Biotechnology Industry Organization

July 20, 2015

Mr. 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

BY ELECTRONIC DELIVERY

Re: Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability; Proposed Rules [CMS-2390-P]

Dear Acting Administrator Slavitt:

The Biotechnology Industry Organization (BIO) is pleased to submit comments on the Centers for Medicare and Medicaid Services' (CMS's) proposed rule entitled *Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability; Proposed Rules*[1] (the "Proposed Rule").

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 patient access to drugs and biologicals. To these ends, BIO supports CMS's efforts to strengthen patient protections available under the Medicaid managed care program, which has undergone a number of statutory changes, as well as

[1] 80 Fed. Reg. 31,098 (June 1, 2015).

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a substantial growth in enrollment, since the Agency last comprehensively addressed the program in 2002. With respect to the specific proposals included in the Proposed Rule:

- BIO supports CMS's recommendations to align Medicaid managed care plan coverage of covered outpatient drugs with coverage in the fee-for-service context, but urges the Agency to adopt certain minimum standards for formularies maintained by plans;
- BIO commends CMS for addressing the extension of Medicaid drug rebates—as well as the related 340B duplicate discount prohibition—to Medicaid managed care utilization, but urges CMS to provide additional detail and guidance to both states and plans with respect to the Agency's duplicate discount proposals;
- BIO supports CMS's proposal to require the provision of managed care encounter data to states, but urges the Agency to provide further guidance regarding the data that must be provided, including to ensure the prevention and identification of duplicate discounts;
- BIO urges CMS to propose certain additional requirements to ensure that Medicare-Medicaid crossover claims adequately prevent duplicate discounts;
- BIO supports CMS's efforts to ensure greater alignment between the Medicaid managed care program and other health coverage programs, including with respect to the applicable appeals and grievance processes;
- BIO supports CMS's proposed principles for setting actuarially sound capitation rates for Medicaid managed care programs and urges CMS to ensure that capitated rates sufficiently anticipate the value of new, innovative therapies;
- BIO supports CMS's efforts to promote innovative payment models, while ensuring beneficiary protections, and urges the Agency to ensure that any such payment initiatives are not used to undermine the delivery of appropriate care to beneficiaries;
- BIO supports the proposed new beneficiary protections outlined in the Proposed Rule with respect to enrollment, authorization of services, and continuation of benefits;
- BIO urges CMS to highlight the need for state-level enforcement of the important patient protections available to Medicaid managed care plan enrollees, including those added by the Proposed Rule;
- BIO urges CMS to take additional steps to advance electronic health information exchange;
- BIO appreciates CMS's focus on network adequacy standards for Medicaid managed care plans in the Proposed Rule, including by establishing standards for availability of assurances, assurances of adequate capacity and services, and network adequacy standards, and urges the Agency to implement BIO's recommendations to build upon the protections outlined in the Proposed Rule;
- BIO supports CMS's efforts to establish quality assessment and performance improvement programs, and urges the Agency to consider certain recommendations to bolster those requirements that are targeted at better management of patients with chronic conditions;
- BIO strongly supports CMS's proposal to establish a Medicaid Managed Care Quality Rating System;
- BIO supports the proposal to extend the comprehensive quality strategy to all state Medicaid programs; and
- BIO supports CMS's clarification in the Program Integrity section of the Proposed Rule that Medicaid managed care plans may not discriminate against certain providers.

BIO also supports efforts made in the Proposed Rule to extend many of the patient protections applicable to Medicaid managed care plans to managed care plans offered through the Children's Health Insurance Program (CHIP). While this comment letter generally focuses on the proposals made in the Medicaid context, to the extent that CMS has proposed to align its proposals between these two programs, our comments should be read to apply to the CHIP-specific proposal as well. We do, however, note two instances in which we urge CMS to revise its proposals with respect to the CHIP program to ensure further alignment with Medicaid.

We also note that, while our comment letter generally responds to proposals in the order in which they appear in the Proposed Rule, we begin our comments with those proposals of greatest interest to BIO's members—namely, CMS's proposals related to covered outpatient drugs, Medicaid drug rebates, and related proposals on managed care plans' provision of encounter data and participation in Medicare crossover claims.

I. Standard Contract Provisions: Covered Outpatient Drugs

CMS proposes to add standards for contracts with MCOs that are contractually obligated to provide coverage of covered outpatient drugs.[2] BIO supports many of these proposals, particularly those that would align Medicaid managed care drug coverage with that available to beneficiaries enrolled in fee-for-service Medicaid. We further commend CMS for issuing guidance to address the extension of Medicaid drug rebates—as well as the related 340B duplicate discount prohibition—to Medicaid managed care utilization. However, we urge CMS to make certain technical clarifications, outline certain minimum standards for the formularies maintained by managed care plans, and provide additional detail on the Agency's duplicate discount proposals in order to ensure that Medicaid MCOs and state Medicaid agencies are taking sufficient steps to identify and exclude 340B utilization from rebate invoices submitted to manufacturers.

A. BIO Supports CMS's Recommendations to Align Medicaid Managed Care Plan Coverage of Drugs With Such Coverage in the Fee-for-Service Context, But Urges the Agency to Make Certain Technical Revisions and to Adopt Certain Minimum Standards for the Formularies Maintained by Such Plans.

CMS makes a series of proposals that would more expressly align coverage of covered outpatient drugs in the Medicaid managed care context to that applicable under Medicaid fee-for-service. CMS relies on its broad authority under section 1902(a)(4) of the Social Security Act (SSA) with respect to these proposals. BIO generally supports these proposals, including:

- CMS's proposed requirement that the coverage of covered outpatient drugs by managed care plans must meet the standards applicable to covered outpatient drugs in the fee-for-service context.[3] We agree with CMS's aim here, and note that the

[2] 42 C.F.R. § 438.3(s) (proposed).
[3] 80 Fed. Reg. at 31,115; 42 C.F.R. § 438.3(s)(1) (proposed).

principle behind this proposal conforms to the more general, existing requirement that Medicaid MCO coverage align with the coverage available in the fee-for-service context.[4] We urge CMS to make three important technical clarifications or changes with respect to this proposal, however.

- First, CMS should clarify that, although it is proposing standards for Medicaid managed care plans' coverage of "covered outpatient drugs" by reference to section 1927(k) of the SSA, such "covered outpatient drugs" represent only a subset of those drugs covered by Medicaid. The Medicaid coverage standard—including for drugs—is defined under section 1902 of the SSA, which generally requires coverage of "medical assistance." The term "medical assistance" is defined, in turn, under section 1905(a) as a number of discrete benefit categories, many of which include prescription drugs, including both pharmacy-dispensed "prescribed drugs,"[5] and medical-benefit drugs.[6] Notably, many of the prescription drugs covered by state Medicaid programs are not "covered outpatient drugs." For instance, Medicaid extends coverage to vaccines under section 1905(a), but vaccines are expressly excluded from the statutory definition of a "covered outpatient drug."[7] The "covered outpatient drug" definition also expressly excludes drugs paid for as part of a bundled payment arrangement.[8] We therefore urge CMS to clarify that its adoption of coverage standards for "covered outpatient drugs" should not be viewed as *reducing* or otherwise limiting mandatory managed care coverage of drugs to only "covered outpatient drugs," and to reiterate that the general standard currently articulated under 42 C.F.R. § 438.206—which provides that "[e]ach State must ensure that all services covered under the State plan are available and accessible to enrollees of MCOs"—remains in force. Moreover, to the extent that CMS intends to adopt a regulation specific to Medicaid managed care plan drug coverage standards, we urge the Agency to do so by reference to section 1905(a), as opposed to section 1927(k).
- Second, BIO notes that the only coverage standard for "covered outpatient drugs" outlined in section 1927—specifically 1927(d)—is related to permissible *limitations* on coverage, rather than an affirmative grant of coverage.[9] Pursuant to section 1927(d)(2), in particular—which represents a very limited exception to the general requirement that Medicaid state plans must cover *all* "covered outpatient drugs" that are subject to a

