



December 22, 2015

**BY ELECTRONIC DELIVERY**

Andrew Slavitt  
Acting Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Hubert H. Humphrey Building, Room 445-G  
200 Independence Avenue, SW  
Washington, DC 20201

**RE: Data Metrics and Alternative Processes for Access to Care in the Medicaid Program Request for Information [CMS-2328-NC]**

Dear Acting Administrator Slavitt:

The Biotechnology Industry Organization (BIO) is pleased to submit comments on the Centers for Medicare and Medicaid Services' (CMS's) Request for Information entitled *Medicaid Program; Request for Information (RFI) – Data Metrics and Alternative Processes for Access to Care in the Medicaid Program*<sup>1</sup> (the "RFI").

BIO is the world's largest trade association representing 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 members' novel therapeutics, vaccines, and diagnostics not only have improved health outcomes, but also have reduced healthcare expenditures due to fewer physician office visits, hospitalizations, and surgical interventions.

Under section 1902(a)(30)(A) of the Social Security Act, CMS and the states have the responsibility to assure that Medicaid payments are not only "consistent with efficiency, economy, and quality of care" but also "are sufficient to enlist enough providers so that care and services are available under the state plan at least to the extent that such care and services are available to the general population in the geographic area"—an obligation referred to as the "access requirement."<sup>2</sup> BIO believes that the Medicaid program is critical for ensuring access to care for some of the country's neediest patients and thus support the Agency's efforts to strengthen the framework of federal review to ensure that states set provider reimbursement rates in conformity with the access requirement, including through this RFI, as well as the concurrently released Final Rule with Comment entitled *Medicaid Program; Methods for Ensuring Access to Covered Medicaid Services* (the "FC") on which BIO also is submitting comments. We believe that it is critical for both CMS and the states to develop and implement thresholds for determining whether access to care in the Medicaid

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<sup>1</sup> 80 Fed. Reg. 67,377 (Nov. 2, 2015).

<sup>2</sup> 80 Fed. Reg. 67,576, 67,577 (Nov. 2, 2015) (referring to the access standard in Social Security Act (SSA) § 1902(a)(30)(A) as "the access requirement").

program is sufficient in order to ensure that patients can access, and maintain access to, the most appropriate care for them.

In the remainder of this letter, BIO responds to the specific questions that CMS poses in the RFI. We appreciate CMS's consideration of our comments in further refining the policies outlined in the FC, as well as in improving access-to-care standards specific to Medicaid managed care and waiver programs.

## **I. Access to Care Data Collection and Methodology**

- ***What do you perceive to be the advantages and disadvantages to requiring a national core set of access to care measures and metrics?***

BIO believes there are a number of advantages and disadvantages to requiring a national core set of access to care measures and metrics and thus recommend that CMS adopt a hybrid approach. Specifically, although we note it is important, and necessary, to allow states to adopt their own access-to-care measures and metrics that take into account state-specific population health issues, we also think it is critical for CMS to develop a national core set of access-to-care measures and metrics in order to both reduce reporting burdens and create uniform tools for assessing the quality and availability of care.

In the FC, CMS notes that “[e]ach state Medicaid program is unique,”<sup>3</sup> and “[a] uniform approach to meeting the [Medicaid access requirement] could prove challenging at this time, given local variations in service delivery, beneficiary needs, provider practice roles, and limitations on data.”<sup>4</sup> Accordingly, in the FC, CMS is granting states “the flexibility to design and implement access measures specific to the characteristics of their state.”<sup>5</sup> While we agree with this approach, nonetheless, it would be beneficial for CMS—either itself or in collaboration with other entities, such as the Office of the Assistant Secretary for Planning and Evaluation (ASPE) or the Medicaid and CHIP Payment and Access Commission (MACPAC)—to establish certain core federal standards that set a “floor” for beneficiary access (i.e., minimum standards below which access to care for the Medicaid population cannot fall).

In particular, there are medical arenas where national standards have already been established and accepted and thus a national core set of standards could easily be developed. This is especially true for preventive services, such as immunizations. The Advisory Committee for Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) creates an evidence-based schedule of recommended vaccinations across the life span. Likewise the United States Preventive Services Task Force (USPSTF) produces evidence-based recommendations for secondary preventive interventions. These nationally recognized recommending bodies produce clinical guidelines that serve as the gold standard and are accepted by many types of healthcare providers. We thus strongly urge CMS to establish national core standards to assess access to these services.

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<sup>3</sup> 80 Fed. Reg. at 67,588.

<sup>4</sup> *Id.* at 67,579.

<sup>5</sup> *Id.* at 67,588.

Moreover, there are prevalent conditions that are common across each of the Medicaid sub-populations, such as behavioral health conditions, diabetes, and asthma, for which access to appropriate treatment can reduce the costs of avoidable hospitalizations and thus result in substantial savings for state Medicaid programs. For example, the prevalence of childhood asthma in the United States increased from 8.7 percent in 2001 to 9.5 percent in 2011. This increased prevalence adds to the total costs incurred by state Medicaid programs given the large pediatric populations that they serve.<sup>6</sup> Indeed, there were approximately 629,000 emergency department visits in 2010 for pediatric asthma for Medicaid/CHIP enrollees with costs ranging from \$282,000 in Alaska to more than \$25 million in California.<sup>7</sup> For beneficiaries with chronic diseases that require consistent access to primary care providers, a national set of access to care measures and metrics can prove advantageous to ensuring these patients have the access they need in order to reduce unnecessary and costly emergency department visits.

In addition to setting these and other national core standards, CMS also should encourage and/or require states to supplement these standards with state-specific measures and metrics that reflect the specific characteristics of that state's Medicaid beneficiaries and providers.

- ***Who do you believe should collect and analyze the national core set data?***

To the extent possible, BIO believes it is important to minimize the burden on states and plans with regard to collecting and analyzing the national core set data. For this reason, we would encourage CMS to be the primary entity responsible for collecting and analyzing this particular data set and to leverage existing data collection infrastructures for this purpose. Additionally, CMS should make the data available for third-party analysis.

- ***Do you believe a national core set of access measures or metrics should apply across all services, or is it more appropriate to target a core set of access measures by service?***

BIO believes that a national core set of access measures or metrics would be more appropriate if they were service-specific. This is because, when evaluating the ability of a given patient to see a provider, it is important to acknowledge that the frequency with which access to a provider is necessary to effectively treat or control his/her condition is likely to be dependent upon the service that is being provided. Without tailoring access measures to that particular service, it will be difficult to ensure that the measures are truly capturing the potential access-to-care barriers that beneficiaries may be facing.

Additionally, BIO encourages CMS to create measures and metrics that are population-specific. As CMS notes in the FC, "[t]o the extent that states understand that there are specific access issues for certain populations, it would be prudent to develop

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<sup>6</sup> Together, Medicaid and the Children's Health Insurance Program (CHIP) served more than 45 million children in federal fiscal year (FFY) 2013, representing more than 1 in 3 children in the United States. The Department of Health and Human Services, 2014 Annual Report on the Quality of Care for Children in Medicaid and CHIP (Nov. 2014).

