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BY ELECTRONIC DELIVERY
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Secretary Kathleen Sebelius
U.S. Department of Health and Human Services
c/o Center for Consumer Information and Insurance Oversight
Office of Oversight, MLS Division, Room 737F
200 Independence Avenue S.W.
Washington, DC 20201

Re: Essential Health Benefits Pre-rule Bulletin

Dear Secretary Sebelius:

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

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 case. 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.

PPACA requires non-grandfathered plans in the individual and small group markets both inside and outside of the state health insurance exchanges,[1] Medicaid benchmark and benchmark-equivalent,[2] and basic health programs[3] to cover EHB beginning in 2014. The essential health benefits package comprises ten categories of items and services, including prescription drug coverage,[4] and may not "discriminate against individuals because of their age,

[1] *See* Patient Protection and Affordable Care Act ("PPACA") § 1301(a), Pub. L. No. 111-148,124 Stat. 119, 162-163, as amended by PPACA § 10104(a), 124 Stat. at 896 (codified at 42 U.S.C.S. § 18021(a) (LexisNexis 2011)).
[2] *Id*. at § 2001(c), 124 Stat. at 276-277 (codified at 42 U.S.C.S. § 1396u-7(b)(5) (LexisNexis 2011)).
[3] *Id*. at § 1331, 124 Stat. at 199-203, as amended by PPACA § 10104(o), 124 Stat. at 902 (codified at 42 U.S.C.S. § 18051 (LexisNexis 2011)).
[4] *Id*. at § 1302(b)(1), 124 Stat. at 163-164 (codified at 42 U.S.C.S. § 18022(b)(1) (LexisNexis 2011)). The ten categories are: ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance abuse disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventative and wellness services and chronic disease management; and pediatric services, including oral and vision care.

disability, or expected length of life."[5] The statute requires HHS to define the EHB through a notice and public comment process.[6]

BIO appreciates HHS' decision to provide the states with the flexibility to select a benchmark plan best suited to provide the necessary coverage for their individual populations. We believe this flexibility will allow for greater competition among health plans in every region, thereby increasing patient choice. At the same time, we urge HHS to prioritize patient access in future rulemaking, particularly as the Department considers how best to evaluate plan formularies to ensure that Exchange enrollees have broad access to critical therapies. The EHB package must be comprehensive and affordable, and must promote a standard that prevents individuals from underinsurance, a growing national trend that cuts across age and income level. Additionally, we urge HHS to issue specific guidance on how the Secretary will ensure that the EHB requirements protect all patients from discriminatory benefit designs, especially those with diverse healthcare needs.

I. General Comments on Benchmark Plans

HHS in the pre-rule bulletin makes clear its regulatory intent that the EHB be "defined by a benchmark plan selected by each State,"[7] which would "serve as a reference plan, reflecting both the scope of services and any limits offered by a 'typical employer plan' in that State."[8] The guidance further allows for states to select from one of four benchmark plans whose benefits would serve as the EHB reference model for health plans wishing to participate in the Exchange. Under this approach, consistent with the Children's Health Insurance Program (CHIP), health plans would be required to "offer benefits that are 'substantially equal' to the benefits of the benchmark plan offered by the State"[9] which may be modified as necessary to reflect the 10 mandated coverage categories.[10]

We encourage HHS to establish in future rulemaking how it will define and measure the "substantially equal" standard to ensure that health plans are complying with regional and/or nationally established guidelines to ensure comprehensiveness of coverage. For example, in some states, the typical employer plan may be less comprehensive than in other states. This may be particularly true in cases where a small group model serves as the benchmark. HHS should therefore implement a mechanism to review the selection of benchmark plans by states to ensure comprehensiveness of coverage and to protect potential enrollees from underinsurance.

