Management [OPM]) using a consistent classification system. Because the various classification systems define and group drugs differently, we believe that requiring consistent reporting will help to facilitate review of formularies and ensure that plans comply with EHB requirements regarding prescription drugs. However, we have significant concerns that reliance on USP alone is not sufficient (discussed below).

B. USP is designed for use with the Part D population.

The USP's MMG classification system was created in accordance with the Medicare Prescription Drug Improvement and Modernization Act of 2003 as a classification system to be used by Part D drug plans.[6] Therefore, the USP MMG categories and classes are tailored to the medications prescribed primarily to the elderly, Medicare population. Enrollees in Exchange plans, however, will be children and non-elderly adults. These populations may have health needs that require medications not well reflected in a classification system designed for use with the Medicare population. In addition, the USP MMG was created for use with drugs provided through the Part D benefit, and thus does not reflect the full range of categories and classes of oral, self-injectible, self-infused, and physician-administered drugs covered by other parts of the Medicare program that may be needed by patients, as discussed in more detail below. This failure to be more inclusive could impede access to therapeutic interventions for patients suffering from life-threatening and debilitating rare diseases and complex chronic conditions. For instance, currently, the USP does not include a category for anti-obesity therapies, despite the fact that many commercial plans offer such coverage. Obesity is a significant risk factor for chronic diseases like diabetes and heart disease, and is estimated to cost the United States health care system $147 billion a year.[7] If USP MMG categories alone are used in determining the minimum number of therapies an EHB plan must cover, in cases where a state's benchmark plan does not include anti-obesity drugs, patients could be denied access to these crucial therapies, and the health care system could lose an opportunity to improve patient outcomes while decreasing long-term costs. For these reasons, BIO is concerned that the USP MMG categories and classes may not sufficiently match the types of drugs enrollees require and that are covered by a typical

[5] Patient Protection and Affordable Care Act ("PPACA") § 1302, Pub. L. No. 111-148, 124 Stat. 131, as amended by PPACA § 10104(b), 124 Stat. at 896 (codified at 42 U.S.C. 18022).
[6] Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2085.
[7] CDC (Centers for Disease Control and Prevention). 2012 (April 27). *Causes and Consequences: What Causes Overweight and Obesity?* Atlanta, GA: CDC, http://www.cdc.gov/obesity/adult/causes/index.html (accessed December 20, 2012).

employer plan. Therefore, relying solely on USP MMG could produce gaps in coverage of necessary prescription drugs for patients facing a myriad of health conditions.

C. The categories and classes should be more detailed to adequately represent the drugs needed by enrollees in Exchange plans.

Moreover, BIO believes that greater granularity in the categories and classes is critical to ensuring that patients have access to the prescription therapies they need most. In Part D, the presence of additional coverage requirements for certain protected classes, along with effective CMS formulary review processes, reduces the need for such granularity. However, if the use of the USP MMG classification system is expanded beyond its use with Part D benefits to use with EHB plans, additional, more specific categories and classes should be added to the system. For example, narrower categories and classes may be necessary to account for distinct therapies with clinically relevant differences, such as selective serotonin reuptake inhibitors (SSRIs) and serotonin-norepinephrine reuptake inhibitors (SNRIs). Although listed in the same USP MMG class, extensive clinical evidence exists on the differences between SSRIs and SNRIs in the treatment of depression. Two separate pharmacological classes for these agents would better ensure that patients suffering from depression have access to the treatment most appropriate for them. Under Part D, all or substantially all drugs in protected classes must be present on plan formularies, lessening the need for granularity in these classes. In order for the USP MMG to ensure adequate coverage of prescription drugs through the EHB, and to serve as the mechanism for verifying compliance with the EHB, more detailed categories and classes are needed.

BIO recommends that CMS consider other classification systems, including the American Hospital Formulary Service (AHFS) system, in updating the USP to create a comprehensive classification system that is sufficiently detailed to reflect the needs of the anticipated Exchange population. Looking to other classification systems to augment the USP MMG would help to ensure that the resulting classification system provides a range of categories and level of granularity that reflect a typical employer plan and supports the type of prescription drug coverage that is consistent with the PPACA requirements for EHB.