[4] 42 C.F.R. § 438.206 (current) ("Each State must ensure that all services covered under the State plan are available and accessible to enrollees of MCOs . . . ."). See also 42 C.F.R. § 438.210 (current).
[5] SSA § 1905(a)(12). See also 42 C.F.R. § 440.120 (defining the term "prescribed drugs").
[6] Medical benefit categories within the definition of "medical assistance" that include prescription drugs include, but are not limited to: SSA §§ 1905(a)(1) (inpatient hospital services); (a)(2)(A) (outpatient hospital services); (a)(5) (physicians' services); (a)(7) (medical care); (a)(13) (other diagnostic, screening, preventive, and rehabilitative services).
[7] SSA § 1927(k)(2) ("the term covered outpatient drug" means . . . a biological product, other than a vaccine . . . ").
[8] SSA 1927(k)(3) ("The term "covered outpatient drug" does not include any drug, biological product, or insulin provided as part of, or as incident to and in the same setting as, any of [certain, specified sites of care] (and for which payment may be made under this title as part of payment for the following and not as direct reimbursement for the drug)").
[9] See SSA § 1927(d) (outlining permissible restrictions on state plan coverage of drugs).

federal rebate agreement—states have excluded some or all of the discrete categories of drugs "subject to restriction" from fee-for-service coverage. Yet many Medicaid managed care plans nonetheless continue to provide coverage for these products. For example, section 1927(d)(2)(A) permits states to exclude from coverage "[a]gents when used for anorexia, weight loss, or weight gain"; however, many managed care plans, recognizing the medical value of these products, nonetheless cover such agents for their Medicaid enrollees. We urge CMS to clarify that managed care plans are not restricted from continuing to cover products excluded by states from fee-for-service coverage pursuant to this provision. We further urge CMS to clarify that 1927(d)(2) is not one of the provisions of 1927 that has been extended to managed care plans in the Proposed Rule, meaning that managed care entities cannot, on their own, restrict access to drugs identified in this provision unless such drugs have been excluded by the state in the fee-for-service context.

- Third, to the extent that CMS adopts a regulatory definition of "covered outpatient drug" for purposes of the drug rebate provisions, described in section (I)(B), below, we note that the definition of covered outpatient drug for purposes of section 1927 has two parts: (1) the general definition in 1927(k)(2); and (2) the limiting definition in 1927(k)(3). As both of these provisions are part and parcel of the statutory definition of a covered outpatient drug, we urge CMS to refer more generally to section "1927(k)" for purposes of any such regulations.

BIO also supports:

- CMS's proposals that would require managed care plans to align their drug utilization review processes with those specified under section 1927 of the Social Security Act, including: (1) that plans operate a drug utilization review (DUR) program for covered outpatient drugs that is consistent with the standards under section 1927(g);[10] and (2) that plans would be required to conduct the prior authorization process for covered outpatient drugs in accordance with section 1927(d)(5).[11]

- CMS's proposal that, if a plan is not contractually obligated to provide coverage of a particular covered outpatient drug, or class of drugs, the state would be required to provide the covered outpatient drug through fee-for-service in a manner that is consistent with the standards set forth in its state plan and the requirements of section 1927 of the Social Security Act.[12] *However, we urge CMS to clarify that this requirement applies for all prescription drugs covered under the state plan, and not solely "covered outpatient drugs" as defined under section 1927(k). We further urge CMS also to include requirements that the managed care plan clearly notify the enrollee, in a specified timeframe, in advance of such instances that the coverage of their drug will be provided by fee-for-service Medicaid, and that the state ensures that such coverage is seamless from the enrollee's perspective.*

[10] 80 Fed. Reg. at 31,115-16; 42 C.F.R. § 438.3(s)(4)-(5) (proposed).
[11] 80 Fed. Reg. at 31,116; 42 C.F.R. § 438.3(s)(6) (proposed).
[12] 80 Fed. Reg. at 31,115.

- CMS's proposal to permit a Medicaid managed care plan to maintain its own formulary for covered outpatient drugs that are under the contract, but when there is a medical need for a covered outpatient drug that is not included on their formulary but that is within the scope of the contract, the plan must cover the covered outpatient drug through a prior authorization process.[13] BIO supports the aspect of this proposal that requires plans to cover all covered outpatient drugs through the prior authorization process to the extent that there is medical necessity for the drug. We believe that this standard is consistent with the requirement under the Medicaid Drug Rebate Statute that, if a state extends Medicaid coverage to prescription drugs, it must cover all drugs subject to the federal Medicaid Drug Rebate Agreement, subject to a few, very limited, exceptions.[14] While these exceptions do permit the imposition of prior authorization requirements, any applicable prior authorization requirements generally may not amount to complete exclusion from coverage.[15] We strongly support any efforts to clearly and expressly articulate that this standard also applies with respect to Medicaid managed care.

While we support the aforementioned proposals, BIO urges CMS to consider the following in finalizing the Proposed Rule: While Medicaid managed care plans would ultimately be required to cover virtually all prescription drugs, the use of formularies by these plans would result 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. We therefore urge CMS to adopt further standards with respect to the formularies that would be maintained by managed care plans pursuant to this proposal. Specifically, we urge CMS to require Medicaid managed care plans to adopt their formularies through a pharmacy and therapeutics committee, as is required under Medicare Part D,[16] as well as the recently updated Essential Health Benefits

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[13] 80 Fed. Reg. at 31,115; 42 C.F.R. § 438.3(s)(1) (proposed).

[14] Social Security Act (SSA) § 1927(d)(1) (outlining the limited exceptions under which a state may permissibly restrict coverage of a drug subject to a Medicaid drug rebate). Specifically, federal law permits state Medicaid programs to subject a drug to prior authorization requirements that comply with the terms of SSA § 1927(d)(5). States are also permitted to exclude or otherwise restrict coverage of a drug in the following limited circumstances: (1) the drug is not prescribed for a medically accepted indication (i.e., an indication not approved by the Food and Drug Administration nor supported by certain medical compendia); (2) the drug is contained on the "list of drugs subject to exclusion (e.g., agents when used to promote fertility, agents when used for the treatment of sexual or erectile dysfunction); (3) the drug is subject to such restrictions pursuant to an agreement between the manufacturer and the state that has been approved by CMS; or (4) the drug is excluded from coverage under the state's formulary established in accordance with SSA § 1927(d)(4), which must nonetheless provide access to the drug via prior authorization.

[15] Federal law provides that only "[t]he following drugs or classes of drugs, or their medical uses, may be excluded from coverage or otherwise restricted:" (1) agents when used for anorexia, weight loss, or weight gain; (2) agents when used to promote fertility; (3) agents when used for cosmetic purposes or hair growth; (4) agents when used for the symptomatic relief of cough and colds; (5) prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations; (6) nonprescription drugs, except, in the case of pregnant women when recommended in accordance with the Guideline referred to in section 1905(bb)(2)(A), agents approved by the Food and Drug Administration under the over-the-counter monograph process for purposes of promoting, and when used to promote, tobacco cessation; (7) covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee; and (8) agents when used for the treatment of sexual or erectile dysfunction, unless such agents are used to treat a condition, other than sexual or erectile dysfunction, for which the agents have been approved by the Food and Drug Administration. SSA §§ 1927(d)(2), (7).

