Biotechnology Industry Organization

December 22, 2015

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: Medicaid Program; Methods for Assuring Access to Covered Medicaid Services; Final Rule with Comment [CMS-2328-FC]

Dear Acting Administrator Slavitt:

The Biotechnology Industry Organization (BIO) is pleased to submit comments on the Centers for Medicare and Medicaid Services' (CMS's) final rule with comment entitled *Medicaid Program; Methods for Ensuring Access to Covered Medicaid Services; Final Rule with Comment*[1] (the "FC").

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.

BIO represents an industry that is devoted to discovering new treatments and ensuring patient access to them. We believe that the Medicaid program is a critical mechanism for ensuring access to care for some of our nation's neediest patients. Accordingly, we closely monitor Medicaid policies at both the state and federal levels for their potential impact on beneficiary access to drugs and biologicals, as well as the medical professionals most appropriate to treat their conditions. To these ends, BIO supports CMS's efforts to strengthen federal oversight with respect to the Medicaid Act's "access requirement,"[2] which obligates states to set Medicaid rates that not only "are 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 plan at least to the extent that*

[1] 80 Fed. Reg. at 67,576 (Nov. 2, 2015).
[2] Id. at 67,577 (referring to the access standard in Social Security Act (SSA) § 1902(a)(30)(A) as "the access requirement").

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such care and services are available to the general population in the geographic area."[3] As CMS recognizes in the FC, "[t]o give meaning to [Medicaid statute's] coverage requirements and options, beneficiaries must have meaningful access to the health care items and services that are within the scope of the covered benefits"[4] and "[r]eviews of access to care are necessary to ensure the state Medicaid program is providing sufficient services to its beneficiaries."[5]

We write to provide feedback regarding the aspects of the FC on which CMS has solicited public input. Specifically:[6]

- BIO supports CMS's decision to move forward with the FC at this time;
- BIO urges CMS to provide more guidance to states regarding the categories of services included in the mandatory access reviews, as well as the treatment of providers of telehealth services for such purposes;
- BIO urges CMS not to permit exceptions to the scope of required access reviews beyond the flexibility already afforded states by the FC;
- BIO supports the access review timeframe described in the FC; and
- BIO urges CMS to direct states to establish specialized mechanisms to receive input from Medicaid beneficiaries with mental illness and/or substance abuse disorders.

We note that BIO also is submitting comments in response to the request for information (RFI) released simultaneously with the FC, which we encourage CMS to take into account 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.[7]

I. BIO Supports CMS's Decision to Move Forward with the FC at This Time.

As an initial matter, we would like to express our strong support for CMS's decision to move forward with implementation of the FC at this time. The Supreme Court's recent decision in *Armstrong v. Exceptional Child Center, Inc.*,[8] effectively forecloses Medicaid beneficiaries' and providers' ability to compel states to set payment rates in a way that does not negatively impact beneficiary access to services through the courts. As CMS notes in the FC, the lack of a private right of action to enforce the Medicaid Act's "access requirement" resulting from this decision underscores both "the primacy of CMS's role in ensuring access" as well as "the need for stronger non-judicial processes to ensure access, including stronger processes at both the state and federal levels for developing data on

[3] SSA § 1902(a)(30)(A) (emphasis added).
[4] 80 Fed. Reg. at 67,577 (emphasis added).
[5] Id. at 67,593.
[6] 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." BIO addresses this issue in our comments in response to the related RFI.
[7] CMS notes in the preamble to the FC that the Agency is "not addressing access to care under managed care arrangements" or "Medicaid waiver and demonstration programs" as part of this "rulemaking effort." 80 Fed. Reg. at 67,582.
[8] 135 S. Ct. 1378 (2015).

beneficiary access and reviewing the effect on beneficiary access of changes to payment methodologies."[9]

BIO supports the FC in that it represents a more systematic approach than currently exists in the Medicaid program for both states and CMS to evaluate beneficiary access to services, while continuing to afford states substantial flexibility as to the precise methodologies employed.[10] Meanwhile, "[f]urther delaying this rule could result in confusion as to the access requirements of section 1902(a)(30)(A) of the Act,"[11] particularly in light of the recent Supreme Court decision in *Armstrong*. While we appreciate and support the need to incorporate stakeholder feedback into the development of the access evaluation processes described in the FC, the Agency has already spent four years refining its May 2011 proposed rule[12] with input from interested stakeholders. Although these policies likely will need further refinement going forward, we support CMS's decision to move forward with the access plan requirements at this time, while simultaneously seeking input from stakeholders, including through the RFI issued simultaneously with the FC.[13]

II. CMS Should Provide More Guidance to States Regarding the Categories of Services Included in the Mandatory Access Reviews, as well as the Treatment of Providers of Telehealth Services for Such Purposes.