<sup>7</sup> Pearson WS, Goates SA, Harry Kissoon SD, Miller SA. State-Based Medicaid Costs for Pediatric Asthma Emergency Department Visits. *Prev Chronic Dis* 2014;11:140139.

remediation plans that focus on improving access for those populations.”<sup>8</sup> Given the potential for population-specific access issues recognized by CMS in the FC, it also will be helpful to have measures that facilitate the identification of these issues on the front end. CMS notes in the FC that “[s]everal commenters suggested that consideration be given to race, ethnicity, rural, and urban, primary language spoken, eligibility subgroup, geography, age and income.”<sup>9</sup> These characteristics are particularly important given the diversity of individuals enrolled in the Medicaid program, particularly as the Medicaid population has changed and grown under the ACA’s recent expansion. For example, for the Medicaid population—many of whom speak English as a second language, or perhaps not at all—a lack of access to translation services may prevent these individuals from receiving needed care. However, we believe that CMS also should consider the development of access standards for sub-populations of Medicaid beneficiaries defined by their medical needs.

For instance, individuals suffering from complex and chronic conditions generally have special needs in terms of the care providers best suited to treat their conditions, and their inability to access to these providers may not be identified by access standards designed for the general population. The need for specific standards also is of particular consideration for the dual-eligible population, including low-income seniors and younger individuals with disabilities who are covered by both Medicare and Medicaid. Currently, about 9 million people are considered dually-eligible, and these beneficiaries often have more complex and costly healthcare needs compared to the general Medicare and Medicaid populations.<sup>10</sup> Additionally, beneficiaries who have serious mental illness would need their own access-to-care measures standards given the very specific needs of this population, and the more limited ability of these individuals to advocate for themselves. To these ends, CMS could identify a list of ‘vulnerable’ mental health conditions (e.g. schizophrenia, bipolar disorder, schizoaffective disorder, major depressive disorder) for which national access measures should be tailored in order to ensure that the national standards do not overlook the needs of these individuals. In sum, it is important to establish a set of access measures that specifically addresses the needs and circumstances of many of the sub-populations served by the Medicaid program.

- ***What information and methods do you believe large health care programs use to measure access to care that could be used by the Medicaid program?***

We believe that existing requirements under the Medicare Advantage (MA) and Medicare Part D programs provide a good starting point for establishing methods to measure access to care. At a minimum, BIO recommends that CMS use the metric “Beneficiary Access and Performance Problems” currently used by the Medicare Advantage Star Ratings program (Measure C28). We further urge CMS to incorporate into this metric certain additional components that assess a state Medicaid program’s provision of certain basic beneficiary protections afforded by current MA and Part D regulations. Specifically, the metric should further assess, at a minimum, whether a State Medicaid Program:

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<sup>8</sup> 80 Fed. Reg. at 67,590.

<sup>9</sup> *Id.*

<sup>10</sup> Kaiser Family Foundation. Dual Eligible Fact Sheet. 2015.

- ✓ Makes timely and correct coverage determinations and notifies enrollees of decision outcomes for services on a standard or expedited basis;<sup>11</sup>
- ✓ Appropriately considers clinical information when rendering a decision;<sup>12</sup> and
- ✓ Properly administers its formulary and/or preferred drug list<sup>13</sup> in conformity with the requirements of Section 1927 of the Social Security Act.<sup>14</sup>

We also believe that CMS should leverage existing standards for beneficiary-reported access issues used by state public health reporting programs, such as established state registries. The information collected by these programs can be leveraged by CMS and state Medicaid programs as a tool to continuously monitor access-to-care issues.

For example, the California Department of Public Health studied cancer incidence data and found that Medi-Cal beneficiaries had disparate outcomes compared to privately insured patients. Specifically, Medi-Cal patients with breast, colon, and rectal cancer were more likely to be diagnosed at an advanced stage of disease and to have less favorable five-year survival rates than persons with other sources of health insurance. Additionally, Medi-Cal patients were diagnosed with advanced (stage IV) prostate cancer more than three times as often as patients with private insurance—18.6 percent compared to 5.6 percent, respectively.<sup>15</sup> These figures highlight the need to investigate access-to-care issues for the Medicaid population, and could imply that Medicaid beneficiaries in other states are faced with similarly disparate outcomes, which may be due to their inability to access appropriate providers. Notably, in order to conduct this study, the California Department of Public Health used data from the California Cancer Registry, California's population-based cancer surveillance system. This and other established state registries routinely collect information related to chronic and other medical conditions and can be a valuable source of information for CMS and the states. Compared to the general population, Medicaid beneficiaries are more likely to suffer from chronic conditions, and therefore evaluating the information collected by these registries can be one way to adequately monitor issues for the most vulnerable Medicaid patients.<sup>16</sup> For this reason, BIO recommends that CMS leverage these state public health reporting programs as a way to potentially locate areas where Medicaid beneficiaries may be having trouble accessing the care they need.

CMS also may wish to consider using existing mechanisms to assess beneficiary- and provider-reported data. As outlined in the FC, a spike in beneficiaries who experience difficulty receiving a particular service in a geographic region could indicate access issues and should be investigated.<sup>17</sup> For this reason, CMS is requiring states to establish public

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<sup>11</sup> 42 C.F.R. §§ 422.568(b); 422.572(a).

<sup>12</sup> 42 C.F.R. §§ 422.566(a); 422.586. See also 42 C.F.R. §§ 423.566(a); 423.578(a)-(b); 423.586.

<sup>13</sup> 42 C.F.R. §§ 423.120(b)(2); 423.104(a); Medicare Prescription Drug Benefit Manual, Chapter 6, Sections 30.2.2.1, 30.2, and 30.3.3.3 and Chapter 7, Section 20.4 and 60.6, available at: <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/Chapter6.pdf>.

<sup>14</sup> **Social Security Act (SSA) §1927.**

<sup>15</sup> Parikh-Patel A, Morris CR, Martinsen R, Kizer KW. 2015. *Disparities in Stage at Diagnosis, Survival, and Quality of Cancer Care in California by Source of Health Insurance*. Sacramento, CA: California Cancer Reporting and Epidemiologic Surveillance Program, Institute for Population Health Improvement, University of California Davis.

<sup>16</sup> In addition to registry data to measure outcomes, CMS should include the use of biomarkers and genetic tests to assess differences in care and outcomes from a process measurement standpoint.

<sup>17</sup> 80 Fed. Reg. at 67,585.

input processes that solicit information from both beneficiaries and providers.<sup>18</sup> One way for states to collect this information from beneficiaries is through existing beneficiary surveys, such as the Agency for Healthcare Research and Quality (AHRQ) Consumer Assessment of Healthcare Provider and Systems (CAHPS) surveys. CMS notes in the FC that the Agency is working with state Medicaid agencies to collect and use the CAHPS survey data for institutional and primary care settings and will continue to assist states in collecting this or similar data in the future.<sup>19</sup> BIO supports this effort and believes obtaining information through this method is an effective way to assess beneficiaries' own estimation of their access to care.

- ***What role can health information technology play in measuring access to care?***

BIO supports the expanded use of health information technology (HIT), which we believe provides a way for patients to be more engaged in their own health care while improving quality of care and producing cost savings. We also believe that HIT has the potential to be a useful tool in measuring access to care. For example, in a given geographic region, states could use HIT as part of a passive monitoring system through which to determine beneficiary access to care. The use of this information may prove especially important for individuals who have fewer tools to advocate for themselves—such as those with mental or behavioral disabilities. For example, if psychiatric visits and/or prescribing patterns begin to decrease in a particular area—as evidenced by data obtained by the state through algorithms written into the HIT platforms of Medicaid providers—this could be recognized as a potential access-to-care problem for individuals needing psychiatric services.