BIO also is concerned that the USP MMG classification system does not adequately recognize the importance of combination drugs. For example, although Exchange plans and non-grandfathered individual and small group policies may opt to cover HIV/AIDS combination drugs, there is no class specific to combination HIV/AIDS drugs, and thus no assurance that plans will cover a combination drug. Adding distinct classes, and applying the “greater of” standard as proposed, would help ensure that these plans do not discourage enrollment of HIV/AIDS patients by leaving the therapies these patients need off their formularies.

D. The USP MMG system should not be used as the classification system for physician-administered drugs.

Our concerns about the limitations of the USP MMG classification methodology are amplified for drugs that are typically covered as part of a comprehensive medical benefit,

such as physician-administered drugs. These "medical benefit" drugs include many life-saving cancer therapies, multiple sclerosis treatments, blood clotting factors, and intravenous antibiotics. Patients requiring these drugs must have access to the complete range of available therapies that the Food and Drug Administration (FDA) has approved to treat a particular condition so that they can be treated in the most clinically relevant and appropriate manner. Because the USP MMG categories and classes were developed for the Medicare Part D drug benefit, the list of categories and classes has never attempted to capture all of these medical benefit drugs that are covered under Medicare Part B.

In addition, the USP MMG categories and classes are not meant to reflect clinically meaningful differences between the mechanisms of action or methods of administration for drugs that are typically administered by a physician. Such therapies often are used for complex and life-threatening conditions, and the decision to use a particular drug is often based on multiple clinical factors, including the patient's diagnosis and co-morbidities and the need to monitor the patient after administration of the drug. Thus, BIO has serious concerns that relying on the USP MMG categories and classes to define part of the "floor" standard for the EHB prescription drug benefit is not sufficient to ensure that plans offer meaningful, robust coverage of medical benefit drugs (i.e., drugs administered by physicians or other health care professionals, or otherwise requiring physician supervision).

Because the USP system was not designed for use with medical benefits, BIO is also concerned that relying on the USP MMG categories and classes as the tool for plans to submit their lists of drugs to the Exchange, the state, or OPM, will not permit those entities to evaluate whether a given plan satisfies the proposed standard with respect to medical benefit drugs. Specifically, if plans are only required to report their lists of covered drugs using the USP MMG categories and classes, and are measured against the EHB benchmark plan based only on those categories and classes, there would be no way for the Exchange, the state, or OPM to compare a particular plan's coverage of physician-administered or other medical benefit drugs to the EHB-benchmark plan's coverage of such drugs and verify compliance with the EHB and non-discrimination requirements of PPACA.

For these reasons, BIO urges CMS to clarify that the proposed EHB formulary standard s only intended to apply to plans' retail pharmacy drug benefits and not to physician-administered drugs that are covered as part of a comprehensive medical benefit. Instead, CMS should specify that plans must offer robust coverage of drugs that are included as part of a comprehensive medical benefit, include a wide range of therapies, and should not rely on the USP MMG categories and classes when determining coverage for physician-administered therapies. Also, plans' coverage should include physician-administered drugs and biologics for which a specialty pharmacy has accepted an assignment of benefits (AOB) for the product.

To accomplish this, BIO asks CMS to ensure that the anti-discrimination provisions of the PPACA and EHB are applied to plans' coverage of physician-administered, not just retail-pharmacy-dispensed drugs, no matter their benefit category. Depending on jurisdiction, an Exchange, the state, or OPM should meaningfully compare and evaluate whether a particular plan is substantially equal to the EHB benchmark plan in terms of its coverage of physician-administered drugs. This is crucial to safeguarding against discriminatory benefit

design for these important therapies. BIO also believes that such an approach is consistent with the coverage of medical benefit drugs under a typical employer-based health insurance plan. Finally, CMS should clarify that therapies provided as part of a comprehensive medical benefit remain subject to the provision in the proposed rule that prohibits substitution of prescription drug benefits, and that this prohibition encompasses all prescription drugs regardless of their coverage under a medical or pharmacy benefit.

E. The lack of specified patient protections for vulnerable patient segments opens the door to discriminatory drug benefit designs.