[16] 42 C.F.R. § 423.120(b)(1).

regulations, which will impose such requirements beginning in 2017.[17] We note that a similar standard applies to covered outpatient drugs to the extent that a state wants to adopt a formulary under section 1927(d)(4).[18] We also ask CMS to regularly monitor the operation of the formularies maintained by Medicaid managed care plans 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 diseases. BIO would welcome the opportunity to provide ongoing feedback to the Agency's efforts in this area.

Finally, BIO urges CMS to ensure that access to medically necessary medical benefit drugs—which generally are not addressed by plan formularies—is similarly protected in the managed care context.

B. BIO Commends CMS for Addressing the Extension of Medicaid Drug Rebates—as Well as the Related Duplicate Discount Prohibition—to Medicaid MCO Utilization, but Urges CMS to Provide Additional Detail With Respect to the Agency's Duplicate Discount Proposals.

Many of the new contract standards related to covered outpatient drugs are based primarily on section 1903(m)(2)(A)(xiii) of the Social Security Act.[19] We would like to commend CMS for taking steps to implement these requirements. It has been over five years since the Affordable Care Act (ACA) added section 1903(m)(2)(A)(xiii) to the Social Security Act, and guidance in this area is sorely needed. Indeed, absent this guidance, many states do not have adequate processes to collect Medicaid rebates with respect to Medicaid managed care utilization, leading to uncertainty for both states and manufacturers with regard to accounting practices. Further, there has been no federal guidance to address the extension of the 340B duplicate discount prohibition to managed care, which has been in place since 2010. Below, we make several recommendations on CMS's proposed approach.

As an initial matter, we note that the delayed issuance of CMS' guidance in no way undermines the fact that the duplicate discount prohibition has applied to Medicaid managed care utilization as of the date that Medicaid drug rebates were extended to

[17] 45 C.F.R. § 156.122(a)(3).
[18] 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 . . .).").
[19] This provision requires, as a condition of federal matching funds, that contracts with Medicaid managed care plans provide that: (1) Covered outpatient drugs dispensed to the entity's Medicaid enrollees are subject to rebates under the Medicaid drug rebate program (MDRP), and that the State will collect such rebates from manufacturers; (2) Capitation rates paid to the entity will be based on actual cost experience related to rebates and subject to the federal regulations requiring actuarially sound rates; and (3) The entity shall report to the State, on a timely and periodic basis to be specified by CMS, information on the total number of units of each dosage form and strength and package size by National Drug Code of each covered outpatient drug dispensed to the entity's Medicaid enrollees for whom the entity is responsible for coverage (other than covered outpatient drugs purchased through the 340B program) in order to include in the state's invoices submitted under the MDRP, as well as such other data as the Secretary determines necessary.

Medicaid managed care enrollees by the ACA. The Medicaid statute, as amended by the ACA, clearly extends the duplicate discount prohibition to managed care rebates by providing that covered outpatient drugs are not subject to Medicaid drug rebates to the extent that such drugs are dispensed by Medicaid managed care organizations "and subject to discounts under section 340B of the Public Health Service Act."[20] The ACA also clearly indicates that the same effective date—January 1, 2010—applies to both the extension of Medicaid drug rebates to Medicaid managed care enrollees, as well as the extension of the duplicate discount prohibition to this utilization.[21] In issuing the final rule, we believe that CMS should expressly note the effective date of the extension of both rebates and the duplicate discount prohibition to the Managed care context, and require states to affirmatively review all rebate requests submitted from the effective date to ensure compliance with the duplicate discount prohibition, as well as refund manufacturers for any Medicaid rebates improperly received.

We further believe that additional detail is required with respect to CMS's specific proposals in order to ensure compliance with the statutory duplicate discount prohibition.

As you know, the 340B statute expressly prohibits "duplicate discounts,"[22] and both the 340B and MDRP statutes include provisions intended to prevent them.[23] In 1993, HRSA—the federal agency that administers the 340B program—established the Medicaid Exclusion File as the mechanism to support the prevention of duplicate discounts.[24] Pursuant to the Agency's guidance on point, covered entities may elect either to "carve in" (i.e., use 340B product for Medicaid patients) or "carve out" (i.e., use non-340B product for Medicaid patients). States may permissibly obtain Medicaid drug rebates on utilization by covered entities that "carve out"; however, utilization by those entities that "carve in" must be identified—by National Provider Identifier (NPI) using the Medicaid Exclusion File and other data points—and excluded from rebate invoices submitted to manufacturers.

There are a number of issues that make it challenging to operationalize HRSA's guidance with respect to the Medicaid Exclusion File, which BIO and other stakeholders—including the National Association of State Medicaid Directors (NAMD)—have outlined for both CMS and HRSA.[25] Among these issues is the fact that, in the context of Medicaid managed care, there is a third party between covered entities and the states (the MCO), which interrupts the flow of data regarding utilization that may permissibly be subject to Medicaid drug rebates. In addition, to the extent that a covered entity contracts with one or more retail pharmacies (aka "contract pharmacies") to dispense covered outpatient drugs to patients of the entity, it is impossible to use the Medicaid Exclusion File to exclude such utilization, as contract pharmacies usually bill both 340B and non-340B utilization using the same NPI number, meaning that 340B utilization cannot be excluded from Medicaid rebate claims on the basis of this NPI.

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[20] SSA § 1927(j)(1).
[21] ACA §§ 2501(c); (f)(2).
[22] Public Health Service Act § 340B(a)(5)(A).
[23] See id.; SSA § 1927(j).
[24] 58 Fed. Reg. 34,058 (June 23, 1993).
[25] See National Association of State Medicaid Directors, Working Paper Series – Medicaid and the 340B Program: Alignment and Modernization Opportunities (May 2015).

The prevention of duplicate discounts is particularly challenging with respect to utilization by AIDS Drug Assistance Programs (ADAPs)—a type of 340B covered entity—in light of two unique 340B program policies. First, ADAPs are the only type of 340B covered entity that may access the 340B discount via a post-purchase rebate (as opposed to a point-of-sale discount or the replenishment model, described below).[26] Yet there currently is *no* federal guidance that addresses duplicate discounts where 340B post-purchase rebates—unique to ADAPs—are concerned. Second, ADAPs may use their federal funding to pay cost-sharing and premiums associated with the coverage for certain drugs on behalf of low-income HIV and AIDS patients—including those enrolled in Medicaid.[27] Because HRSA urges manufacturers to continue past practices of paying 340B rebates to ADAPs with respect to cost-sharing expenditures,[28] there exists a substantial risk that, with respect to a covered outpatient drug for a Medicaid beneficiary for which an ADAP has paid the associated cost-sharing (including even nominal cost-sharing), the state will claim a rebate from the manufacturer and the ADAP will claim a 340B rebate from the manufacturer—precisely the double dipping that the Medicaid and 340B statutes expressly prohibit.

These challenges are confounded by the fact that there currently are no uniform requirements that covered entities identify that a particular claim was (or was not) for a Medicaid patient and/or permissibly 340B, that they pass this information on to Medicaid managed care plans, or that such plans, in turn, provide these data to the states. Moreover, states do not uniformly provide claims-level data to manufacturers to enable the identification of duplicate discounts that have occurred.