Underinsurance is especially harmful to the rare disease patient community, specifically in terms of locating the right specialist and having access to the most appropriate medicine. The average diagnosis times for some rare diseases can be as long as ten years from the onset of symptoms. BIO urges HHS to require Exchange plans to provide an adequate number of in-

[5] *Id*. at § 1302(b)(4)(B), 124 Stat. at 164 (codified at 42 U.S.C.S. § 18022(b)(4)(B) (LexisNexis 2011)).
[6] *Id*. at § 1302(b)(3), 124 Stat. at 164 (codified at 42 U.S.C.S. § 18022(b)(3) (LexisNexis 2011)).
[7] Center for Consumer Information and Insurance Oversight. "Essential Health Benefits Bulletin." Issued December 16, 2011. pp.8.
[8] *Ibid.*
[9] *Ibid*. at 12.
[10] *Ibid*. at 12.

network providers across medical specialties to ensure earlier diagnosis, and thus earlier access to the therapy best suited for the needs of the individual patient. Additionally, we believe that it is critically important for the agency to specifically require coverage of prescription drugs and their administration under both the pharmacy and medical benefits.

As we will discuss in more detail in section II of this letter, patient access to therapy must not be limited by a flawed formulary design. Patients must have access to the full range of medically necessary medications in each therapeutic class and category under both pharmacy and medical benefits, and must be protected from discriminatory practices limiting coverage, including excessive cost-sharing. While BIO appreciates HHS' emphasis on state flexibility in implementing health exchanges, we also recommend that the Department to provide specificity on these issues sooner rather than later, in order to allow for efficient implementation.

II. Formulary Design and Utilization Management Controls

A. Formulary Design

HHS proposes to allow health plans to develop and use formularies to manage the costs and utilization of prescription drugs. Under the benchmark approach, HHS intends to require plans to cover those categories and classes of drugs listed in the benchmark plan, but would allow plans to choose which drugs to cover within each category. HHS proposes to establish a minimum floor of drug coverage by clarifying that "if a benchmark plan offers a drug in a certain category or class, all plans must offer at least one drug in that same category or class, even though the specific drugs on the formulary may vary."[11] HHS further indicates that "drug category and class lists would be provided by the U.S. Pharmacopoeia (USP), American Hospital Formulary Service (AHFS), or through a similar standard."[12]

In this section, BIO offers recommendations for how plans under the Exchange should manage their formularies in terms of the formulary standard followed, regular review of formularies, and ensuring timely access to new medical interventions. BIO urges HHS to establish a formulary standard which promotes adequate access to the full range of medically necessary drugs and biologicals covered under both the pharmacy and medical benefits. Specifically, it will be critical for HHS to establish clear guidance on formulary standards designed to ensure that plans provide meaningful access to needed therapies and comply with PPACA's nondiscrimination requirements. We also urge HHS to provide for standards that require expeditious review of new drugs and biologicals, as well as new indications for already approved therapies.

[11] *Ibid*. at 13.
[12] *Ibid*.

1. Formulary Standard

i. *The EHB must be consistent with typical employer plan benefits.*

PPACA expressly requires that the Secretary ensure that the scope of the EHB is equal to the scope of benefits provided under a typical employer plan.[13] As HHS notes in its bulletin, typical employer plans generally provide for comprehensive drug benefits. Permitting qualified health plans to offer a prescription drug benefit, or coverage for drugs and biologics under the medical benefit, based on a standard far below that of a typical employer plan would be inconsistent with the statutory provisions governing the development of the EHB. A recent Avalere study shows that typical prescription drug coverage under employer plans includes coverage of a significant number of drugs in each therapeutic class, well beyond the HHS-proposed minimum. The nationally-available FEHBP has an open formulary, covering all commercially available drugs approved by FDA. On average, the small group plans studies covered 70% of available drugs in therapeutic classes reviewed.[14] This shows that the typical employer plan coverage is far more robust than that proposed in the pre-rule. We urge HHS to ensure that the EHB appropriately reflect the benefits afforded by a typical employer plan, as required by PPACA.