BIO is disappointed that CMS ignored recommendations to apply additional safeguards that protect access to medically necessary therapies for the most vulnerable patient populations. CMS adopted such protections in the Medicare Part D program "because it was necessary to ensure that Medicare beneficiaries reliant upon these drugs would not be substantially discouraged from enrolling in certain Part D plans, as well as to mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations."[8] Although BIO understands the need to balance access with affordability, we believe additional safeguards are just as necessary within the context of vulnerable populations enrolling in health insurance in the individual and small group markets. The enhanced drug benefits requirements in the proposed rule move in the right direction, but are insufficient to protect these populations. Without additional patient protections, the level of granularity of the USP MMG categories and classes are simply inadequate to ensure that the most vulnerable patients have access to clinically appropriate medications. We fear that without measures protecting access for vulnerable patient populations, plans may purposefully design their prescription drug benefits to deter enrollment by individuals who need drugs that treat serious diseases. Also, we note that overall Part D costs are well below the original estimates and that spending growth has been flat over the last several years, suggesting that reasonable protections can be consistent with cost control.[9] BIO strongly urges CMS to consider implementing additional safeguards that protect vulnerable beneficiaries from discrimination with regard to access to ensure that they are not prevented from obtaining necessary therapies once enrolled in a plan.

F. CMS should broaden the "chemically distinct" standard to consider combination products and extended release products. However, this terminology does not accurately characterize, and cannot be applied to, biologics.

Although BIO supports CMS' proposal that formularies should be broadly inclusive of available therapies to ensure an adequate number of drugs are covered, CMS did not include in the regulatory text the language on the "chemically distinct" standard it refers to in the preamble, making it difficult for us to respond to the specific proposal. BIO is nevertheless concerned that the term "chemically distinct" cannot be applied to biologics because of the difference between the scientific principles on which they are manufactured and those used to produce small molecule drugs (for which the term was originally coined).

[8]Centers for Medicare and Medicaid Services, Medicare Prescription Drug Benefit Manual, Chapter 6 – Part D Drugs and Formulary Requirements (Feb. 19, 2012).
[9] Kaiser Family Foundation. 2012 (May). *Medicare Part D Spending Trends: Understanding Key Drivers and the Role of Competition*, available at http://www.kff.org/medicare/upload/8308.pdf.

CMS should not use this antiquated standard to limit the number of biologics EHB plans cover. Additionally, we ask that CMS broaden its guidance on this issue to include combination products and extended release products.

G. EHB requirements should support timely access to new and innovative medications.

Every American who is enrolled in a plan offering EHB should be guaranteed timely access to new and innovative medications. Although the USP is meant to be revised "from time to time to reflect changes in therapeutic uses of covered Part D drugs and the additions of new covered Part D drugs,"[10] the infrequency with which the USP updates its categories and classes in practice presents a significant barrier to accessing these medications. The latest version of the USP does not include any drugs approved after April 2011. This is the version against which benchmark plan formularies will be assessed. The next version is expected in March 2014, but under the proposed rule there is no mechanism that requires a plan to consider new therapies before the EHB-benchmark drug list is re-evaluated for 2016. BIO is concerned that, in the absence of timely updates to the USP MMG and a strategy for more quickly incorporating those updates into the EHB, patients will lack access to innovative health care, such as first-in-class drugs, that are not represented in existing categories or classes. For example, recent developments in the treatment of hepatitis C involve the creation of direct-acting antivirals, which demonstrate significant improvements in outcomes over older treatments, but version 5 of the USP MMG standards does not differentiate between types of hepatitis or modes of action of products, calling into question whether patients will have access to these vital new therapies. We urge CMS to develop a system to account for therapies or indications that have been approved after the release of the latest version of the USP MMG system. To ensure patient access to newly approved medications, BIO recommends that CMS require new therapies be reviewed and added to plan formularies within 90 to 180 days through a process that mirrors the review process performed by independent Pharmacy and Therapeutic Committees in Medicare Part D.

H. CMS should ensure that plans have transition fill policies in place to ensure medication stability for enrollees that switch health plans.

It is critical that plans maintain a degree of predictability and consistency for beneficiaries with complex medical needs. For beneficiaries transitioning into a Qualified Health Plan (QHP) that does not cover a drug they have been stabilized on, abrupt changes in their drug coverage during this time can have a strong negative effect on adherence, especially for patients with chronic diseases. The same can be said for patients who are not able to switch plans outside of open enrollment and experience a mid-year formulary change. Any reductions in drug adherence for these patients can lead to poorer health outcomes and higher costs.

[10] Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2085.