BIO is therefore very supportive of CMS's initiative to emphasize managed care plans' existing obligations under section 1903(m)(2)(A)(xiii) of the Social Security Act, including requirements for managed care plans to report utilization to the state within 45 calendar days after the end of the quarterly rebate period, and to implement procedures to identify and exclude 340B utilization from these reports. However, BIO urges CMS to require the use of a single, consistent reporting format, as well as to identify a core set of variables that must be transmitted to the states, for this purpose. We also urge CMS to

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[26] 63 Fed. Reg. 35,239, 35,242 (June 29, 1998).

[27] See Clarifications Regarding Use of Ryan White HIV/AIDS Program Funds for Premium and Cost-Sharing in Medicaid, Policy Clarification Notice No. 13-06.

[28] The HIV/AIDS Bureau (HAB) within HRSA has purported to expand the circumstances in which an ADAP may claim a 340B rebate to encompass situations in which an ADAP expends *any* amount to pay the cost-sharing associated with the coverage of a drug, even if its expenditure does *not* exceed the 340B ceiling price for the drug. See 2012 HAB ADAP Manual at 81 ("[An] ADAP may pursue rebates from manufacturers for drug costs, when they have paid for all *or any part* of the costs of the prescription including cost sharing or co-payments."). There is no basis in the 340B statute or in the statutorily prescribed PPA that serves to implement the 340B ceiling price requirement for the expansion of an ADAP's entitlement to a 340B rebate. Rather, the 340B statute and the PPA define a manufacturer's obligation as one of charging a covered entity a price for a drug that does not exceed the 340B ceiling price for a drug. 42 U.S.C. § 256b(a)(1); PPA at II(a). HRSA has issued a statement acknowledging the unlawfulness of this purported policy by merely urging manufacturers to extend 340B discounts in this context. See Letter to Whom It May Concern from Mary Wakefield, HRSA Administrator (available at: hab.hrsa.gov/manageyourgrant/adap340Bletter.pdf). Notwithstanding the unlawfulness of HAB's purported policy, confusion persist regarding a manufacturer's obligation to provide a 340B discount where an ADAP's cost-sharing expenditure does not exceed a drug's ceiling price, especially given that HAB has not withdrawn its purported policy and HRSA has not established any additional policy. Moreover, HRSA continues to "urge" manufacturers to pay 340B rebates to ADAPs consistent with HAB's purported policy. Id.

provide more detailed guidance in terms of the procedures for identifying and excluding 340B utilization. In addition, we strongly urge CMS to reiterate and reinforce the important and ongoing role of states to ensure rebates are appropriately requested and not violative of the statutory prohibition against duplicate discounts.

i. CMS Should Require Specific Reporting Formats and Data Points for Consistency.

BIO urges CMS to adopt a standardized format for the reporting of rebate utilization data by managed care plans that can be easily and directly utilized by all states and manufacturers (e.g., an electronic format rather than a PDF or image file) in order to produce operational efficiencies for Medicaid managed care plan sponsors, manufacturers, third-party claims vendors, and CMS.

With respect to pharmacy-dispensed drugs, we urge CMS to adopt the NCPDP format, as the claims reporting format to standardize, and therefore streamline, this process. NCPDP has been widely recognized as the industry standard in this area, and the NCPDP's format is routinely used for processing most pharmacy dispensing and claims adjudication in the United States.[29] Given the increasing adoption of the NCPDP format across payors, including some state Medicaid programs, there seems to be no reason for CMS not to adopt this nationally, and readily available, standardized information format for purposes of the submission of Medicaid managed care plan's pharmacy-dispensed rebate data.

In addition, BIO believes it is necessary to provide additional guidance to states and managed care plans regarding a standardized format to submit physician-administered drug rebate data. While there is no current industry standard in this area that BIO is aware of, there are coding and claims data best practices that could be applied to achieve this purpose. We therefore urge CMS to further explore ways to standardize formatting for physician-administered drug data to set a national standard, and to issue necessary and appropriate guidance to states and managed care plans with respect to all drug types. BIO would welcome the opportunity to provide ongoing feedback on the Agency's efforts in this area.

Finally, BIO urges CMS to identify certain, summary-level utilization data points that must be reported by managed care plans to states for this purpose. Unless managed care plans provide at least certain, specified data points to the states, it will be impossible for states to accurately and appropriately seek rebates on managed care utilization, or to provide manufacturers with the summary-level data sufficient to support such requests. Specifically, in order to enable states to provide consistent summary-level data to support rebate invoices across both managed care and fee-for-service utilization, we urge CMS to require managed care plans to report the summary level data points identified by CMS in proposed 42 C.F.R. § 447.511.[30] To enable states to verify

[29] For more information about NCPDP, please see: http://www.ncpdp.org/about-us/faq.
[30] See 77 Fed. Reg. 5318, 5345 (Feb. 2, 2012). These data points include: (1) The State code; (2) National Drug Code; (3) Period covered; (4) Product FDA list name; (5) Unit rebate amount; (6) Units reimbursed; (7) Rebate amount claimed; (8) Number of prescriptions; (9) Medicaid amount reimbursed; (10) Non-Medicaid amount reimbursed; (11) Total amount reimbursed.

these summary-level data, we further urge CMS to require managed care plans to provide certain additional, claims-level encounter data, as described in greater detail in section II of this letter, below.

ii. CMS Should Provide Further Detail Regarding MCO Procedures to Exclude 340B Utilization.

CMS also proposes to require that Medicaid managed care plans have in place procedures to exclude utilization data for drugs subject to discounts under the 340B Drug Discount Program from these utilization reports.[31] While we strongly support this proposal, we believe that additional guidance is needed with respect to this proposed requirement. For instance, we strongly urge CMS to implement the following two recommendations, both of which BIO has made during our previous engagement with the Agency:

- Medicaid MCOs should be directed, under their contracts with the states, to identify, using HRSA's Medicaid Exclusion File, those covered entities that "carve-in" (i.e., use 340B drugs for their Medicaid patients) and use this information—together with the 340B-specific claims-level encounter data we recommend that CMS require in section II, below—to exclude such entities' 340B utilization from the utilization data submitted to the state for purposes of collecting Medicaid drug rebates. We note that this process is complicated by the fact that, due to the "replenishment model" widely used by covered entities, 340B status is generally determined retroactively, rather than at the point-of-sale. We strongly urge CMS to work with HRSA to either ensure that there are mechanisms for managed care plans and states to identify this utilization as 340B, or to prohibit the retroactive identification of 340B claims in this manner. We further urge CMS, together with HRSA, to ensure that contract pharmacies are using the NPI of the covered entity to whose patients the pharmacy is dispensing 340B drugs (rather than the pharmacy's own NPI) to enable use of the Medicaid Exclusion File to identify and exclude 340B utilization by such pharmacies. Moreover, due to the unique duplicate discount challenges posed by utilization in the context of ADAPs, described above, we urge CMS to specify that a managed care plan, or fee-for-service Medicaid program, is not entitled to a Medicaid rebate if a 340B rebate was claimed by an ADAP. CMS also should direct each Medicaid managed care entity, through their contract with the state, to report to the state each instance in which an ADAP has paid all or part of any cost-sharing associated with a covered outpatient drug for a Medicaid beneficiary, and to further prohibit states from claiming a Medicaid drug rebate from manufacturers in each such instance. To ensure that all such reporting can more readily be effectuated, CMS must work with HRSA to impose conforming requirements on ADAPs and all other covered entities under the 340B Program.