In the FC, CMS is "requesting public comment on the service categories selected for inclusion in baseline analysis" and "added to the list of required ongoing reviews."[14] BIO believes that the list of core services identified in the FC as subject to mandatory access reviews—both baseline and ongoing—is sufficiently comprehensive, particularly given that additional reviews will be required for all services subject to a rate reduction proposal by the state,[15] and may be conducted to evaluate access concerns identified through the public input process described in the FC.[16] That said, we believe that CMS should provide states with additional clarity regarding the types of providers included in each of the categories identified. Specifically, as finalized in the FC, states are required to conduct access reviews that target: (1) primary care services; (2) physician specialist services; (3) behavioral health services; (4) pre- and post-natal obstetric services; and (5) home health services. While CMS does provide a few examples of provider types within each of these service categories, we believe that additional guidance is necessary. We discuss BIO's recommendations with respect to the first two categories, below. We also

[9] 80 Fed. Reg. at 67,579.
[10] 80 Fed. Reg. at 67,579 ("[t]his final rule with comment period recognizes the importance of stronger processes and data to ensure access to care while supporting state flexibility to design the appropriate measures to demonstrate and monitor access to care.").
[11] Id. at 67,581.
[12] 76 Fed. Reg. 26,342 (May 6, 2011).
[13] As CMS notes in the FC, the RFI "solicits input from states, providers, beneficiaries and other members of the public on the feasibility of and methodologies related to the following four specific approaches: Developing a core set of measures of access that all states would monitor and publicly report on; Measuring access to long term care and home and community supports; Setting national access to care thresholds; and Establishing a process for access to care that would allow beneficiaries experiencing access issues to raise and seek resolution of their concerns." 80 Fed. Reg. 67,377, 67,379 (Nov. 2, 2015).
[14] Id. at 67,583, 67,584.
[15] 42 C.F.R. § 447.203(b)(6).
[16] 80 Fed. Reg. at 67,586.

ask HHS to confirm that the category of "behavioral health services" includes both "mental health and substance abuse disorder treatment," as the term is not defined consistently in every instance throughout the FC.

In addition, we urge CMS to provide greater guidance on the manner in which states should consider the provision of telemedicine or telehealth services as part of their access monitoring efforts.[17] While BIO supports telemedicine and telehealth services as a means of providing access to care to otherwise medically-underserved populations, BIO firmly believes that telehealth and telemedicine services should augment, but not replace, in-person healthcare services. Accordingly, we believe that CMS should create clear standards that permit the consideration of these remote services in assessing access to care for Medicaid beneficiaries only to the extent that in-person care is infeasible or completely unavailable. We also urge CMS to recognize that telehealth services may not represent adequate access for certain patient populations and types of care.

A. Primary Care

In the category of primary care services, CMS notes in the FC that the Agency is including services "provided by a physician, FQHC, clinic, or dentist" among the service categories states must review as part of the access monitoring review plan.[18] While we support this clarification, we believe that further guidance is needed.

First, we urge CMS to clarify that this category includes providers of both adult and child immunizations services. Vaccines are one of the most important primary care interventions across the life span. Primary care providers (pediatricians, family practice, internal medicine and obstetrician/ gynecologists) all deliver vaccines recommended by the Center for Disease Control and Prevention (CDC) Advisory Committee for Immunization Practice (ACIP). It is vital that all of the primary care provider types listed above are able to administer vaccines, particularly to adolescents, pregnant women and adults with chronic conditions, such as asthma, cardiovascular disease and diabetes. However, many potential Medicaid beneficiaries, especially adults, may not have access to a routine primary care provider. Many adults seek vaccination services from alternative provider locations, such as retail pharmacists, public health clinics and community health centers. 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.

Second, while we support CMS's decision to identify pharmacy services as a type of primary care, we believe that CMS should reconsider its decision not to include specialty

[17] Id. at 67,585 ("We have not set out specific requirements for out-of-state providers in this final rule with comment period. To the extent that individuals in the state obtain access to a particular type of service through out-of-state providers, including through telemedicine or telehealth, or the extent that individuals in a geographic area generally obtain services through out-of-state providers, the state will need to consider such providers in reviewing access to care.").
[18] 42 C.F.R. § 447.203(b)(5)(ii)(A).

pharmacies on the list of provider types subject to mandatory access reviews.[19] Although the term "specialty pharmacy" does not have a single definition, those pharmacies that have self-identified as specialty pharmacies are dispensing an increasing number and variety of prescriptions in this country. Additionally, these pharmacies often provide support to, and streamline the delivery process for, patients who need therapies that have specific handling and storage requirements, and their providers. Measuring Medicaid beneficiary access to specialty pharmacies on an ongoing basis is therefore important to ensure that this population maintains access to the important therapies that are increasingly being dispensed through this modality.

Finally, while mail order pharmacies also are providing an increasing role in the dispensing of prescriptions, we would like to echo the concerns of other commenters that "states will attempt to satisfy pharmacy access requirements simply by demonstrating or offering the availability of mail order pharmacy, which may not be adequate for certain Medicaid beneficiaries."[20] Accordingly, we support CMS's clarification in the preamble to the FC that "[t]o the extent that mail order pharmacies are not adequate or appropriate for some Medicaid beneficiaries, availability of mail order pharmacies would not constitute access to pharmacies."[21]

B. Specialty Care

As relates to specialty care, CMS also provides limited examples of the types of specialists that should be subject to ongoing reviews, including: cardiology, urology, and radiology. While we support that this is not an exhaustive list,[22] we believe that additional categories of providers should be specifically identified such that states have further clarity as to those provider types CMS understands fall within the category of specialty care. These should include, at a minimum, those specialist types with a specialty code assigned by CMS.