To provide a basic degree of predictability for enrollees, plans should allow for clear grandfathering standards (minimum of 90 days) for patients that have been stabilized on a non-formulary medication and ensure the provision of an emergency supply of any new prescriptions (72 hours) that are not covered on a QHP's formulary to allow time for patients to complete the necessary appeals process without any lapses in treatment.

II. CMS should specify appeals and exceptions procedures to protect access to needed care.

It is critical that health plans provide meaningful exceptions and appeals processes that allow enrollees to obtain coverage for medically necessary drugs that are not on the plan's drug list. BIO appreciates CMS's clear recognition that these procedures are important safeguards for patient access to needed treatment, especially new and innovative therapies, and supports CMS's proposal to require plans to "have procedures in place to ensure that enrollees have access to clinically appropriate drugs that are prescribed by a provider but are not included on the plan's drug list."[11] We also request that CMS clarify that this requirement also applies to drugs that are covered as part of a comprehensive medical benefit. BIO also believes that to best meet patients' needs, exceptions and appeals processes should be streamlined, easy for patients and their health care providers to navigate, and subject to specific time limits, so that patients can timely access the treatment that they need. This is especially important to protect access to care for vulnerable patients with complex and rare conditions, who are most likely to benefit from new and innovative therapies that may not yet be included on a plan's drug list. BIO therefore encourages CMS to provide more specific guidance to plans about procedures CMS considers sufficient to ensure that patients have access to needed treatments. Finally, we recommend that CMS include these requirements in regulatory text, as the proposed rule seems only to require that plans allow a patient to request coverage, not that the plans actually have to pay for a product found to be clinically appropriate.

III. CMS should specifically prohibit the use of specialty tiers.

Although the proposed rule emphasizes CMS' commitment to protecting consumers, while at the same time giving states flexibility, we are concerned that the proposed rule lacks specific guidance to prevent QHPs and other non-grandfathered plans in the individual and small group markets from imposing excessively high cost-sharing for medications taken by patients with chronic, complex, or life-threatening diseases. For example, the proposed rule does not specifically address plans' use of specialty tiers in the prescription drug benefit. However, the Actuarial Value (AV) Calculator, which will be used to determine the actuarial value of plans, includes an option through which issuers can indicate that their plan includes a specialty tier, suggesting that CMS not only permits specialty tiers but encourages them. We have serious concerns about the impact specialty tiers also could have on extremely vulnerable patients, and strongly urge CMS to bar the use of excessive cost-sharing required by prescription drug benefit plans with specialty tiers.

[11] 77 Fed. Reg. at 70,652, 70,670 (proposed 45 C.F.R. § 156.120(c)).

Specialty tiers disparately impact patients who are particularly medically vulnerable and in need of the drugs placed in those tiers. Inclusion of specialty tiers in prescription drug benefit designs can significantly impact the affordability of drugs, and result in patients not filling prescriptions or opting for less effective medications. Research has shown that high patient out-of-pocket costs are correlated with an increase in non-adherence to medication.[12,13] BIO is concerned that permitting specialty tiers under the EHB coverage standard will hinder some patients from starting necessary treatment. In the long run, patients with serious, chronic diseases who delay needed treatment are likely to develop more complex conditions that require higher levels of care, and that may ultimately cost the system more. As noted by these academic researchers, specialty tiers have a disproportionate impact on vulnerable patients' access to medications, which is directly at odds with the prohibitions on plan benefit designs that discriminate based on age, disability, or expected length of life.

Furthermore, section 1302(b)(2) requires that "the scope of the essential health benefits… is equal to the scope of benefits provided under a typical employer plan,"[14] and specialty tiers do not meet this standard. The inclusion of specialty tiers is *not* typical in employer-sponsored insurance. Current research finds that only between 13 and 17 percent of employer-sponsored insurance plans use specialty tiers today.[15] Therefore, we encourage CMS to specifically prohibit the use of specialty tiers in its definition of the EHB, and to remove the option for specialty tiers in the AV Calculator.