Similarly, for immunization services, state Immunization Information Systems (IIS) serve as a registry mechanism for vaccines for persons of all ages, but can also help identify those beneficiaries who require a vaccine. Many state immunization champions feel that the IIS could actually allow for a better and more accurate calculation of immunization rates, while also facilitating best practices in terms of reaching at-risk adolescents and adults for recommended vaccines.

- ***What do you believe are the primary indicators of access to care in the Medicaid program?***

BIO believes that a wide array of indicators are important to evaluate access to care in the Medicaid program. Indeed, we believe that all of the indicators identified by CMS in the RFI—including provider participation and location, appointment times, waiting room times, call center times, and prescription fill times—are essential for this purpose. However, we believe that the indicator deemed “primary” for this purpose will vary based on the type of service being sought or provided, as well as the population being served. For this reason, in addition to urging CMS to establish access-to-care measures that are both service- and

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<sup>18</sup> 42 C.F.R. § 447.203(b)(7) (requiring states to have “ongoing mechanisms for beneficiary and provider input on access to care (through hotlines, surveys, ombudsman, review of grievance and appeals data, or other equivalent mechanisms) . . .”).

<sup>19</sup> 80 Fed. Reg. at 67,591.

population-specific, as described above, we urge the Agency also to tailor the indicators upon which access is evaluated along those lines.

For instance, in the preamble to the FC, CMS discusses a comment submitted in response to the proposed rule, which suggested that, if at least 80 percent or more of the service providers for a particular service (e.g., hospitals, physicians, labs) in a given area are enrolled in the Medicaid program, that would reasonably mean access is available. While 80 percent of service providers may be an appropriate standard generally, to the extent that CMS were to establish an indicator of access to care of this nature, the Agency should consider setting thresholds within each service category and potentially for different patient populations.

We also encourage CMS to also consider the following indicators, considered by the National Association of Insurance Commissioners (NAIC), when developing revisions to their Network Adequacy Model Act, which can be used individually or in concert:

- ✓ Maximum travel time and distance standards in miles by county to access a full time equivalent primary care physician, specialist, facility or other health care provider.
  - ✓ Minimum ratio of providers to covered persons for primary care physician, specialist, and other health care provider.
  - ✓ Minimum number of full time equivalent physicians and healthcare providers needed to meet the needs of patients within limited English proficiency, diverse cultural and ethnic backgrounds, and with physician and mental disabilities.
  - ✓ Maximum time and distance standards in miles by county to access full time equivalent diagnostic and ancillary services.
  - ✓ Maximum time and distance standards in miles by county to access general hospital services with emergency care.
  - ✓ Maximum allowable wait times for an appointment with a primary care physician, specialist, and other health care provider.
  - ✓ Regularly assessment of provider capacity, including the availability of providers to accept new patients.
  - ✓ The breadth of hours of operation for network providers.
  - ✓ The ability of physicians to admit patients to nearby hospitals.
- ***What do you believe CMS should consider in undertaking access to care data collection in areas related to:***

While BIO has specific feedback regarding each of the areas of access-to-care data collection identified in the RFI (described below), as a general matter, we urge CMS to take into consideration the differences between and among distinct Medicaid sub-populations when undertaking access-to-care data collection in all of the identified areas. It is important to remember that, although there are some access-to-care standards that can be applied to all geographic areas and populations, given the variety of geographic areas and populations served by the Medicaid program, data collection activities will be most effective if they are able to account for these differences. In addition, as noted in the FC, CMS

should take steps to ensure that access to advances in technology (e.g. biomarker testing<sup>20</sup>, low-dose CT lung cancer screening<sup>21,22,23</sup>, etc.) that have an impact on the delivery of care in the Medicaid program is considered when measuring access to care across all of these areas.<sup>24</sup>

- ***Differences between fee-for-service (FFS) and managed care delivery.***

While BIO appreciates that there may be differences in the care-delivery system and, potentially, the populations served by Medicaid FFS versus managed care, to the extent practicable, we strongly urge CMS to align the measures and metrics adopted to assess access to care across these two programs. We do not believe that a beneficiary's access to care should depend on whether he or she is enrolled in Medicaid FFS or managed Medicaid. Moreover, there are specific considerations in the areas of network adequacy, care management processes, and system requirements for which CMS should put an emphasis on the need for alignment. While we recognize that there are differences between FFS and managed care in these domains, including the way systems are used and/or funded, there is, nevertheless, a need to minimize any potential gaps in access, including by aligning the measures used to evaluate access to care in both programs.

- ***Variations in services such as acute and long-term care.***

Although basic principles for access should be consistent across service types (e.g., acute vs. long-term care), BIO notes the importance of using separate, appropriately tailored standards for acute versus long-term care services, given the unique characteristics of individuals requiring long-term care, as well as trends indicating barriers to access for these services.

As the largest payer of long-term care, Medicaid plays an undeniably important role in the provision of long-term services and supports (LTSS). However, access to long-term care has been negatively impacted by the movement of LTSS into managed care in many states. To illustrate, from FY 2008 to FY 2013, the percentage of LTSS provided through managed care organizations increased from 4 percent to 10 percent, with considerable additional growth expected to continue.<sup>25</sup> Additionally, data indicate that beneficiaries' experience with long-term care is strongly influenced by where they live, given the substantial variation in how states provide long-term care. The increasing shift to managed care, as well as the noticeable state-by-state variation, demonstrates the need for more data collection activities that specifically address beneficiary access to long-term care.

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<sup>20</sup> Molecular testing guideline for selection of lung cancer patients for EGFR and ALK tyrosine kinase inhibitors: guideline from the College of American Pathologists, International Association for the Study of Lung Cancer, and Association for Molecular Pathology; Arch Pathol Lab Med. 2013 Jun; 137(6): 828-860.

<sup>21</sup> Decision Memo for Screening for Lung Cancer with Low Dose Computed Tomography (LDCT), 2015, available at: <https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=274>.

<sup>22</sup> Aberle DR, Adams AM, Berg CD, Black WC, Clapp JD, Fagerstrom RM, et al.; National Lung Screening Trial Research Team. Reduced lung-cancer mortality with low-dose computed tomographic screening. *New Engl J Med*. 2011;365(5):395-409

<sup>23</sup> Pinsky PF, Church TR, Izmirlian G, Kramer BS. The National Lung Screening Trial: results stratified by demographics, smoking history, and lung cancer histology. *Cancer*. 2013.

<sup>24</sup> 80 Fed. Reg. at 67,593.

<sup>25</sup> Ryan, Jennifer, et al. *Rebalancing Medicaid Long-Term Services and Supports*. Health Affairs – Health Policy Briefs. September 17, 2015.



- ***Variations in access for pediatric and adult populations and individuals with disabilities.***

BIO supports the separate identification of standards for access to pediatric services, as it reflects the clinical reality that pediatric care is a physician specialty that requires specific training and expertise. This is especially critical in this context given the large proportion of children who are insured through the Medicaid program.

BIO also believes it is important for CMS to adopt standards specific to certain sub-populations within the Medicaid program's adult population, including seniors and persons with disabilities. Seniors and persons with disabilities have long faced barriers to care, which have only been exaggerated by the movement of these populations to managed care in recent years. These care gaps may be made even more prominent by the rising cost of care and calls for standards to manage the needs of these growing populations.