Additionally, it is important that HHS ensure some uniformity across plans to allow for continuity of treatment for patients who, for a variety of reasons beyond their control, may need to switch health plans.

ii. *One drug per category or class is not adequate.*

Although BIO appreciates HHS' promotion of a formulary standard reflecting the flexibility and broad discretion provided under Part D, we strongly object to HHS' suggestion that a benchmark plan offering only one drug per class or category would satisfy the broader category of prescription drugs under the EHB, or that this standard would be non-discriminatory. Focusing on the quantity of drugs per class offered by a benchmark plan undercuts the notion that a formulary should be designed with a holistic approach to patient care. Managing formulary options for cancer, for instance, requires consideration of a patient's medical history and complications, side effects, tumor characteristics, stage of cancer, and must also recognize and account for patient preference and other treatment modalities such as surgery and radiation. Similar considerations with regard to a patient's characteristics, medical history, co-morbidities, and tolerability must be made for treating certain chronic rare diseases and conditions, including bleeding disorders and immune deficiencies, for which there are multiple unique, non-interchangeable interventions in each therapeutic class. By setting a floor of one product per category or class for a drug formulary, HHS is disregarding the therapeutic value of providing patients with multiple unique, non-interchangeable drugs and biologicals in the same therapeutic class from which the patient and physician can identify the best therapeutic intervention for the patient's individual needs. Such a policy directly conflicts with the concept of personalized

[14] The Avalere study is available at http://www.avalerehealth.net/wm/show.php?c=1&id=896.

medicine, which was one of the underlying tenets of health care reform.[15] BIO believes that formularies established by qualified health plans should include access to a broad range of therapies.

HHS' proposal for a minimum therapy requirement on top of an ill-defined formulary standard is likely to result in significant inconsistencies across formularies and will hinder patient access to medically necessary therapies. For example, drugs are defined and classified differently across the various formulary classification systems, including those referenced by HHS in its pre-rule; this can have a significant impact on how formulary standards under the EHB are followed. Two products may be classified under the same category or class by one system, while they are treated under separate categories or classes by another system. Some systems may define a category based on the diagnosis, while others are based on body systems. USP, for instance, classifies antivirals as its own category and includes classes such as antihepatitis and protease inhibitors, among others within that category. AHFS, on the other hand, catalogs antivirals as a class defined under the broader category of anti-infective agents, and designates HIV fusion inhibitors and protease inhibitors as sub-divisions of a larger antiretroviral sub-class. Using the latter as a standard for classification, and applying a one-drug per category or class minimum could result in a plan formulary that includes protease inhibitors while excluding fusion inhibitors, although both work in distinct ways to disrupt different stages of HIV's life cycle, and may be clinically appropriate to the same patient at different stages of the disease.

In order to balance the need for flexibility with consistency and clinical comprehensiveness across Exchange formularies, BIO recommends that HHS require plans to adhere to the Part D USP category and class structure, without any minimum coverage requirements. If HHS is determined to set a minimum, discriminatory, "bare bones" standard that lacks comprehensiveness, the Department should require plans to cover at least two, rather than the proposed one, chemically and/or biologically distinct therapies per class, when available. Additionally, in order to ensure that the individual clinical needs of patients are being met, all available formulations, delivery methods, and dosages should be available for the same drug.

iii. *HHS' minimal threshold for formulary coverage is inconsistent with the requirement that the EHB not discriminate and take into account subpopulations.*

HHS' establishment of a minimum therapy requirement may influence states, in an effort to control costs, to select a benchmark plan that is restrictive – and even discriminatory – in its drug formulary. PPACA expressly requires that the Secretary develop the EHB in a manner that does not discriminate based on age, disability, or expected length of life.[16] Moreover, the law requires that the health benefits defined as essential not be denied to individuals on the basis of age, expected length of life, present or predicted disability, or other factors.[17] A formulary that does not provide adequate coverage for individuals with severe or chronic diseases may be inherently discriminatory. For instance, therapies used to treat serious diseases such as HIV or

[15] *See, e.g.*, The Hon. Max Baucus. Call to Action: Health Care Reform 2009. pp. 35-37(2008).
[16] PPACA § 1302(b)(4)(B).
[17] PPACA § 1302(b)(4)(D).

cancer typically are not interchangeable. A plan that includes a single therapy from the antineoplastics category, for example, will necessarily be discriminating against individuals with certain types of cancer. Cancer treatment is complex, and the types of agents used continue to evolve rapidly. Antineoplastics may be used for more than one organ system, for more than one type of cancer, for different stages of diseases, and often in combination with other agents. This is why CMS designated antineoplastics as a protected category under the Medicare Part D benefit, ensuring that the full range of treatment options are available to the most complex patients affected with the disease. The same is true for the other classes that CMS has recognized as protected since the beginning of the Part D benefit.