BIO has concerns that the AV Calculator may not accurately reflect the benefits of plans beyond their cost-sharing structure. In addition, we are concerned that the AV Calculator's emphasis on cost-sharing and tolerance for specialty tiers may lead plans to distort the structure of their drug benefits in a manner that is ultimately harmful to patients. We have two particular concerns. First, it appears the AV Calculator specifically encourages the use of specialty tiers, despite the negative consequences specialty tiers can have on the health outcomes of vulnerable patients. Secondly, by using an example of a 75 percent coinsurance rate for specialty drugs, the AV Calculator's Frequently Asked Questions seems to recommend the use of extremely high cost-sharing, which could have a devastating impact on patient access to drugs with or without specialty tiers.

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[12] *See* Blesser Streeter, S., Schwartzberg, L., and Johnsrud, M. (May 2011). Patient and plan characteristics affecting abandonment of oral oncolytic prescriptions. *American Journal of Managed Care,*17.

[13] *See* Gleason, P. et al. (2009). Association of prescription abandonment with cost share for high-cost specialty pharmacy medications. *Journal of Managed Care Pharmacy*, 15(8): 648-58.

[14] PPACA, § 1302(b)(2).

[15] *See* Julia Appleby, "Workers Squeezed As Employers Pass Along High Costs Of Specialty Drugs," August 22, 2011 at http://www.kaiserhealthnews.org/stories/2011/august/22/workers-squeezed-as-employers-pass-along-high-costs-of-specialty-drugs.aspx and Kaiser's 2012 Employer Health Benefits Survey, specifically figure 9.2 at http://ehbs.kff.org/?page=charts&id=1&sn=8&ch=2677 which finds only 14 percent of all plans have four-tier pharmacy benefits.

IV. Robust oversight of plan benefit designs and implementation is a key safeguard against discrimination.

Policies such as specialty tier cost-sharing, prior authorization, and step therapy/fail first protocols acutely affect patients, especially those with rare diseases. BIO is concerned that the structure of EHB plans could lend themselves to discriminatory utilization management techniques that ignore the value of the most appropriate therapeutic interventions. CMS must ensure that meaningful oversight over plans' prescription drug benefit designs guards against discrimination.

BIO supports the proposed broad prohibition on discrimination in "[a plan's] benefit design, or the implementation of its benefit design," based on "an individual's age, expected length of life, or present or predicted disability, degree of medical dependency, quality of life, or other health conditions."[16] BIO also supports CMS' proposed approach to "allow states to monitor and identify discriminatory benefit designs, and the implementation thereof."[17] We agree with the IOM and CMS that states have an important role in monitoring to ensure that plans do not deviate from typical plan offerings, such as adopting unusual cost-sharing or limiting benefits with certain characteristics. In fact, we believe such monitoring is critical to meaningful oversight and must also be paired with active enforcement in order for states to effectively safeguard against discrimination.

BIO is therefore concerned that the proposed rule does not establish a sufficiently robust oversight or enforcement framework or provide states with essential guidance to implement such a program. The regulatory text does not expressly require the Exchanges, states, or OPM to monitor plans for compliance with the prohibition on discrimination. BIO recognizes that the Exchanges established in each state are charged with certifying that the QHPs offered through the Exchanges meet federal requirements, including that the QHPs provide EHB, as well as monitoring ongoing compliance with those requirements and establishing a process for decertifying a QHP.[18] BIO nevertheless urges CMS to adopt an express requirement in the regulatory text of the rule that the Exchanges, states, and OPM monitor for non-discrimination.

This approach would make clear that states are also responsible for monitoring compliance with the EHB prohibition of discrimination in benefit design and implementation for all other non-grandfathered individual and small group plans offered outside of the Exchanges, as those plans must also satisfy EHB but are not subject to certification and decertification by the Exchanges. While BIO appreciates the need for state flexibility to develop mechanisms for monitoring of and enforcement against plans, BIO recommends that CMS provide the Exchanges, the states, and OPM with more detailed guidance regarding what mechanisms are sufficient to guarantee that plans do not design benefits or implement those designs in a manner that discriminates against vulnerable patients with significant, complex health care needs.

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[16] 77 Fed. Reg. at 70,670 (proposed §156.125(a)).
[17] 77 Fed. Reg. at 70,653.
[18] 45 C.F.R. §§ 155.1000, 155.1010, 155.1080; *see also* 77 Fed. Reg. 18,310, 18,406 (Mar. 27, 2012).