CMS also may consider adopting adult-specific standards for immunization access, which should assess access across a wide number of provider types, including retail pharmacies. While pediatric vaccinations are generally administered by a limited number of practitioners (i.e., pediatricians, family practice physicians, and public health clinics), adult immunizations are offered in a host of settings that should be included in any evaluation of access to preventive care. In particular, retail pharmacies—which may help improve access to these services for adults with chronic conditions as well as those in underserved geographies—are a very important provider of vaccines to adults served by Medicaid. These community immunization providers are even more important in underserved areas like major metropolitan cities and rural or pioneer counties, where there are fewer primary providers and/or beneficiaries may need to travel great distances to seek services. Therefore it is important to assess beneficiary access to these complementary immunizers to help ensure that beneficiaries have access to vital immunization services at all ages.

- ***Variations in access for rural and urban areas.***

BIO also supports the distinction between rural and urban areas, which is why we believe that, although CMS should develop a core set of national measures and metrics that represents the “floor” for determining access to care for the Medicaid population, states should be able to supplement these standards with measures and metrics that are better tailored to assess access to care given the unique characteristics of the state and its Medicaid program. For instance, states may need to tailor standards that assess access to care based on the distance that a Medicaid beneficiary must travel to see a care provider based on the geographic region in which that individual resides.

- ***Consider also individuals with chronic conditions who may have limited functional support needs related to activities of daily living but nonetheless require more intensive care than other Medicaid beneficiaries, such as persons living with HIV/AIDS.***

As noted previously, BIO believes it is important to establish measures and metrics that are specifically tailored to evaluate access to care for certain patient sub-populations,

including individuals with chronic conditions. This includes individuals who may have limited support needs related to activities of daily living, but nonetheless require more intensive care than other Medicaid beneficiaries. In addition to including persons living with HIV/AIDS in this category (a category that CMS specifically recognizes in the RFI), CMS also may want to consider individuals with serious mental illness or substance abuse disorders, as well as the populations specifically identified in the FC, such as: children and young adults with end-stage renal disease (ESRD) and adolescents ages 12-21 as a distinct subgroup of the pediatric population due to their significant unmet health needs.<sup>26</sup>

- ***Do you believe questions in provider and beneficiary surveys should be consistent for Medicaid and Medicare beneficiaries?***
  - ***If not, what differences do you believe should be accommodated for the Medicaid program, including differences in covered services?***

BIO believes that a certain degree of consistency in provider and beneficiary surveys for the Medicare and Medicaid programs is important to allow for easier and more accurate dissemination, collection, and analyzation of data. This is especially important for the dual-eligible population, who qualify for both programs, and often consists of individuals with the most costly and complex healthcare needs, as noted previously. However, it is important that CMS develop Medicaid-specific surveys, and that such surveys are designed appropriately to account for the socio-economic status and cultural differences among the populations served by these two programs.

## **II. Access to Care Thresholds/Goals**

- ***Do you believe CMS should set thresholds for Medicaid access to care? If so, do you believe such thresholds should be set at the national, state or local levels? Why?***

BIO does believe that CMS should set certain core thresholds for Medicaid access to care. Specifically, akin to our recommendation that CMS establish certain minimum federal measures and metrics to assess access to care, BIO also asks CMS to consider establishing federal minimum thresholds for this purpose. Additionally, although we acknowledge that the RFI is focused on access issues in the FFS population, to the extent possible, we would encourage CMS to extend any established federal minimum thresholds to managed care plans. While specific access requirements by provider type and care setting must reflect the realities of individual states, as well as the various geographic locations within each state, BIO strongly believes that all Medicaid patients deserve a minimum standard of access to care no matter where they live, or whether they are enrolled in Medicaid FFS vs. managed Medicaid.

BIO also believes that these minimum access-to-care thresholds should be supplemented by thresholds established at the state level that account for local context, both in terms of the characteristics and medical needs of the enrollee population and the availability of specific provider services. However, CMS should develop an internal process

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<sup>26</sup> See 80 Fed. Reg. at 67,590.

to comprehensively review the impact of the implementation of these requirements on patient access within each state.

- **If CMS sets Medicaid access thresholds, how do you believe they should be used?**

If CMS does in fact set some federal thresholds, which BIO would support for the reasons just articulated, we believe that such standards should be used to define what constitutes an access deficiency for purposes of triggering a state's obligation to "develop and submit a corrective action plan to CMS within 90 days of discovery of an access deficiency."<sup>27</sup> Without set thresholds, it will be difficult, perhaps even impossible, for CMS to uniformly apply this standard nationwide. Federal thresholds also are necessary to determine whether a state plan amendment (SPA) will be approved or disapproved.<sup>28</sup> Additionally, thresholds are needed to know when there is a higher than usual level of beneficiary, provider, or stakeholder access complaints that triggers a determination that an access-to-care issue exists in a particular state.<sup>29</sup> Finally, as CMS notes in the RFI, federal thresholds would be helpful as benchmarks to assess state improvement, as well as in appeals processes for beneficiaries that have difficulty accessing services.

### **III. Alternative Processes for Access Concerns**

- ***What do you believe are the advantages and disadvantages of either a complaint resolution process or a formal appeals hearing for access to care concerns?***

In the RFI, CMS asks stakeholders what they perceive to be the advantages and disadvantages of either a complaint resolution process or a formal appeals hearing for access to care concerns. Additionally, in the FC, CMS notes that the Agency is "exploring the feasibility of requiring a state level formal hearings process where access to care concerns will be independently heard by a hearings officer."<sup>30</sup> In order to address the question posed in the RFI, we believe that further information is necessary with respect to this question. For instance, it is not clear to us what the intended purpose of this hearing would be. If CMS intends for the hearing process to be used to address statewide deficiencies in access to care, BIO does not believe this is a productive use of state resources, as CMS has set out other, sufficient processes through which to monitor and correct these issues (e.g., the mechanisms for ongoing beneficiary and provider input outlined in the FC). However, BIO would strongly support a hearings process to the extent its purpose was to facilitate individual access to care. While it would require the expenditure of additional state resources, we believe that such a hearings process would provide an additional avenue for beneficiaries to bring their complaints to the state in order to obtain access to care that has been denied.

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<sup>27</sup> *Id.* at 67,596.

<sup>28</sup> *Id.* 67,587 (in the FC, CMS notes that the Agency has not "at this time, required any specific thresholds that would determine an amendment to be approved or disapproved.").

<sup>29</sup> *See* 42 C.F.R. § 447.203(b)(5)(II)(G).

<sup>30</sup> 80 Fed. Reg. at 67,591.

To the extent that the hearings process envisioned by CMS falls into this latter category, we also believe it is important for CMS to specify whether the complaint resolution process and formal appeals hearing would be used for issues related to access to providers alone or could also be extended as a mechanism through which beneficiaries could raise access concerns with regards to other services, such as needed therapies. While we believe that both hearings processes are critical to ensure needed access to care, we further believe that the requirements should be different for each. For example, given that a delay in access to therapies of even a few days or weeks can negatively affect both patient adherence and outcomes, there should be a more expedited timeframe for hearing processes designed to secure access to needed prescription drugs or laboratory services. As stated in our comment letter in response to the *Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability Proposed Rule* (the “Medicaid MCO Proposed Rule”)<sup>31</sup>, we urge the Agency to consider aligning the applicable timeframe for hearings and appeals related to prescription drug access with the Medicare Part D program timeframe, under which plans must render a decision within seven days.<sup>32</sup> With certain exceptions, hearings related to access to a particular provider are less emergent. Nonetheless, BIO firmly believes that CMS should establish standards for expedited hearings in both instances.