- We urge CMS to add a standard contract term requiring Medicaid MCOs to have Medicaid-specific Bank Identification Number and Processor Control Number combinations (BIN/PCNs). Many insurers currently operate both Medicaid MCOs and

[31] 80 Fed. Reg. at 31,115; 42 C.F.R. § 438.3(s)(3) (proposed).

private insurance plans using the same BIN/PCN for both types of plans. This makes BIN/PCNs an unreliable basis for determining whether a patient is a Medicaid beneficiary, as such determinations are often made post-adjudication. This information is critical for covered entities that have elected to "carve out" (i.e., use non-34B drugs for their Medicaid patients) to be able to identify those patients who should not receive 340B product. Requiring insurers to use a separate BIN and PCN for their Medicaid plans would remedy this problem. We further urge CMS to require states to provide access to a list of all Medicaid managed care BINs/PCNs to the state's Medicaid providers. States should be directed to compile this information and provide it to Medicaid providers that also are covered entities in a timely manner, such as through a state website accessible to Medicaid providers.

II. BIO Supports CMS's Proposal to Require the Provision of Managed Care Encounter Data to States, But Urges the Agency to Provide Further Guidance Regarding the Data That Must Be Provided.

The ACA added provisions related to routine reporting of encounter data by managed care plans as a condition of federal matching funds.[32] Specifically, the ACA amended section 1903 of the Social Security Act to require such plans to report "patient encounter data" for contract years after January 1, 2010 to the state in a timeframe and a level of detail to be specified by the Secretary. In the Proposed Rule, CMS proposes to codify this requirement in regulations that would require plans to provide encounter data to states, certify such data, and attest to its accuracy.[33]

BIO appreciates CMS's efforts to implement this encounter data requirement that has been in place since 2010. We believe that the provision of these data by Medicaid managed care plans will assist state Medicaid agencies in overseeing Medicaid managed care programs in a number of respects. Among other issues, we believe that these data are absolutely necessary to implement the duplicate discount prohibition in the context of Medicaid managed care utilization. Moreover, further CMS guidance in this area is clearly necessary, given the OIG's recent findings that not all states report Medicaid managed care encounter data as required, in some cases because states "were unable to collect required encounter data from managed care entities."[34] We believe, however, that additional guidance is necessary to ensure that encounter data reported by managed care plans is sufficient to facilitate this activity.

Specifically, while we appreciate CMS's interest in maintaining flexibility to adapt to payment changes over time, we believe that CMS should articulate data elements that must be reported by plans with respect to both pharmacy-dispensed and physician-administered drugs in order to facilitate implementation of the duplicate discount prohibition, rather than waiting to do so in future guidance.

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[32] ACA §§ 6402(c)(3); 6504(b)(1).
[33] 42 C.F.R. §§ 438.604(a); 606(a)-(b) (proposed).
[34] OIG, Not All States Reported Medicaid Managed Care Encounter Data as Required, OEI-07-13-00120 (July 2015).

For purposes of pharmacy-dispensed medications, we urge CMS to require managed care plans to report to the states the claims-level detail data elements shared with the Agency and HRSA's Office of Pharmacy Affairs in June 2014 by the 340B Pharmaceutical Company Operational Work Group, which are based on NCPDP claims elements, and are included as an attachment to this letter. These data elements would enable the identification of both Medicaid patients and 340B utilization—both of which are necessary to prevent and identify duplicate discounts. In particular, we strongly urge CMS to require use of NCPCP 340B submission clarification code, value of 20 for real-time claims submissions.[35]

For purposes of physician-administered drugs, we recommend that CMS require use of a "UD"-modifier—together with the Healthcare Common Procedure Coding System (HCPCS) code and NDC—to identify 340B products on all claims for physician-administered 340B-purchased drugs. Notably, without the inclusion of this modifier, it is impossible to identify which uses of physician-administered drugs are subject to the 340B discount and are thus barred from being subject to Medicaid rebates.

Finally, with respect to both pharmacy-dispensed and physician-administered drugs, such data also should be sufficient to be able to identify if an ADAP has paid any cost-sharing associated with a covered outpatient drug for a Medicaid beneficiary and if the state has claimed a Medicaid drug rebate from the manufacturer with respect to the drug. Without such data, there is no way to even begin to ensure that there are no duplicate discounts where ADAPs are concerned.

BIO further believes that this proposal could be strengthened if CMS were to require states to provide these claims-level encounter data, in turn, to manufacturers—or at least make this information readily available to manufacturers through state databases. Without these claims-level data, manufacturers cannot verify compliance with the duplicate discount prohibition because there is no other way of truly verifying whether there has been a duplicate discount in the absence of these data. The only other options are inefficient means of guessing whether a duplicate discount may be present, which wastes the resources of manufacturers, covered entities, and the Medicaid system. For instance, manufacturer audits of individual covered entity purchases are ineffective in tracing and identifying 340B-purchased products in the summary format of state Medicaid rebate claims invoices to manufacturers. As the OIG noted in its 2014 MDRP report, owing to the states' failure to provide standardized claims-level data to manufacturers, state and manufacturer efforts to resolve disputes over Medicaid drug rebates—including with respect to potential duplicate discounts—are delayed.[36] We

[35] Where 340B eligibility is determined post-adjudication, and the real-time submission clarification code cannot be applied, providers should be required to submit to Medicaid managed care plans an Information Reporting (340B-N1) subsequent to service to essentially attach the 340B Submission Clarification Code (20) to the paid claim after the fact. Under this scenario, the provider will submit two transactions to the plan at different times: (1) at the point of service, in the regular course of business, a transaction is submitted with no section 340B information; (2) at a subsequent time, a 340B-N1 is submitted with the 340B clarification code included. This information should be provided, in turn, to the states for purposes of excluding such utilization from rebate invoices.

[36] This is supported by NAMD's report as well, which notes that "remedying disputes is time and resource consuming for the state Medicaid agency. Specifically, it is typical for the CE to require claims-level detail from the Medicaid agency in order for the CE to resolve the dispute and determine possible repayment."

therefore urge CMS to adopt the OIG's recommendations to provide such data—including a core set of variables that are provided in the same standardized format by each state—to manufacturers, upon request.[37]

III. CMS Should Propose Additional Requirements to Ensure that Crossover Claims Adequately Prevent Duplicate Discounts.

CMS proposes a new contract provision for managed care contracts that cover Medicare-Medicaid dually eligible enrollees and delegate the state's responsibility for coordination of benefits to the health plan. Specifically, in states that use the automated crossover process for fee-for-service claims, the contract would need to provide that the plan sign a "Coordination of Benefits Agreement" and participate in the automated crossover process administered by Medicare.[38] While we support this proposal, we strongly urge CMS to include additional requirements to ensure compliance with the statutory duplicate discount prohibition.

To implement the Deficit Reduction Act of 2005 (DRA) requirements,[39] claims for many physician-administered drugs are required to include NDCs.[40] Medicare providers billing for dual-eligible beneficiaries also are required to enter the NDC and the drug quantity on claims for physician-administered drugs.[41] These claims are then submitted to Medicare contractors, which transfer the NDC information to Medicaid for the billing of Medicaid rebates (referred to as a "crossover claim").