A. Strict guidance regarding utilization management is needed.

BIO is disappointed that the proposed rule does not provide strict guidelines for the design and application of utilization management techniques by health plans. These techniques can discourage patients from receiving needed treatment and cause patients to suffer adverse health consequences. Section 1562(d)(1) of PPACA permits group health plans and health insurance issuers to implement utilization management techniques "that are commonly used as of the date of enactment of this Act."[19] The proposed rule goes beyond this limitation, and permits utilization management techniques so long as issuers do not use such techniques to "discriminate against certain groups of people."[20] Although the statute precludes HHS from issuing a rule that prohibits such practices, it does not preclude the Agency from setting reasonable limits on the application of such practices.[21] We strongly urge CMS to adopt a system to regularly monitor and certify that plan utilization management techniques, including those already commonly used, are not discriminatory and do not block patient access to necessary medications under either the pharmacy or medical benefits. CMS should require QHPs to publish all utilization management techniques that are used so that patients may make an informed decision in selecting the most appropriate QHP for their individual needs.

Additionally, although we oppose step therapy/fail first protocols, at the very least CMS should specify that QHPs must base any mandated treatment protocols on consensus-based, peer-reviewed treatment guidelines. This should increase the likelihood that patients and providers have the flexibility to design a treatment regimen based on the patient's characteristics, the severity of the disease, and medical history, including any co-morbidities and known medicinal tolerability issues.

B. Broad provider networks are an important component of non-discrimination.

In order to ensure that EHB is a meaningful set of benefits, it is vital that plans establish a broad network that includes a wide range of both health care professionals and health care settings that are conveniently located throughout the plans' service areas. This is crucial to ensure access to immunizations and rare disease specialists and therapies—especially in light of the proposed rule's application of out-of-pocket annual maximums only to costs accrued in-network.

i. Access to Immunizations

One example that illustrates the importance of a broad network to promote individuals' access to health care is providers of immunizations. As we noted in our comments on the EHB Bulletin issued in December 2011, we are deeply committed to making sure that all individuals, regardless of age and insurance status, are able to access immunizations where and when it is most preferred by the recipient. BIO believes that encouraging plans to have broad networks of immunization providers—such as retail

[19] PPACA § 1563(d)(1).
[20] 77 Fed. Reg. at 70,653.
[21] Patient Protection and Affordable Care Act ("PPACA") § 1563(d)(1), 124 Stat. 119, 269, *amended by* PPACA § 10107(b)(1), 124 Stat. at 911 (codified at 42 U.S.C.S. § 18120 (LexisNexis 2012)).

pharmacies, public health clinics, and school clinics—is critical to overcome financial and non-financial barriers to accessing immunization services.

One of the hallmark tenets of PPACA is the requirement that health plans cover all vaccines recommended by the Centers for Disease Control and Prevention's (CDC's) Advisory Committee on Immunization Practices (ACIP) for all ages without cost sharing when administered by an in-network provider. The intent of this provision was to increase access to immunizations for covered individuals. To fulfill this intent, BIO recommends the proposed rule clarify that a network of providers for immunization services must include those health care providers and locations allowed by state law to provide such services and should not be limited to physician office settings. The services should be delivered in these complementary settings under the same first dollar coverage provisions as applicable in physician offices.

The inclusion of complementary immunizers in provider networks will improve vaccination rates, thereby reducing medical care costs, morbidity, and mortality. Adults have demonstrated a preference to be vaccinated outside their medical home, where and when it is convenient for them, and the system has evolved to support that access. More than 150,000 pharmacists are currently trained to administer most vaccines in the U.S.,[22] and according to data from the CDC, during the 2010-2011 influenza season, nearly 20 percent of adult influenza vaccines were administered in retail pharmacies.[23] If a health plan's provider network is inadequate and the plan denies first dollar coverage of pharmacy-administered vaccines, an immunization opportunity may be lost. Or, alternatively, the individual may pay out-of-pocket entirely and none of this cost will count toward meeting the deductible or annual out-of-pocket limit.

In addition to supporting the inclusion of retail pharmacies in provider networks, BIO and many other public health stakeholders have supported efforts underway at the CDC to include other complementary immunization sites, such as public health clinics and school-based clinics, in provider networks. The most significant CDC initiative, known as the Billing Project, works with state health departments, public health clinics and health insurers to include public health clinics in provider networks. To date, 35 states or large cities have begun to plan or implement the Billing Project, which will allow them to directly bill insurers for immunization services provided to insured persons of all ages.