- ***Who do you believe should be the responsible party (for example, the state or federal government, an independent third party, a civil servant, an administrative law judge, etc.) to hear beneficiary access to care complaints and/or appeals?***

BIO believes that beneficiary access-to-care complaints and/or appeals should be handled through a four-tiered review process. This process should begin with an informal process such that the complaint or appeal can be addressed in the most efficient and expeditious manner. This process should then become increasingly formal at each level to ensure that the final decisions are made by independent entities based on the best available evidence.

Specifically, BIO believes that a Medicaid beneficiary should begin by making an informal access-to-care complaint and/or appeal directly to either the state Medicaid agency, or the managed care plan, depending on whether the beneficiary participates in traditional FFS or Medicaid managed care. If the request cannot be resolved through this informal mechanism, a formal review process should be in place—which adheres to the timelines identified below—through which the state Medicaid agency adjudicates exceptions and appeals requests made by Medicaid beneficiaries participating in FFS Medicaid. For beneficiaries participating in Medicaid managed care, the managed care plan may act as the formal adjudicator in an exceptions of appeals review process.

Subsequent to this first level of formal review, BIO strongly supports a federal requirement that state Medicaid plans establish an external formal review process such that an enrollee, whose initial exceptions or appeals request has been denied, can request a secondary review of the request by an independent organization. The same timelines for the review and enrollee notification of a determination would apply as those governing the

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<sup>31</sup> 80 Fed. Reg. 31,098 (June 1, 2015).

<sup>32</sup> 42 C.F.R. § 423.590(a)(1).

standard and expedited review process, described in more detail below. An external, independent, review process to assess the merits on which a request was denied is a critical patient protection that is necessary to ensure coverage decisions are made based on a clinical assessment of an individual patient's circumstances.

Along these lines, BIO further asks CMS to consider the feasibility of requiring states to establish an additional tier in the external exceptions review process, such that if an independent organization, as described above, renders a decision against the patient's exception request, the individual has the option to make a final appeal. There are several ways that this fourth level of review could be established. For example, in the Medicare Part D program, this additional appeal tier involves review by the HHS Office of Medicare Hearings and Appeals.<sup>33</sup> We also note that in other segments of the market, such a final review of an exceptions request can involve the state insurance commissioner.<sup>34</sup>

- ***Do you believe there are existing and effective processes to resolve consumers' concerns regarding health care access issues that might be useful for all state Medicaid programs?***

In order to give appropriate consideration to a provider's clinical recommendation and expertise with regard to a given therapy, several states have enacted prescriber-prevails laws that allow prescribers to use their reasonable professional judgment to successfully appeal for drugs that are not on plan formularies or that have prior authorization requirements for patients suffering from certain disease states. These laws provide vulnerable patient populations who rely on these needed therapies from unnecessary delays in care. For example, as of July 1, 2013, the prescriber prevails provision for Medicaid managed care plans in New York was expanded to include "medically necessary prescription drugs in the anti-depressant, anti-retroviral, anti-rejection, seizure, epilepsy, endocrine, hematologic, and immunologic therapeutic classes, including non-formulary drugs" that are determined by the prescriber to be medically necessary.<sup>35</sup> These laws allow patients to access needed medications even when they are not on plan formularies through the submission of clinical documentation by prescribers to plan issuers. We believe similar laws could be enacted and utilized by other state Medicaid plans in order to provide an effective process through which consumers, under the direction of their providers, could resolve healthcare access issues related to appropriate therapies.

- ***Lack of timeliness of an appeal could undermine the time sensitive efforts associated with remediating an individual's access to medical services. You may want to consider providing information on the following:***
  - ***How could appeals be expedited? What outcomes could an appeals officer offer if services are unavailable to Medicaid beneficiaries? Are there other non-appeal based processes that could be used instead?***

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<sup>33</sup> Centers for Medicare and Medicaid Services (CMS). 2014. *Medicare Prescription Drug Appeals & Grievances; Flow Chart: Medicare Part D Appeals Process*, available at: <http://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/downloads/partdappealsflowchart.pdf>.

<sup>34</sup> For example, see Maryland Insurance Administration. *How the Appeals and Grievances Process Works*, available at: <http://www.mdinsurance.state.md.us/sa/consumer/appeals-and-grievances.html>.

<sup>35</sup> Shah, Nirav and Sue Kelly. Expanding Prescriber Prevails in Medicaid Managed Care in Certain Drug Classes. New York State Department of Health.

BIO agrees with CMS that lack of timeliness of an appeal could undermine the time-sensitive efforts associated with remediating an individual's access to medical services. As noted in BIO's comment letter in response to the Medicaid MCO Proposed Rule, we believe that beneficiaries should receive a decision on an expedited appeal within 72 hours for questions regarding access to necessary providers. However, as with appeals generally, we urge CMS to consider adopting a shorter timeframe for expedited appeals with respect to prescription drugs. Specifically, we recommend that CMS adopt a 24-hour timeframe for determinations on expedited appeals for drugs and biologicals, in order to align with the standard applicable to expedited exceptions in the context of the Exchanges,<sup>36</sup> as well as the 24-hour timeframe for prior authorization of drugs applicable under section 1927 of the Social Security Act.<sup>37</sup> Additionally, we believe it is critical to include standards for expedited reviews with regards to access issues that put a patient's life in immediate danger. For example, this can include access to a targeted therapy for a patient diagnosed with fast-progressing cancer. For extremely time-sensitive issues, CMS should include specific processes that must be followed in order to provide beneficiaries immediate access to the life-saving treatments and services they may need.

#### **IV. Access to Care Measures**

##### **a. Measures for Availability of Care and Providers**

- ***CMS is soliciting public comment the definition of a "geographic area."***

As CMS notes in the FC, "[t]he actual definition of geographic area may vary by state and the extent and need to which states review and monitor access based on a geographic area may depend on the data and other information that states are required to review as part of the framework of" the FC.<sup>38</sup> For instance, CMS points out that "states may receive information that access to care is an issue in one specific region within the state and focus monitoring and remediation strategies on that region. Other states may have more statewide access concerns that require a county-by-county analysis and strategy to address access on a statewide basis."<sup>39</sup>

BIO agrees that the definition of a geographic area should vary state by state and thus believes that states should be charged with defining geographic regions based on their own state-specific factors. That said, states should be directed to define the geographic areas they will use for purposes of assessing and ensuring compliance with the access requirement on a prospective basis, rather than on an ad-hoc basis once an access issue has arisen. Although states should nonetheless retain the authority to tailor their corrective actions to the access issue in question, which may involve taking action across multiple state-defined geographic areas, or focusing the corrective actions on a specific region within one or more state-defined geographic areas.

- ***CMS is soliciting public comment on the following availability of care and providers measurement areas within geographic areas:***

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<sup>36</sup> 45 C.F.R. § 156.122(c)(1).

<sup>37</sup> SSA § 1927(d)(5).

<sup>38</sup> 80 Fed. Reg. at 67,585.

<sup>39</sup> Id.

- ***Primary care physicians (including pediatricians) and clinicians accepting any/new patients and physician specialists accepting any/new patients.***

BIO believes that availability-of-care measures with respect to both primary care physicians and physician specialists—particularly with respect to those providers accepting new patients—are fundamental criteria to assessing the sufficiency of Medicaid reimbursement rates.

With respect to access to specialists, BIO believes that any applicable standards should ensure beneficiary access to at least one of each type of specialist and, as appropriate and necessary, subspecialist that is accepting new patients. To these ends, we believe that CMS should identify a list of certain core specialist types to which all Medicaid beneficiaries should have access. This should include, at a minimum, those specialist types with a specialty code assigned by CMS.