By including the NDC information on crossover claims, states can identify manufacturers to bill for Medicaid rebates, where applicable, even if Medicaid paid only a small portion of the claim. Because 340B covered entities submit claims for physician-administered drugs furnished to duals directly to Medicare (and the claim is automatically crossed over to Medicaid by CMS), the entity may not think of dual patients as "Medicaid patients"—yet the state is seeking Medicaid rebates on this utilization. If the hospital "carves out" (i.e., elects not to use 340B product for Medicaid patients and thus does not appear in HRSA's Exclusion File), it may inadvertently use 340B product on these patients, resulting in duplicate discounts. If the hospital "carves in," on the other hand (i.e., elects to use 340B product for Medicaid patients), it may fail to include the appropriate identifiers on the claim form (e.g., "UD" modifier, Medicaid provider number), also resulting in duplicate discounts.[42]

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[37] The OIG specifically recommended that CMS work with states and manufacturers to: (1) identify a core set of variables that states could transmit to manufacturers; and (2) develop a standardized format for these core set of variables. OIG, Medicaid Drug Rebate Dispute Resolution Could be Improved, OEI-05-11-00580 at 15 (Aug. 2014).
[38] 80 Fed. Reg. at 31,116; 42 C.F.R. § 438.3(t).
[39] SSA § 1927(a)(7) (requiring states to collect Medicaid drug rebates from manufacturers for physician-administered drugs as a condition of federal matching funds).
[40] SSA § 1927(a)(7)(C).
[41] CMS, Medicare Claims Processing Manual, Pub. No. 100-04, Transmittal 1401.
[42] The impact of these duplicate discounts is not insubstantial. A Berkeley Research Group (BRG) analysis of Medicare fee-for-service claims data from 2010-2013 identified an estimated $1.56 billion in Medicare Part B payments incurred by dual eligibles for covered outpatient drugs. Extrapolating this to the MA population identifies an additional $0.39 billion in payments. These Part B payments translate to an estimated $1.14 billion in potential duplicate discounts overpaid by manufacturers, if all of the dual eligible payments resulted in a duplicate discount. Berkeley Research Group, Dual Eligible Duplicate Discounts: Estimate of Potential

While covered entities should be able to identify dual-eligibles (since the 20 percent Medicare Part B coinsurance cannot be billed to the beneficiary), it is unclear whether existing data systems can make this cross-reference for 340B purposes. To the extent the covered entity's Medicaid provider number is not included on the Medicare claim form (and then included on the crossover claim), the state Medicaid agency would have to cross-walk the Medicare number to the Medicaid provider number, and then to the Exclusion File in order to avoid submitting a rebate for that drug—a process that states may not be doing or may not be able to do if the data systems are not set up to perform this function. Moreover, the rising enrollment of duals in Medicaid managed care exacerbates these concerns.

We agree with CMS that, requiring Medicaid managed care plans to participate in the cross-over process may reduce the administrative burden for providers, who would otherwise have to file multiple claims. Accordingly, we support this requirement in order to encourage providers to serve this vulnerable population. However, to reduce the risk of duplicate discounts in these instances, BIO urges CMS to require that Medicaid managed care plans ensure that the Medicaid provider number (e.g., NPI) of those Medicaid providers that "carve-in" is included on all Medicare claims for duals to facilitate the use of the Exclusion File in this instance. Moreover, CMS should require these plans to ensure the inclusion of 340B identifiers, in particular the "UD" modifier, to identify 340B-purchased physician-administered drugs, not only on Medicaid claims, as noted in section II, above, but also on Medicare claims for dual eligibles. CMS also should make sure that these data points end up on the crossover claims sent to state Medicaid agencies.

IV. BIO Supports CMS's Efforts to Ensure Greater Alignment Between the Medicaid MCO Program and Other Health Coverage Programs.

Throughout the Proposed Rule, CMS notes the Agency's intent to align Medicaid MCO standards with those applicable to Medicare Advantage (MA) organizations and private health insurance issuers in order to reduce confusion and limit inefficiencies for plans that operate in both the public and private markets, as well as to enhance beneficiary protections.[43] BIO supports this approach and agrees that CMS should adopt standards that are already working in other programs, to the extent that they afford equivalent or better patient protections to those already available to enrollees of Medicaid managed care plans. Specifically, BIO supports:

- CMS's proposal to permit Medicaid managed care plans to require only one level of internal appeal, after which an enrollee would be able to request a state fair hearing

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Exposure (2013). We note that these estimates are conservative in that BRG only considered drugs with a J-code and only when paid separately (i.e., not as a bundled payment) with a bill code of 131. There are quite likely duplicate discounts in the dual eligible population that are attributable to drugs reimbursed as part of a bundled payment, but we do not consider these drugs to be "covered outpatient drugs" per the limiting definition at 1927(k)(3) of the Social Security Act.

[43] 80 Fed. Reg. at 31,101.

(SFH) upon receiving notice from the managed care plan upholding an adverse benefit determination.[44]

- CMS's proposal, as part of this change, to remove the standard for the enrollee's written consent for the provider to file an appeal on an enrollee's behalf,[45] and agree with the Agency that there should not be a filing deadline for grievances.[46]

- CMS's proposal to set the timeframe for an enrollee or provider to file an appeal to within 60 calendar days of receipt of the notice of an adverse benefit determination.[47] BIO supports this proposal in the sense that it eliminates the possibility that states would impose filing deadlines as short as 20 days, and aligns with standards already applicable to MA organizations,[48] private insurance issuers,[49] and group health plan sponsors.[50] *Nonetheless, we urge CMS to ensure that Medicaid managed care plans are clearly indicating to beneficiaries the need to file an appeal with this new, potentially shorter timeframe.*

- CMS's proposal to shorten the timeframe for decisions on appeals from 45 to 30 days, which, as CMS notes, aligns with the standards currently applicable in the MA program.[51] *We urge the Agency to consider, however, establishing a shorter appeals timeline with respect to prescription drug appeals. At a minimum, we urge CMS to consider aligning the applicable timeframe with the Medicare Part D program timeframe, under which plans must render a decision within seven days.*[52]

- CMS's proposal to clarify the timeframe for rendering decisions on expedited appeals from 3 days to 72 hours.[53] *However, as with appeals generally, we urge CMS to adopt 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, as well as the 24-hour timeframe for prior authorization of drugs applicable under section 1927 of the Social Security Act (which CMS proposes to expressly apply to Medicaid managed care plans in the Proposed Rule).*[54]

- CMS's proposal to strengthen the notification requirements following the extension of the timeframe for the resolution of a grievance or appeal, when the extension was not requested by the enrollee (i.e., when the MCO requests an extension and is able to demonstrate to the state agency that additional information is necessary and the

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[44] 80 Fed. Reg. at 31,104; 42 C.F.R. § 438.402(b) (proposed) ("Each MCO, PIHP, and PAHP may have only one level of appeal for enrollees."); 42 C.F.R. § 438.402(c)(i) (proposed) ("An enrollee may request a State fair hearing after receiving notice under § 438.408 that the adverse benefit determination is upheld.").
[45] Id. at 31,104; 42 C.F.R. § 438.402(c)(1)(ii) (proposed).
[46] Id. at 31,104; 42 C.F.R. § 438.402(c)(2) (proposed).
[47] 42 C.F.R. § 438.402(c)(2) (proposed).
[48] 42 C.F.R. § 422.582.
[49] 45 C.F.R. § 147.136(b)(2)-(b)(3).
[50] 29 C.F.R. § 2560.503-1(h)(2).
[51] 42 C.F.R. § 422.564(e).
[52] 42 C.F.R. § 423.590(a)(1).
[53] 80 Fed. Reg. at 31,105; 42 C.F.R. § 438.408(b)(2)-(3) (proposed).
[54] 45 C.F.R. § 156.122(c)(1).

extension is in the interest of the enrollee), including to require the plan to provide "prompt oral notice of the delay."[55] *BIO supports these additional notification requirements, but urges CMS to articulate clear guidance in terms of the requirements that a managed care plan must meet to establish that such a delay is in the best interest of the beneficiary in question.*

- CMS's proposal to make a related change that would require an enrollee to exhaust the managed care plan's appeal process prior to requesting a SFH.[56]

- CMS's proposal to revise the timeframe enrollees have to request a SFH.