The proposed rule should be modified to clarify that provider networks for immunization services should include those health care providers and locations allowed by state law to provide such services. Furthermore, BIO recommends that the rules clarify that these services should be administered without cost-sharing or point-of-care, out-of-pocket charges, even if these are reimbursed later.

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[22] *See* Rothholz M. Role of Pharmacists in Adult Vaccination: Overview from the American Pharmacists Association. Presentation to the National Vaccine Advisory Committee. September 14, 2011.
[23] CDC. Place of influenza vaccination among adults – United States, 2010-11 influenza season. *MMWR Morb Mortal Wkly Rep*. 2011;60(23):781-785.

ii. Access for Patients with Rare Diseases

For patients with rare conditions, access to a medical specialist is especially vital. Obtaining the proper diagnosis of a rare disease can take several years for some patients. Regardless of whether the condition is acute or chronic, the lack of knowledge of rare diseases and the lack of available diagnostics are among several factors that contribute to these challenges. From the onset of symptoms, patients may make multiple visits to the emergency room, the primary care physician, and multiple specialists before receiving a proper diagnosis. For example, primary immunodeficiency diseases may take more than twelve years for a provider to properly diagnose.[24] Moreover, because of their knowledge in the specific rare condition, medical specialists are best equipped to work with the patient to design the most appropriate treatment regimen. QHP provider networks must be designed in a manner that will ensure patient access to medical specialists, especially when considering that the annual limit on patient cost-sharing will not apply to services obtained through out-of-network providers, as we detail below.[25]

iii. Impact of Out-of-Network Cost-Sharing

BIO appreciates that CMS established provider network adequacy standards for all QHPs offered through the Exchanges and required the Exchanges to ensure that all QHPs meet those standards.[26] CMS proposes that, for network plans, cost-sharing for benefits provided outside of the network will not count toward an enrollee's annual dollar limit on out-of-pocket expenditures or annual dollar limit on deductibles,[27] to which BIO objects. Though it will be especially important that states ensure that plans have broad networks with a range of providers, as noted above, there is likely to be considerable cost pressure in this market on plan insurers. Out-of-network services are not as rare as CMS implies in the rule: as many as 8 to 11 percent of people enrolled in network-based plans today seek care outside of their network, and in many cases this is involuntary, either for emergent health care needs, provider referrals to labs, or because their network does not have a necessary specialist.[28] Furthermore, it is clear from the AV material that HHS expects much more plan tiering in the future for QHPs as an important tool for improving quality and constraining costs.

HHS, therefore, should set standards for network adequacy in light of the treatment of out-of-network, out-of-pocket costs. Should CMS finalize what we believe is a short-sighted proposal regarding out-of-network services, BIO urges CMS to require network plans to have an exceptions process through which enrollees would be permitted to seek

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[24] *See, e.g.*, Immune Deficiency Foundation, Primary Immunodeficiency Diseases in America: 2007 15 fig. 12 (2009) (illustrating that the average diagnosis time for primary immunodeficiency diseases is approximately 12.4 years).
[25] 77 Fed. Reg. at 70654.
[26] 45 C.F.R. §§ 156.230, 155.1050.
[27] 77 Fed. Reg. at 70,654, 70,671 (proposed § 156.130(c)).
[28] *See* Hoadley J, Lucia K, Schwartz S. Unexpected Charges: What States Are Doing About Balanced Billing," California Health care Foundation, April 2009, page 4, and Kyanko K, Curry L, Busch S. Out-of-Network Physicians: How Prevalent Are Involuntary Use and Cost Transparency? *Health Services Research*, 2012.

treatment from an out-of-network provider and count those costs towards the annual limit on cost-sharing when the plan's network does not include a clinically appropriate provider.

V. Safeguards should ensure formularies are based on clinical evidence and reflect current standards of care.

BIO is concerned that, although the proposed rule expands the EHB standard for drug coverage, it still provides inadequate guidance to ensure that formulary design is clinically appropriate and not based solely or predominantly on cost factors. We appreciate that insurers operating in the Exchange will be permitted to use a variety of cost-containment tools, but it is critical that providers have the flexibility to tailor the appropriate course of treatment for each individual patient, taking into account a range of patient-specific factors such as a given patient's health condition and treatment history. We urge CMS to require transparency with regards to the inclusion or exclusion of evidence or clinical information in plan benefit designs, the analytical methods used, and the limitations in the quality of evidence and methods.