CMS also should consider including subspecialists on the list of providers accepting any new patients to whom beneficiaries must have access. For example, oncologists is a specialty type assigned a specialty code by CMS—given the importance of timely and convenient access to this type of specialists for those with cancer—not all cancers are the same, and access to subspecialists, where they are available in a given geographic area, can be crucial to ensure patients obtain expert and individualized care. Thus, the Agency should consider including the subspecialties of the five most prevalent cancers by incidence: breast, prostate, lung, colorectal, and melanoma. Similarly, we urge the Agency to require the inclusion of sub-specialists that treat patients suffering from rare diseases. Rare diseases, particularly those affecting pediatric populations, require highly skilled sub-specialists that may not be reflected in typical specialist networks. Patients must have access to these sub-specialists.

- ***Specialty care (for example, addiction and psychiatric services, home and community based services, specialty pharmacy) accepting any/new patients.***

As articulated in BIO's comments in response to the FC, CMS should consider including measures to assess the availability of specialty pharmacies to the Medicaid population. BIO believes it is important to distinguish between retail and specialty pharmacies given the different services provided by these two types of pharmacies, and the extent to which patients with complex, chronic conditions (e.g., MS, Hepatitis C, HIV, Crohn's) rely on specialty pharmacies. Specialty pharmacies are dispensing an increasing number and variety of prescriptions in the U.S. and often provide support to, and streamline the delivery process for, patients who need therapies that have specific handling and storage requirements, and their providers. Therefore, it is important to measure Medicaid beneficiary access to specialty pharmacies on an ongoing basis in order to ensure that this population maintains access to the important therapies that are increasingly being dispensed through this modality.

Furthermore, given the major shortage in behavioral healthcare services—both addiction and psychiatric—in many areas throughout the country, particularly rural regions,

having measures to assess the availability of these services is also critical to the Medicaid population with these conditions. Oftentimes, Medicaid beneficiaries experience higher rates of addiction and mental illness than other patient groups, and therefore usually have even fewer options to obtain the needed care. For this reason, it is critical to include measures that assess Medicaid beneficiary access to these essential specialty services.

- ***Physicians and clinicians experiencing difficulties referring patients to specialty care and psychiatrists experiencing difficulties referring patients with serious mental illness to primary care.***

BIO supports the use of measures to assess the difficulty practitioners face referring their Medicaid patients to specialty care. According to MACPAC, “difficulty getting referrals from primary care providers or health plans can lead to delays obtaining timely diagnosis and treatment” that can be detrimental to a patient’s health. For this reason, CMS may wish to consider the use of the MACPAC statistics for children and adults who reported that getting referrals was a problem for them. Although MACPAC currently includes this measure as a beneficiary-reported measure, it also may be beneficial to include provider-reported statistics when looking at the ability to receive and provide referrals. Oftentimes, the physician is in a unique position and encounters difficulties on the back-end that the patient is either unaware of or does not understand. We believe it is important to measure access to care by receiving input from multiple sources so that a breadth of access issues can be recognized and, ultimately, resolved.

Additionally, a related provider-reported statistic that CMS may wish to consider is the MACPAC statistic for the percentage of the primary care physician’s patient care revenue that comes from Medicaid and CHIP. According to MACPAC, “this measure shows the distribution of responses for Medicaid/CHIP by office-based physicians to the question: ‘Roughly what percent of your patient care revenue at the reporting location comes from the following: Medicare? Medicaid/CHIP? Private insurance? All other sources?’” Relevant to the Medicaid access standard, a change in revenue distribution could indicate a change in Medicaid/CHIP workforce capacity (e.g., an increase in the percentage of revenues that come from Medicaid/CHIP beneficiaries could indicate that other providers in the area are no longer accepting such patients).

Finally, to the extent that patient-reported outcomes are developed by the National Committee for Quality Assurance (NCQA) and others that address access to cancer care specifically, use of these measures should be adopted in an expedited manner, given the poor outcomes reported for Medicaid patients with cancer in comparison to patients with other types of insurance.<sup>40</sup>

- ***Other.***

In addition to ensuring access to a range of services and providers, CMS also may want to consider monitoring patient access to essential drugs and biologicals, in light of recent access problems due to the increased use of restrictive formularies and prior authorization management tools by certain Medicaid programs/plans. In fact, CMS

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<sup>40</sup> See: [https://www.ucdmc.ucdavis.edu/iphi/resources/1117737\\_CancerHI\\_100615.pdf](https://www.ucdmc.ucdavis.edu/iphi/resources/1117737_CancerHI_100615.pdf).



highlighted these problems in a recent letter to state Medicaid Directors, which reminded states of their obligation to provide access to, and coverage for, new therapies when there is a reasonable clinical indication for their use.<sup>41</sup> Ensuring patient access to drugs and biologicals is critical to help patients maintain their condition, or prevent advancement of disease.

Specific to Medicaid managed care, we also urge CMS to consider the following: While Medicaid plans are ultimately required to cover virtually all prescription drugs in accordance with section 1927 of the Social Security Act, the use of formularies by these plans results in an increased burden on enrollees and their providers to the extent they need to obtain access to medically necessary, off-formulary drugs through a prior authorization process. Specifically, as articulated in BIO's comments in response to CMS's Medicaid MCO Proposed Rule, we urge CMS to require state Medicaid plans to adopt their formularies through a pharmacy and therapeutics committee, as is required under Medicare Part D,<sup>42</sup> as well as the recently updated Essential Health Benefits regulations, which impose such requirements beginning in 2017.<sup>43</sup> We note that a similar standard applied to covered outpatient drugs to the extent that a state wants to adopt a formulary under section 1927(d)(4).<sup>44</sup> We also ask CMS to regularly monitor the operation of plan formularies and take steps to ensure that these formularies do not unduly restrict access to medically necessary drugs, including through the use of unduly burdensome prior authorization requirements, and are not discriminatory against those enrollees with complex, chronic conditions.

#### **b. Measures for Beneficiary-Reported Access**

In the RFI, CMS asks for feedback regarding the inclusion of a number of beneficiary-reported access measures. As CMS notes in the FC, "[i]f a state experiences a spike in beneficiaries who experience difficulty receiving a particular service in a geographic region, this could indicate access issues and should be investigated."<sup>45</sup> We agree and therefore strongly support CMS's efforts to establish a mechanism for soliciting input from beneficiaries with respect to any issues they may have accessing appropriate care.

- ***CMS is soliciting public comment on the following beneficiary reported access measurement areas:***
  - ***Beneficiaries reporting a usual source of primary care.***

This is a common measure of potential access to health care and should be considered for reporting purposes. Individuals who have regular access to primary care providers are able to receive important preventative care that can help decrease unnecessary, and costly, visits to the emergency department.

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<sup>41</sup> CMS Release No. 172, Medicaid Drug Rebate Program Notice: Assuring Medicaid Beneficiaries Access to Hepatitis C (HCV) Drugs (Nov. 5, 2015), <https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/Rx-Releases/State-Releases/state-rel-172.pdf>.

<sup>42</sup> 42 C.F.R. § 423.120(b)(1).

<sup>43</sup> 45 C.F.R. § 156.122(a)(3).

<sup>44</sup> SSA § 1927(d)(4)(A) ("A State may establish a formulary if the formulary meets the following requirements . . . the formulary is developed by a committee consisting of physicians, pharmacists, and other appropriate individuals appointed by the Governor of the State (or, at the option of the State, the State's drug use review board . . .).").

<sup>45</sup> 80 Fed. Reg. at 67,585.