- CMS's proposal to require an MCO to effectuate a reversal of an adverse benefit determination within 72 hours.[57]

V. BIO Supports the Proposed Principles for Setting Actuarially Sound Capitation Rates for Medicaid Managed Care Programs and Urges CMS to Ensure that Capitated Rates Sufficiently Anticipate the Value of New, Innovative Therapies.

BIO supports the three principles underlying CMS's proposed approach to actuarially sound capitated rates. First, we agree that capitation rates should be sufficient and appropriate for the anticipated service utilization of the populations and services covered under each Medicaid managed care contract.[58] CMS notes that, built into this principle is the concept that an actuarially sound rate should result in appropriate payments for both the state and the federal government, while promoting program goals, where feasible, such as quality of care, improved health, community integration of enrollees, and cost containment—aims that BIO supports. Second, we agree that an actuarial rate certification underlying the capitation rates should provide sufficient detail, documentation, and transparency of the rate setting components in order to enable another actuary to assess the reasonableness of the methodology and the assumptions supporting the development of the final capitation rate. Third, we support that a transparent and uniformly applied rate review and approval process based on actuarial practices should ensure that both the state and the federal government act effectively as fiscal stewards and in the interests of beneficiary access to care.

Based on these principles of actuarial soundness, in the Proposed Rule, CMS outlines six proposed steps for rate setting for MCO capitated payments, which include, among other things: (1) the collection or development of base data from historical experience; and (2) the development and application of appropriate and reasonable trends to project benefit costs in the rating period, including trends in utilization and prices of benefits.[59] CMS notes that these steps are proposed to ensure more transparency and uniformity in rate setting, and to ensure that rates are high enough to ensure beneficiary access to care. However, it is not clear that this rate setting strategy,

[55] 80 Fed. Reg. at 31,106; 42 C.F.R. § 438.408(c)(2) (proposed).
[56] 42 C.F.R. § 438.408(f)(1) (proposed).
[57] 80 Fed. Reg. at 31,106; 42 C.F.R. § 438.424 (proposed).
[58] Id. at 31,119.
[59] Id. at 31,121; 42 C.F.R. § 438.5(b) (proposed).

in particular the proposed process for trend development, will adequately account for costs, such as the costs of new, innovative therapies not included in the baseline.

Specifically, in terms of the development of trends for purposes of projecting benefit costs, CMS requires only that such trends must be reasonable and developed in accordance with generally accepted actuarial principles and practices, based on actual experience from same or similar populations.[60] We believe that further guidance is necessary here. In particular, consistent with CMS's proposed principle that "capitation rates should be sufficient and appropriate for the anticipated service utilization of the populations and services covered under each Medicaid MCO contract," we urge the Agency to require states to ensure that the anticipated cost of new, innovative therapies is incorporated into the trend data used for rate-setting purposes.

We similarly urge CMS to specify in proposed section 438.5(f) that adjustments may permissibly be made in order to reflect not only "appropriate programmatic changes, the health status of the enrolled population, [and] non-benefit costs," but also developments in the area of medical innovation, including the availability of new medical technologies and therapies. One possibility to account for the use of new, innovative technologies that become available between rate updates would be to provide appropriate adjustments and/or other payments to account for the full cost of such technologies. CMS should consider using existing, national mechanisms to help states identify such technologies, such as the annual Healthcare Common Procedure Coding System (HCPCS) application process, Medicare's Hospital Outpatient Prospective Payment System (OPPS) applications for transitional pass-through payments,[61] or Medicare's Inpatient Prospective Payment System (IPPS) new technology add-on payment (NTAP) applications.[62] Moreover, CMS must ensure states, in providing such adjustments, do not restrict access to lifesaving, innovative therapies for Medicaid enrollees and that all standards outlined in the Proposed Rule and otherwise applicable to Medicaid-covered drugs are applied.

VI. BIO Supports CMS's Efforts to Promote Innovative Payment Models, While Ensuring Beneficiary Protections, and Urges the Agency to Ensure that Any Such Payment Initiatives Are Not Used to Undermine the Delivery of Appropriate Care to Beneficiaries.

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[60] Id. at 31,122; 42 C.F.R. § 438.5(d) (proposed).

[61] Pass-through status is provided for certain "new" drugs, devices and biological agents that were not being paid for as a hospital outpatient department service as of December 31, 1996, and whose cost is "not insignificant" in relation to the OPPS payment for the procedures or services associated with the new drug, device, or biological. SSA § 1833(t)(6).

[62] New technology add-on payment (NTAP) status is provided for products that: (1) represent "an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries"; (2) are "new"; and (3) for which the current MS-DRG rate is inadequate. 42 C.F.R. § 412.87. We note that, while we are generally supportive of the criteria used to identify drugs for NTAP payments, CMS has been applying these criteria in an overly restrictive manner in recent IPPS rulemaking cycles. We also strongly believe that the amount of NTAP payments—current set at the lesser of: (1) 50 percent of the estimated cost of the new technology; or (2) 50 percent of the difference between the cost of the case and the standard MS-DRG payment—are insufficient to cover the costs of new technologies. That said, the Medicaid managed care program lacks a payment mechanism for new technologies entirely, and the NTAP model could provide a good starting point for purposes of establishing one.

CMS makes several proposals related to the existing special contract provisions in order to reflect recent developments in the area of innovative payment and contracting. According to CMS, these changes are aimed at providing states and plans with flexibility in this area, while extending certain beneficiary protections. BIO supports CMS's efforts to recognize the increasing role of innovative payment models in driving the provision of high-quality, efficient care, and underscores the importance of CMS's efforts to ensure that such models do not undermine the delivery of quality, individualized care to Medicaid managed care enrollees.

For instance, in the Proposed Rule, CMS proposes a new standard for incentive arrangements with managed care plans—specifically that these arrangements would be required to be designed to support program incentives tied to meaningful quality goals and performance measure outcomes.[63] We agree that this change is important to ensure that incentive payments actually "support delivery system reform initiatives that include incentive arrangements for quality goals and outcomes."[64]

CMS also proposes to formalize the Agency's "longstanding policy on the extent to which a state may direct the MCO's, PIHP's or PAHP's expenditures under a risk contract." CMS also clarifies in the preamble to the Proposed Rule that the proposed regulations are "not a barrier to the operation of programs that promote wellness among beneficiaries by Medicaid managed care plans."[65]

BIO generally supports CMS's proposed approach, primarily because it affords flexibility for both states and managed care plans to "promote paying for quality or health outcomes rather than the volume of services," which we believe is important to enable the adoption of new and evolving innovative payment models by both entities.[66] We also agree that the proposal to allow states to set minimum reimbursement standards and/or raise provider rates is "critical to ensuring timely access to high-quality, integrated care."[67] We believe, however, that CMS should take this opportunity to link requirements related to provider payment with the proposed network adequacy standards articulated elsewhere in the Proposed Rule. Specifically, we urge CMS to establish a definition or threshold that would trigger the obligation for states to intervene and require plans to pay specific practitioners more to the extent that the number and types of participating providers at the lower rate are insufficient to ensure patient access to appropriate care.