In addition to these non-discrimination requirements, PPACA requires that the Secretary consider the health care needs of diverse segments of the population – including women, children, persons with disabilities and other groups – in establishing the EHB.[18] Again, a formulary standard that fails to ensure that the medical needs of diverse segments of the population will be met is not consistent with the statutory requirements for development of the EHB.

iv. *Protected classes are important for ensuring non-discrimination.*

In addition, we urge HHS to adopt the six protected classes recognized under Part D. As CMS has recognized, these protected classes include medications taken by patients who could suffer adverse and costly health consequences if their access to such drugs were restricted. Should HHS not reconsider its position on carrying over the protected classes to the EHB, we request that the Department in future guidelines detail the oversight activities it will assume in order to protect the most vulnerable patient populations from discriminatory practices by health plans participating in the Exchange.

v. *Formularies should be required to include medically accepted indications.*

In addition, BIO recommends that the EHB include access to medically accepted off-label uses of drugs, such as those recognized by Medicare-accepted compendia and as cited in the National Guideline Clearinghouse. BIO strongly supports these standards for identifying medically accepted indications because they help to protect beneficiary access to the most appropriate treatment options, as supported by the latest clinical research.

In conclusion, with respect to the establishment of the prescription drug benefit under the EHB, we urge HHS to promote a formulary standard and implement protections that reduce the number of underinsured in this country. Designing an EHB package that promotes a restrictive formulary and exposes patients with severe disease to formulary exclusions is contradictory to the intent and plain language of PPACA. While provisions in the law that provide premium and cost-sharing assistance to low- and middle-income enrollees are critical to reducing the trend of underinsurance, this type of assistance will do nothing to help patients enrolled in a plan that simply does not cover the medications they need.

[18] PPACA § 1302(b)(4)(C).

2. Formulary Review

BIO believes it is crucial that HHS ensure that there is a well-validated system in place, whether it be at the federal or state level, to monitor Exchange plan formularies to ensure that benefit designs do not discourage enrollment and that patients are able to access medically necessary therapies. In order to protect enrollees from discriminatory practices, BIO requests that HHS in future guidance establish principles and best practices that plan pharmacy and therapeutics committees be required to follow in designing and regularly reviewing their formularies. HHS also should ensure that a well-validated and consistent process is used to review plan formularies on a timely basis. Under the Medicare Part D benefit, CMS has developed a well-validated method of reviewing plan sponsor formularies as part of an annual bidding process, to ensure that beneficiaries have adequate access to a variety of medications. CMS also reviews requests for mid-year formulary changes and conducts retrospective oversight activities, including audits, to ensure compliance with formulary requirements under the program. We urge CMS to consider these principles when providing plans with clear guidance on the importance of comprehensive formulary review.

Formulary review may entail the following activities: monitoring compliance with formulary standards that promote access to a wide variety of medications; ensuring review and availability of FDA approved drugs and indications within 90-180 days; publishing abandonment data for drugs available under both pharmacy and medical benefits; and instituting review measures that protect beneficiaries from excessive cost-sharing. Additionally, an audit process should be in place for HHS to periodically review plan formularies to ensure compliance with its requirements and to ensure patient protection from discriminatory practices. This process should include corrective actions that must be taken by noncompliant plans to restore patient access in a timely manner. In addition, HHS should specify that the Office of Inspector General (OIG) will annually audit health plans subject to EHBs. Plans that OIG finds to be non-compliant should be subject to civil monetary penalties (CMPs).

3. Timely Access to New Medications

BIO represents an industry that is devoted to discovering new and innovative treatments and therapies and ensuring patient access to them. Our members are continually developing promising new medicines. It is imperative that these new therapies be available to patients in a timely manner following FDA approval so that they may have the advantage of these life-saving and life-prolonging innovations. BIO requests that HHS ensure that health plans operating in the Exchanges make reasonable efforts to review each new chemical entity and biologic license application within 90 days of its market release and make decisions regarding formulary placement within 180 days of their release onto the market, unless the plan provides a clinical justification for not making such a determination. This mirrors the current practice CMS has established in the Medicare Part D program. We also request that HHS require that plans consider new indications for existing therapies within 90 days of approval of the new indication. Should HHS adopt a similar protected class standard to Medicare Part D, we would also request that new drugs within any protected classes be added to formularies within 90 days, as is the case under the Medicare program. Finally, any drugs and biologicals approved under FDA's accelerated review process should be subject to review within a 90-day timeframe.