- ***Beneficiaries reporting difficulty finding a specialist/general clinician, not taking any new patients and/or the beneficiary's insurance.***

This is a key measure when attempting to determine beneficiaries' access to care. Without the ability to see a specialist/general clinician, regardless of the barrier to access, individuals may forego needed medical care. This measure is especially important for patients covered by the Medicaid program, as they may have other barriers (e.g., language, transportation) that could hinder their ability to access a medical specialist.

- ***Beneficiaries able to access specialists or behavioral health care if they have: Chronic conditions, heart disease, behavioral health issues, etc.***

BIO believes this is an especially important measure for the Medicaid population, given that these patients tend to suffer from complex, chronic conditions and behavioral health conditions at a higher rate than the general population, making it especially critical for them to have access to specialists that treat those conditions.

- ***Children and adults able to access appropriate immunizations and/or seasonal vaccines.***

Vaccines are one of the most important primary care interventions across the life span. For this reason, BIO strongly supports the inclusion of measures to track Medicaid beneficiary access to appropriate immunizations and seasonal vaccines for both children and adults. As noted previously, there are a number of primary-care providers that deliver ACIP-recommended immunizations (e.g., pediatricians, family practice, internal medicine, obstetricians/gynecologists). It is vital that all Medicaid beneficiaries—especially adolescents, pregnant women, and adults with chronic conditions such as asthma, cardiovascular disease, and diabetes—have access to these provider types to be able to regularly receive recommended vaccines. When access to a routine primary care provider is limited, however, many adults seek vaccination services from alternative provider locations (e.g., retail pharmacies, public health clinics and community health centers). Therefore it is important to collect information related to access for a broad array of primary care providers to ensure that beneficiaries have access to vital immunization services at all ages.

- ***Beneficiaries reporting delayed care and reason for delay.***

As stated above, there are a number of reasons why beneficiaries may be unable to access the care they need. Asking beneficiaries for a specific reason for their delay in care is critical to address access-to-care issues. Without receiving specific details regarding what caused a delay in care, it can be difficult for states to understand the problems facing their population and how to resolve the underlying issues.

- ***Unmet need for specialty, primary, follow-up, dental, prescriptions, and mental health and substance abuse treatment due to cost concerns.***

BIO strongly supports the inclusion of measures to identify unmet need for items and services due to cost concerns. This is especially important in the Medicaid program, given that individuals enrolled in Medicaid have lower incomes and assets, which can make it even more difficult for them to access services that have even very modest cost-sharing requirements. Moreover, in situations in which cost concerns prevent patient adherence to medication regimens, this becomes particularly significant, as the amount of cost-sharing to which a beneficiary is subjected has been shown to be inversely proportional to the likelihood of adherence to a therapy. Non-adherence can not only be detrimental to an individual patient's health outcomes—especially in the case of chronic disease treatment—but can result in higher overall health expenditures (e.g., from increased hospitalization, need for supportive care, physician office visits, and surgical interventions).

One way to capture this information is through a beneficiary experience survey, like AHRQ's CAHPS surveys. States should be required to report to CMS the results of metrics designed to assess cost-related barriers to beneficiaries' access to care. However, BIO acknowledges that beneficiary surveys may not be sufficient as measures of access in certain populations, and may even be challenging to conduct (e.g., with the Medicaid population with serious mental illness). In these instances, we recommend that CMS utilize an additional mechanism to collect access data. Specifically, CMS should track plan rejections and reversals, and analyze the frequency of these events by state. This information may assist the Agency in pinpointing the source of access challenges: for example, an excess (e.g., compared to a national average or benchmarked population) of rejections may indicate that a state Medicaid program has imposed cost-sharing requirements that interfere with patient access, either generally or to certain types of care, while an excess of reversals may signify that state Medicaid policies are structured, or are being implemented, in a manner that is inconsistent with desired clinical practice. Outliers identified by such analyses could be further investigated based on criteria that assess scope, frequency, and duration. In addition to beneficiary surveys, this automated process may improve the efficiency and effectiveness of federal oversight. CMS, in turn, should play an oversight role in identifying systematic, structural barriers to access related to cost concerns and work with states and stakeholders to overcome these barriers in a timely fashion.

- ***Beneficiaries getting needed care quickly.***

As acknowledged by the NAIC's Network Adequacy Model Act, an important component of access to care is the "access to emergency services twenty-four hours per day, seven days per week." BIO agrees with NAIC that individuals should be able to quickly access needed emergency care regardless of the time of day. We therefore encourage CMS to include this measure, and would recommend that CMS expand the measure to more closely align with NAIC's definition of emergent care to include that beneficiaries are able to access care every day of the week, at all hours of the day. However, although immediate access to needed emergency care is critical, we note that BIO supports the efforts of state Medicaid agencies and plans to properly incentivize the diversion of non-emergent care needs to a more appropriate care setting than an emergency department (ED).

Along these lines, we would like to encourage CMS to investigate and establish measures that assess the ability of beneficiaries to obtain timely access to high-level stroke care. Ischemic stroke affects hundreds of thousands each year and leaves many with new disability and at increased risk for complications, recurrent stroke, and clinical deterioration.

Functional outcomes for this population vary widely based on regional and local differences, and many of these patients are discharged to long-term care. We believe that CMS should establish measures to assess whether states and Medicaid plans have implemented stroke systems of care and telestroke programs, both of which seek to ensure optimal care and limit disability.

We also recommend that CMS investigate overall treatment rates for stroke as a potential measure to help gauge access to high-level stroke care across various regions, states, counties, and even hospitals. A recent report from the University of Michigan highlighted the wide variety of thrombolytic treatment rates across counties in the United States.<sup>46</sup> According to the study, only 4.2 percent of more than 844,000 stroke victims received thrombolytic therapy or another urgent stroke treatment. If given in the first few hours after a stroke, thrombolytic therapy can restore blood flow in the brain and prevent the damage that causes stroke-related disability and drives up the long-term cost of caring for stroke survivors. While some places such as Stanford, California, and Asheville, North Carolina have as many as 14 percent of stroke patients receiving thrombolytic therapy, in one-fifth of hospital regions, no patients received thrombolytic therapy. Perhaps even more disturbing, according to the report variation in treatment rates was found to track with lower average levels of education and income and higher unemployment in hospital service areas. For these reasons, we believe including measures that assess treatment rates for stroke are incredibly important for the Medicaid population.

### **c. Measures Regarding Service Utilization**

Utilization may go up or down unrelated to Medicaid reimbursement rates. As CMS notes in the FC, a reduction in utilization may result from policy changes that improve the efficiency of care, without lowering access or quality. We agree with CMS that state rate-setting policies should discourage over-utilization.<sup>47</sup> However, as CMS further notes in the FC, “[i]f a state experiences a severe decline in service utilization without a plausible explanation, there may be an access concern worthy of investigation.”<sup>48</sup> Accordingly, we believe that it is important for CMS to establish mechanisms for states to track service utilization by Medicaid beneficiaries. As noted above, we urge the Agency to consider harnessing HIT to automate this process, to the extent possible.

- ***CMS is soliciting public comment on the following service utilization measurement areas:***
  - ***Trends in emergency room utilization relative to primary and mental health and substance abuse treatment care utilization.***

As stated above, BIO believes individuals should have access to care in an emergent situation twenty-four hours per day, seven days per week. However, over-utilization of the ED is not only extremely costly, but it can be a good indicator for when access to primary care is lacking. As noted in the MACPAC report to Congress, Medicaid enrollees had a greater number of ED visits per 100 persons than those did with private insurance or no

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<sup>46</sup> Skolarus, L. et. al. 2015. Marked Regional Variation in Acute Stroke Treatment Among Medicare Beneficiaries. *Stroke* 46(7):1890-1896.