To create uniform criteria for access to clinically appropriate drugs, including access to drugs supported by clinical guidelines and compendia, BIO further urges CMS to set a national standard for QHPs and non-grandfathered individual and small group policies. Such criteria would include processes for appeals and grievances, mirroring requirements of Medicare Part D plans. CMS has stated that it expects Part D plans to "accommodate national guidelines and offer treatment options for a variety of medical conditions, including (but not limited) to asthma, diabetes, depression, lipid disorders, hypertension and HIV." CMS goes on to state that its authority to impose these requirements is rooted in the statutory requirement that Part D plans not substantially discourage enrollment by certain Part D eligible individuals (again, in short, not discriminate). BIO believes that the prohibition of discrimination provisions in PPACA related to the EHB and QHPs provides the statutory authority for the Secretary to institute a similar policy to protect enrollees in the individual and small group marketplaces with significant health needs.

VI. The approach to state-required benefits and EHB should be clarified.

PPACA provides that states may require QHPs to offer benefits "in addition to" EHB, but requires the states to defray the cost of those additional benefits by making payments either to the individual enrollee or the issuer on behalf of the enrollee.[29] The proposed rule defines these additional state benefits to include only state-required benefits enacted after December 31, 2011; state-required benefits enacted on or before December 31, 2011 generally would be considered part of EHB and therefore states would not be required to pay the costs of those benefits.[30] CMS further explains in the preamble that it interprets state-required benefits "to be specific to the care, treatment and services that a state requires issuers to offer to [their] enrollees," but not to include "state rules related to provider types, cost-sharing, or reimbursement methods."[31] CMS then provides a list of

[29] PPACA § 1311(d)(3)(B).
[30] 77 Fed. Reg. at 70,668 (proposed § 155.170).
[31] *Id.* at 70,647.

state-required benefits for each state on the CMS Center for Consumer Information and Insurance Oversight (CCIIO) web site.

BIO generally supports this approach, but respectfully requests that the list that CMS has provided for each state represents the comprehensive list of state-required benefits for purposes of this PPACA provision. Thus, a state must consider only whether the benefits on this list are either reflected in its EHB-benchmark plan or, if not, the market (i.e., individual, group) to which the state-required benefit applies for purposes of determining when the benefit is within the meaning of EHB. Any other state laws imposing requirements on health plans would be outside the scope of the state-required benefits for purposes of 2014 and 2015. This would provide the clarity necessary to clearly identify state-required benefits subject to the PPACA analysis of whether they are part of EHB. Any other state laws with which health plans also must comply would not be subject to this analysis, and a state would not be required to cover the cost of any such requirements.

VII. CMS should specifically require mental health parity as required by Congress.

BIO would also like to acknowledge the inclusion of the requirements of the Mental Health Parity and Addiction Equality Act (MHPAEA) of 2008 in the proposed rule. However, CCIIO has recognized in its overview of state selected EHB-benchmark plans that selections might not yet comply with the requirements of MHPAEA.[32] We believe the existing policies for states to supplement coverage for any of the 10 required EHB benefit categories should also explicitly apply for mental and behavioral health services. Clear direction is needed for appropriate evaluation of the covered benefits and services of QHPs and non-grandfathered individual and small group policies against the EHB-benchmark plans, including any supplemental benefits, to guarantee patients have access to these critical mental and behavioral health care services. We urge CMS to make clear in the final rule that mental health parity is required for compliance with EHB standards

[32] CCIIO notes, "The benchmark plans displayed may not comply with the mental health parity standards. However, as described in proposed section 156.115(a)(2), mental health parity would, under our proposal, be required for compliance with EHB standards." This notation appears on CCIIO's website, available at http://cciio.cms.gov/resources/data/ehb.html but not in the proposed rule preamble or regulatory text.

VIII. Conclusion

BIO appreciates the opportunity to comment on this proposed rule. We look forward to continuing to work with CMS and interested partners in designing and implementing the EHB package. Please feel free to contact Laurel Todd at (202) 962-9220 if you have any questions or if we can be of further assistance. Thank you for your attention to this very important matter.

Sincerely,

/s/

Laurel L. Todd
Managing Director
Reimbursement and Health Policy