B. Utilization Management Controls

Because of the potential for patients to suffer adverse health consequences, BIO urges HHS to provide strict guidelines for the design and application of utilization management techniques by health plans. Section 1562(d)(1) of the PPACA permits group health plans and health insurance issuers to implement utilization management techniques "that are commonly used as of the date of enactment." Some of the more commonly applied tools are prior authorization and step therapy or fail-first protocols. Additionally, cost-sharing and specialty tiers are used by payers as a cost-containment tool to control utilization. BIO has specific recommendations for the design and application of such utilization management techniques, which are discussed in more detail in sections to follow. In addition to those recommendations, we urge HHS to ensure that a system is in place to regularly monitor and certify that plan utilization management techniques, including formularies, step therapy or fail first protocols, and prior authorization, are not discriminatory and not impeding patient access to medically necessary medications under both pharmacy and medical benefits.

1. Cost-sharing

The pre-rule notes that additional guidelines will be forthcoming regarding cost-sharing and benefit design. In this guidance, HHS should create general guidelines that allow for flexible benefit design across therapeutic categories, while ensuring that cost-sharing amounts for drugs covered under the medical or pharmacy benefits do not deter access to medically necessary medications. Multiple studies have shown that, even for severe life-threatening diseases such as cancer, significantly more patients abandon treatment at higher co-pays. A recent study in the *Journal of Oncology Practice* found that one-tenth of new oral chemotherapy prescriptions are not filled by patients, and furthermore, the rate of prescription abandonment increased with out-of-pocket cost required. Examining both Medicare and private payer claims data, the authors of the study found that claims for which patients were required to pay $500 or more had the highest rate of abandonment and those for which patients had copays of $100 or less had a significantly lower rate of abandonment.[19] When patients do not adhere to their treatment regimens as established by their health care providers, their conditions may worsen, ultimately creating higher health system costs. This phenomenon is not limited only to oral cancer drugs, but occurs across multiple disease states and drug classes, particularly those that treat serious and chronic diseases. In the interest of transparency, we further request that HHS require the insurance plans to disclose patient cost-sharing requirements, including deductibles, co-payments, and co-insurance amounts that are applicable to both in-network and out-of-network covered services and certify that they are non-discriminatory.

2. Specialty Tiers

BIO is greatly concerned about the use of formulary specialty tiers and their impact on individuals with serious and rare diseases. Drugs and biologics that are placed on specialty tiers are often subject to coinsurance, rather than flat copays, which can lead to patient noncompliance

[19]Streeter et al. "Patient and Plan Characteristics Affecting Abandonment of Oral Oncolytic Prescriptions." *Journal of Oncology Practice* Volume 7 Issue 3S. July 2011.

and, ultimately, poor health outcomes. BIO believes that specialty tiers are inherently discriminatory due to the high cost-sharing imposed on the most vulnerable patient populations. Safeguards must be in place to protect patients, especially those with severe disease, from excessive cost-sharing and discriminatory plan benefit designs such as specialty tiers.

As described above, we believe that the non-discrimination provisions of PPACA – which require that the EHB not discriminate based on a number of factors as well as require that the needs of diverse segments of the population are taken into account – require that the EHB standards ensure that qualified health plans provide a meaningful range of benefits. We ask that HHS in future guidance make clear that the opportunity to appeal all tier placement and cost-sharing decisions should be part of a transparent and clearly defined appeals and exceptions process developed by health plans in the Exchange. Should specialty tiers be permitted in the EHB, we request that the Department in future guidelines detail the oversight activities it will assume in order to protect the most vulnerable patient populations from discriminatory practices by health plans participating in the Exchange.