We also urge CMS to provide examples of subspecialists that must be included in state access reviews. Access to sub-specialists is necessary to ensure that patients in need of specific types of care—often for chronic, complex diseases like cancer—have timely access to the most appropriate provider for them. As just one example, not all cancers are the same, and access to subspecialists, where they are available in a given geographic area, can be crucial to ensuring patients obtain expert and individualized care. CMS may therefore wish to identify 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 with rare diseases must have access to these sub-specialists.

[19] 80 Fed. Reg. at 67,589.
[20] Id.
[21] Id.
[22] The list, wherever it appears throughout the FC, is prefaced by "for example." See, e.g., id. at 67,586.

III. CMS Should Not Permit Exceptions to the Scope of Mandatory Access Reviews Beyond the Flexibility Already Afforded States by the FC.

In the FC, CMS solicits comment "on whether [the Agency] should consider further rulemaking or guidance, as appropriate, to allow for . . . exemptions to the scope of required access reviews . . . including whether to permit streamlined approaches to measuring access to care based on specific circumstances within states."[23] CMS is "particularly interested in whether states with higher percentages of beneficiaries enrolled with managed care organizations should be exempt from conducting the ongoing access data reviews and/or the rate reduction monitoring procedures and what thresholds for such exemptions would be appropriate."[24]

BIO does not believe that CMS should allow such exemptions. Particularly in those states that have largely shifted to Medicaid managed care, those beneficiaries that remain in Medicaid fee-for-service (FFS) tend to be the most vulnerable. Indeed, as CMS itself states in the FC, "many of the individuals who remain in state FFS systems may have complex care needs."[25] It is particularly critical that states assess, on an ongoing as well as on an as-needed basis, the impact of Medicaid reimbursement policies on access to care for these vulnerable individuals. BIO therefore strongly urges CMS not to exempt states, including those with "higher percentages of beneficiaries enrolled with managed care organizations," from "the ongoing access data reviews and/or the rate reduction monitoring procedures."

Rather, as CMS itself suggests, we believe that the FC provides states with sufficient flexibility to be able to address their unique circumstances, including the degree of managed care penetration into their Medicaid markets. Specifically, as CMS notes in the FC, "states already have significant flexibility within the final provisions of the rule to choose measures within their access monitoring review plans that are tailored to state delivery systems."[26] As CMS further observes, "[t]his could allow, for instance, a state with high levels of managed care enrollment to focus on specific care needs of the populations that remain in FFS after a managed care transition."[27]

IV. BIO Supports The Access Review Timeframe Described in the FC.

In the FC, CMS is providing "an opportunity for comment specifically on the access review requirements, including . . . the timeframe for submission."[28] BIO supports the access review timeframe described in the FC. Specifically, CMS has proposed to require states to conduct ongoing reviews with respect to core services every three years. We think that this strikes a better balance, as compared to the proposed rule, by limiting the scope of services subject to review to core services (as opposed to all services covered by the State Plan), but requiring such reviews to occur on a more regular basis (i.e., every three, as opposed to five, years). We believe that this timeframe, as finalized, will reduce

[23] Id. at 67,583.
[24] Id.
[25] Id.
[26] Id.
[27] Id.
[28] Id. at 67,576.

the burden on states, while making it more likely that beneficiary access issues will be identified in a timely manner. Specifically, while not all services will be covered by the review, particularly if CMS incorporates our comments in section II, above, we believe that the reviews will include a sufficient number and array of services such that most wide-ranging access gaps will be identified. This, together with the more targeted reviews described in the FC, should identify most, if not all, access issues related to Medicaid provider reimbursement rates.

V. CMS Should Direct States to Establish Specialized Mechanisms to Receive Input from Medicaid Beneficiaries with Mental Illness and/or Substance Abuse Disorders.

In the FC, CMS "encourage[s] states to develop specialized mechanisms that would be responsive to input from beneficiaries from . . . populations that have particular access concerns" other than those identified in the FC (e.g., tribes, tribal organizations, and Indian Health Providers).[29] While we support the Agency's efforts to "provide[] states with considerable flexibility to determine appropriate public input mechanisms,"[30] we urge CMS to specifically direct states to establish such mechanisms with respect to Medicaid beneficiaries with mental illness and/or substance abuse disorders. These patients, which represent a disproportionate share of Medicaid recipients, often face significant challenges advocating for themselves, and may find it difficult to negotiate processes and procedures established for the general population.

VI. Conclusion

BIO appreciates the opportunity to comment on the FC. We appreciate the efforts that CMS has made to ensure that Medicaid beneficiary access to providers is at least comparable to that available for individuals enrolled in Medicare and the private insurance market. We look forward to continuing to work with CMS to address these critical issues in the future, including as the Agency looks to provide further guidance with respect to these new requirements based on stakeholder feedback received in response to both this FC and the related RFI. 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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[29] Id. at 67,596.
[30] Id. at 67,598.