<sup>47</sup> 80 Fed. Reg. at 67,585.

<sup>48</sup> Id.

coverage.<sup>49</sup> Therefore, BIO believes it is especially important to include measures that monitor trends in ED utilization for the Medicaid population.

To these ends, BIO recommends that CMS consider adopting certain MACPAC statistics that assess beneficiary use of the ED, including:

1. *Had an ER visit in past 12 months and most recent ER visit was related to a serious health problem or an access barrier*—this measure is helpful in determining poor access to primary care and/or substance abuse and mental health services, or could indicate a need for more education about the importance of using primary care providers when possible, rather than the ED; and
2. *Had 2 or more ER visits during the past 12 months*—this measure is helpful because a high use of ED services may signify complex health needs or poor access to primary care and/or substance abuse and mental health services.

Tracking this information is important in order for CMS and the states to find geographic areas where it may be difficult for beneficiaries to access primary care providers in order to obtain the services they need to receive an early diagnosis and/or maintain a condition. This information also would be useful in trying to ascertain the need for better access to mental health and substance abuse treatment. Delaying this care can lead to overutilization of the ED, which can not only have a negative impact on overall patient health but also is very costly for the healthcare system.

#### **d. Comparison of Payments**

While we agree with CMS that payment rates alone are not a measure of access,<sup>50</sup> as CMS notes in the FC, “[p]ayment rate changes do not comply with the Medicaid access requirements if they result in a denial of sufficient access to covered care and services.”<sup>51</sup> Moreover, “[b]ecause the statutory provisions at section 1902(a)(30)(A) of the Act refer to payment rates and comparisons to the general population, it is necessary for states to compare Medicaid payment rates to the rates of Medicare or private payors.”<sup>52</sup> Accordingly, BIO supports CMS’s efforts to set standards for such comparisons.

We also support CMS’s efforts to ensure that payment rates are assessed based on site of service. To these ends, we ask CMS to collect data at a more granular level related to payments at different sites of service (e.g., hospital outpatient versus physician office) and provider types (e.g., rural health center versus academic center) since costs can be different based on where care is received. This, in turn, can impact beneficiary access to needed services.

- ***CMS is soliciting public comment on the following comparison of payment measurement areas:***

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<sup>49</sup> Medicaid and CHIP Payment and Access Commission. *Report to the Congress on Medicaid and CHIP*. Chapter 4 – Examining Access to Care in Medicaid and CHIP. March 2011.

<sup>50</sup> 80 Fed. Reg. at 67,597.

<sup>51</sup> *Id.* at 67,579.

<sup>52</sup> *Id.* at 67,585.

- ***Payment rates for services set at a specific percentage of Medicare.***

Given the perception that Medicaid provider rates are, on average, often significantly lower than Medicare rates, CMS should begin collecting data in order to evaluate Medicaid payment rates as a percentage of Medicare rates. Such data collection efforts should stratify payment rates for the two programs based on: (1) patient type (e.g., disease state); (2) site of service (e.g., hospital outpatient versus physician office); (3) physician type; (4) service provided; and (5) geographic location (e.g., state, Medicare locality). Through the collection of this data, CMS can monitor changes in Medicaid payment policy in order to determine how these rates may be affecting beneficiaries' access to care within specific patient or provider sub-populations. When significant access issues arise, it will be beneficial to have these data available to see if increases in payment rates could be a potential solution for any noticeable decreases in access to care.

- ***Medicaid payment rates compared to surrounding states, Medicare, commercial payers.***

Inadequate Medicaid payment can translate to barriers for access. Recent studies have found that Medicaid beneficiaries have had more trouble finding a physician who is willing to accept their insurance. Additionally, specialist physicians and clinics are far more likely to deny appointments to Medicaid and CHIP children than to privately insured children.<sup>53</sup> Accordingly, we support efforts to compare Medicaid rates to those of other payors. While we do not believe that differential reimbursement rates necessarily mean that beneficiaries do not have access to the providers they need, such differences can be an important indication that Medicaid policies may not be sufficiently supportive of beneficiary access to care. We note, however, that access to private payor reimbursement rates may be a challenge for states, as such information may be considered proprietary by the payors. We therefore urge CMS to work with stakeholders to establish a mechanism to enable states to compare their rates to private payor rates without compromising the confidential and proprietary nature of these data.

Similarly, access to care for the Medicaid population can vary state to state. While there likely are an array of factors that contribute to this disparity, payment rates may be one such factor. Accordingly, we support efforts by the Agency to encourage or require the comparison of Medicaid rates across states. To minimize the burden on states, however, the Agency may wish to direct states to compare their rates only to certain other states (e.g., neighboring states, states with similar Medicaid programs and/or Medicaid populations).

- ***Acquisition costs compared to Medicaid payments for pharmaceuticals.***

BIO supports CMS's efforts to ensure that Medicaid payments for pharmaceuticals and vaccines are sufficient to cover provider acquisition costs, and urge CMS to use existing mechanisms of reporting such data rather than establishing new systems. Adequately

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<sup>53</sup> Paradise, Julia and Rachel Garfield. What is Medicaid's Impact on Access to Care, Health Outcomes, and Quality of Care? Setting the Record Straight on the Evidence. The Kaiser Commission on Medicaid and the Uninsured. August 2013.

reimbursing providers for the drugs and biologicals they provide to their patients is essential for ensuring adequate access to the treatments that Medicaid patients—many of whom suffer from multiple chronic conditions—need to either help maintain a condition or prevent the advancement of disease.

Additionally, coverage of immunizations and their administration is essential for the Medicaid population, and yet, studies have found that adult immunization rates for Medicaid beneficiaries are very low. Currently, many state FFS plans set reimbursement rates for vaccines that are below the acquisition cost paid by the provider. Inadequate reimbursement rates for recommended immunizations can disincentivize providers from proactively administering vaccines to their patients, despite their essential role as a preventive service.

Furthermore, BIO notes the importance of ensuring that such payment rates are adequate to accommodate new technologies and innovative therapies. BIO strongly encourages CMS to actively monitor Medicaid reimbursement rates for pharmaceuticals and vaccines to ensure that these payments at least cover provider acquisition costs, as well as adequately reimburse providers for their administration services, to ensure robust access to these vital products and services.

- ***Comparisons or measures that would inform managed care rate adequacy (the payment managed care plans make to providers).***

CMS notes in the FC that they would expect states to include Medicaid managed care payment rates in these comparisons to the extent practicable.<sup>54</sup> This is important, particularly given that CMS is interested in equity in access between Medicaid FFS and managed care. Rate setting should also attempt to account for the introduction of new technologies to ensure access to such services and care for Medicaid beneficiaries.

## **V. Conclusion**

BIO appreciates the opportunity to comment on the RFI. We support CMS's efforts to ensure Medicaid beneficiaries have access to needed providers through the increased use of national, state, and local access-to-care measures, metrics, and thresholds. We look forward to continuing to work with CMS in the future to address these critical issues, including as the Agency looks to provide further guidance based on stakeholder feedback received in response to both this RFI and the related FC. Please feel free to contact us at (202) 962-9200 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/

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<sup>54</sup> 80 Fed. Reg. at 67,592.

Acting Administrator Slavitt  
December 22, 2015

Laurel L. Todd  
Managing Director, Reimbursement  
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