3. Step Therapy or Fail First Protocols

One of the most challenging utilization management techniques for patients and providers to overcome is step therapy or fail first protocols. Such coverage limitations create barriers to access in the form of denials, disruption of the continuity of care, and treatment delays. Under these mechanisms, a payer will not cover a specific drug or a treatment protocol (i.e., prophylaxis use of a drug) until the patient has failed first on one or more preferred treatment options.

For some step therapy protocols, there can be multiple layers of restrictions. For example, a physician prescribes a biological for prophylaxis to replace low or non-existent levels of protein or dysfunctional proteins in order to prevent life threatening attacks associated with a rare disease. The payer could first require the patient to fail first on the least expensive drug option for episodic treatment; only after the patient meets a certain criteria would the payer deem the patient eligible for a prophylaxis regimen. Even then, the payer could require that the patient also fail on the least expensive prophylaxis treatment option, such as anabolic steroids (less than ideal due to health consequences associated with long term use), before the payer will cover the more expensive biological for the prophylaxis regimen. These impediments for the sickest of patients prevent access to the most medically appropriate therapy for their individual needs, ultimately leading to higher costs for the health care system as a whole.

Increased health care system costs can occur because of the increased need for physician visits, hospitalizations, and surgical interventions due to treatment delays, which are often the result of the need for the physician to demonstrate the medical necessity of a specific therapeutic intervention. In these situations, not only is the treatment delayed, but the continuity of care is disrupted and the risk of adverse events and immunogenic responses is increased. At the extreme, the impact of step therapy requirements that the patient has to undergo to obtain the most clinically appropriate therapy can be the difference between life and death; in some instances may lead to the course of the disease being so negatively altered as to necessitate a

much more intensive treatment and a much less desirable outcome or prognosis than should have been the case.

While it is reasonable for payers to promote adherence to treatment guidelines, we are concerned where payers engage in clinical decisions that are best made by the physician and patient. BIO thus recommends that HHS limit the application of step therapy or fail first protocols to newly diagnosed patients, and to require plans to implement well-defined exceptions processes that allow for case-by-case analysis based on the patient diagnosis, disease progress, and treatment history. Previously treated patients for chronic rare diseases and conditions should not be subject to step therapy or fail first protocols. Further, BIO urges HHS to require plans that implement step therapy or fail first protocols for prescription drugs to do so in a manner consistent with the current treatment guidelines for the disease or condition established by a national medical specialty society, if available.

Additionally, exceptions or appeals should be reviewed and resolved within seven days or less, in order to prevent adverse outcomes that occur as a result of delayed treatment. Such plans must expeditiously grant coverage to the drug as prescribed if the prescribing physician demonstrates, at any time during the treatment protocol, that the preferred treatment under this utilization management technique for the disease or condition has been ineffective for the covered patient, is reasonably likely to be ineffective for the covered patient based on known relevant physical or mental characteristics and medical history of such individual, or is reasonably likely to cause an adverse event, negative long term health consequences, or any other physical harm to the covered patient.

4. Broad Provider Networks for Access to Immunizations

BIO recommends that HHS strongly encourage health plans to create and maintain the broadest system of in-network providers to best deliver immunizations to children, adolescents and adults as required by the PPACA. BIO was highly encouraged by the vaccine provisions included in the PPACA. In particular, BIO believes that provisions that require first-dollar coverage of all ACIP-recommended vaccines by health plans and the creation of an EHB for all individuals will offer significant opportunities to decrease barriers and increase access to vital vaccines. However, additional non-financial barriers to immunization services for children, adolescents and adults remain.

All individuals, regardless of age and insurance status, should be able to access immunizations where and when is most preferred by the recipient. Therefore, BIO strongly supports efforts underway at the Centers for Disease Control and Prevention (CDC) to increase the number and types of "immunizers" within all communities, including public health clinics, school-based clinics, pharmacists, employers and other community immunizers. This initiative, known as the Third-party Billing Project, seeks to work with health departments, public health clinics and health insurers to include public health clinics, school-based clinics and pharmacies as in-network providers for immunizations.

Recognizing all potential immunization sites as "in-network" providers should help ensure adequate reimbursement of providers for their immunization efforts and will allow

patients broader access to immunization services. To best enhance vaccination rates, is it critically important for health plans to recognize all potential immunization sites as "points-of-service" for which reimbursement is permitted.

II. Balancing Costs and Coverage

A. Use of Evidence Based Medicine by Exchange Plans

Representing an industry committed to discovering new cures and ensuring patient access to them, BIO strongly supports efforts to increase the availability of accurate, scientific evidence to inform clinical decision-making. BIO believes that individual patients and their doctors should be armed with the best available information to help assess the relative clinical benefits and risks of various treatment alternatives. However, BIO is concerned that such information may be used strictly as a means to contain costs, rather than deliver health care value by improving patient health outcomes. While insurers operating in the Exchange should be permitted to use a variety of cost-containment tools, it is crucial that providers have the flexibility to tailor the appropriate course of treatment for each patient based on individual patient preferences and clinical circumstances. Any application of evidence based medicine should be transparent as to the inclusion or exclusion of evidence or clinical information, the analytical methods used, and discussion should be available outlining limitations in the quality of the evidence and methods used.

B. Diverse Populations

As established in PPACA, plans under the Exchanges are prohibited from designing benefits in ways that discriminate against individuals with diverse healthcare needs, such as those with rare diseases. As detailed above, BIO has made several recommendations that will assist HHS in ensuring that the Agency will protect individuals with rare diseases from discriminatory practices while providing access to the therapies necessary to treat their conditions.

The Secretary must also recognize that patients may respond differently to the same intervention in ways that cannot be anticipated, and that the needs of the individual must be taken into consideration. For example, even within the same disease, subgroups of patients may respond differently to the same medication. Intravenous immune globulin is an example where, although multiple products are available, all have varying indications and each product works differently in treating primary immune deficiency. It is crucial that the EHB account for the variability of patients with this disorder and the subgroups therein. Thus, "one-size-fits-all" policies that ignore the variability among individual patients in treatment efficacy, safety, and tolerability must be avoided.

III. Updating the EHB

HHS in its pre-rule bulletin indicates that it will "assess whether enrollees have difficulties with access for reasons of coverage or cost, changes in medical evidence or scientific advancement, market changes not reflected in the benchmarks and the affordability of coverage as it relates to EHB."[20] We agree with HHS in that updates to the EHB should include an in depth assessment of whether patients are accessing affordable and quality health care.

The EHB package should be updated in a regular and timely way to maintain relevance to current medical practice and ensure consistency with the evolution of scientific evidence and advancements. Congress expressly provided for this process in PPACA, requiring periodic review of the EHB addressing any gaps in access or changes in evidence base, as well as an assessment of how the EHB will be updated to address any gaps and changes.[21] We also urge HHS to ensure that the EHB requirements be disseminated to patients, providers, and other stakeholders in a timely and efficient manner.

Patient choice and access to all therapies and services must be preserved and carefully monitored. A process should be in place for an external or governmental auditor to examine the impact of essential benefit requirements on patient access to needed therapies. In addition, a resource should be made available to beneficiaries to register specific instances of reduced or limited access to treatments or therapies, as well as broader concerns with coverage policies.

With regard to benefits for drugs and biologicals, adequate patient safeguards must be in place to ensure that beneficiaries not only have a wide range of treatment options, but also access to those therapies that are most medically appropriate for their individual needs. New prescription medicines can become available rapidly, and health plans should be positioned to extend coverage, particularly for lifesaving therapies, in an efficient manner.

Finally, updating the EHB requirements should ensure the leveraging of best practices and coverage models that may be in place in the states or certain commercial plans. As the Secretary makes determinations on updates to the essential package, new and novel state programs that go above and beyond the current essential package should be considered on the national scale if states can show that such approaches are having a positive effect on patients' access to new therapies or novel treatments. The same is true for some commercial plans outside of the exchange that may have novel programs and coverage designs in place, which have proven to benefit patients.

[20] CCIIO, pp. 13.
[21] PPACA § 1302(b)(4)(G).

IV. Conclusion

BIO appreciates the opportunity to comment on this pre-rule bulletin. We look forward to continuing to work with HHS 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