In addition, BIO strongly supports that CMS is proposing to adopt a degree of federal oversight over these arrangements, which we believe is necessary to ensure that these novel payment arrangements are not used as a mechanism to reduce access to needed care. For example, CMS has articulated its expectation that, as part of the federal approval process, states will demonstrate that these arrangements "are based on utilization and the delivery of high-quality services."[68] CMS's review also will "ensure

[63] 80 Fed. Reg. at 42 C.F.R. § 438.6(b)(2) (proposed).
[64] Id. at 31,123.
[65] Id. at 31,125.
[66] Id. at 31,124.
[67] Id. at 31,124.
[68] Id. at 31,124; 42 C.F.R. § 438.6(c)(2)(i)(A) (proposed).

that state directed expenditures support the delivery of covered services."[69] As CMS notes, the "ultimate goal" of these state-directed expenditures should be "to support improved population health and better care at lower cost," not to limit beneficiary access to care. Accordingly, we further support CMS's proposal that approval of the arrangement be linked to supporting at least one of the objectives in the state's comprehensive quality strategy,[70] and that CMS's approval of these reforms will not be automatically renewed, but rather subject to ongoing evaluation, presumably based on the evaluation plan to be required under the proposed new rules.[71]

Relatedly, CMS proposes that any contract arrangement that directs expenditures made by the managed care plan for delivery system or provider payment initiatives would be required to use a common set of performance measures across all payers and providers.[72] According to CMS, "[h]aving a set of common performance measures would be critical to evaluate the degree to which multi-payer efforts achieve the stated goal of collaboration." We agree that having common performance measures would be helpful for purposes not only of evaluation, but so that providers and plans are aware of the standards against which they will be evaluated. However, we strongly urge CMS to provide further guidance as to these performance measures, which should be developed with robust stakeholder feedback and through a public comment process. Among other things, we strongly urge CMS to ensure that any quality measures used in this context meaningfully evaluate whether a particular enrollee is receiving the most appropriate course of treatment, and serve as a bulwark against the perverse incentives that can be brought about by a solitary focus on cost-containment (i.e., under-utilization of appropriate and medically necessary care). In addition, we urge CMS to develop robust means of risk-adjustment with respect to these measures, and ensure that provider and plan performance on these measures is benchmarked to true peers, in order to ensure that Medicaid providers and plans are not dissuaded from furnishing care to the sickest, most vulnerable patients for fear of lowering their level of performance.

Finally, CMS also proposes to implement specific standards with respect to withhold arrangements—a specific type of incentive payment. Specifically, CMS would define "withhold arrangements" as "a payment mechanism under which a portion of the capitated rate is paid after the MCO, PIHP, or PAHP meets targets specified in the contract."[73] CMS's current regulations are notably silent on this increasingly popular payment mechanism and CMS therefore proposes to add standards governing such arrangements. Specifically, CMS proposes that the capitation rate under the contract with the managed care plan—minus any portion of the withhold that is not reasonably achievable—must be certified as actuarially sound.[74] BIO agrees with CMS's concern that an excessively large withhold could inappropriately reduce the amount received by a plan on a prepaid basis to the extent that the amount is insufficient to cover expected benefit costs, which would result in rates that are not actuarially sound, and supports CMS's

[69] Id. at 31,124.
[70] Id. at 31,124; 42 C.F.R. § 438.6(c)(1)(i)(C) (proposed).
[71] Id. at 31,125; 42 C.F.R. §§ 438.6(c)(2)(i)(D); (F) (proposed).
[72] Id. at 31,125; 42 C.F.R. § 438.6(c)(2)(ii) (proposed).
[73] Id. at 31,122; 42 C.F.R. § 438.6(c)(1)(v) (proposed).
[74] Id. at 31,123; 42 C.F.R. § 438.6(b)(3) (proposed).

efforts to ensure that payment incentives, including withhold payments, are not used to undermine the delivery of appropriate care to beneficiaries.

As to this last point, we urge CMS to take into consideration the challenges of ensuring patient access to care in the context of certain innovative payment models, including bundled payment methodologies. Specifically, bundled payments generally are established based on historical data, an approach that is inherently incapable of capturing the benefits and costs of new medical technologies, including innovative therapies. Failing to allow for new technologies in the bundle development or implementation process may limit patients' access to the evolving standard of care. CMS should work with states to develop a transparent and predictable process for incorporating innovative medical technologies into any bundles used in the Medicaid managed care context and, once any such bundles are implemented, establish robust mechanisms for updating the bundle to reflect improvements in the standard of care. One possibility to provide for the use of new, innovative technologies that become available between bundle updates would be to carve these technologies out of bundled payment mechanisms. Technologies eligible for such carve-outs could be identified using criteria such as those eligible for OPPS transitional pass-through payments, or the IPPS NTAPs. CMS and the states would then need to ensure that managed care plans receive a separate, additional payment for the use of these new technologies and that such payments, in turn, are passed on to Medicaid providers, as appropriate. In the end, it is important that cost-containment not be the primary goal of any alternative payment model.

VII. BIO Supports the Proposed New Beneficiary Protections Regarding Beneficiary Enrollment, Authorization of Services, and Continuation of Benefits Outlined in the Proposed Rule.

Throughout the Proposed Rule, CMS makes clear efforts to establish new protections that BIO believes are necessary to afford beneficiary choice, as well as access to needed care. In particular, we believe that these changes are necessary to ensure that beneficiaries are able to access the treatments and therapies most appropriate to them, including while a health plan is resolving a disputed denial of services.

A. BIO Supports CMS's Proposed Beneficiary Protections with Respect to Enrollment and the New Beneficiary Support System.

With respect to beneficiary enrollment, BIO agrees with CMS that beneficiaries are best served when they affirmatively exercise their right to make a choice of delivery system or plan enrollment.[75] We further agree that beneficiaries should have the opportunity to make an informed choice and that the state should provide a seamless transition to managed care. Accordingly, we support CMS's proposal to apply a consistent standard for all managed care enrollment processes by establishing broad parameters for a state's enrollment process, which apply to both voluntary managed care and mandatory managed care.[76] Specifically, as proposed, managed care programs would be required to provide a period of at least 14 days of fee-for-service coverage,

[75] Id. at 31,133.
[76] Id. at 31,134; 42 C.F.R. § 438.54 (proposed).

during which time an enrollee would be able to make an active choice of his or her managed care plan.[77] We agree with CMS that this period is important, particularly given that Medicaid managed care enrollees may be "locked in" to their selected health plan for up to one year and, contrary to the standard articulated in the Proposed Rule, urge CMS to apply this same standard to managed care plans offered through CHIP. We further support the proposed requirement that states be required to advise beneficiaries of the managed care plan they will be enrolled in through the default or passive enrollment process to the extent that they do not make an active choice of plan during this 14-day period.

As CMS notes, access to comparative information is critical to the ability of beneficiaries to make an informed decision in the plan-selection process. Accordingly, we support CMS's proposal that all beneficiaries must be given the information, education, and opportunity to participate in their choice of managed care plan.[78] Specifically, we support that states would be required to develop informational notices to clearly explain to the potential enrollee the implications of not actively making the decisions available to them and allowing the passive or default enrollment take effect.[79] Relatedly, in the Proposed Rule, CMS proposes to establish a Beneficiary Support System to provide counseling to help beneficiaries make informed choices on their health plan,[80] given that "some beneficiaries may need additional assistance when evaluating their choices."[81] BIO supports this proposal, in addition to the proposed requirement that, with respect to voluntary programs, to the extent a beneficiary is passively enrolled, the state would be required to send the beneficiary a confirmation regarding the plan selection and inform the beneficiary of the option to dis-enroll from the plan within 90 days.[82]

It is BIO's longstanding position that, one of the most important aspects of the plan-selection process is ensuring that a beneficiary's current medical providers are included in the network of whichever plan is selected. Accordingly, BIO strongly supports CMS's proposed requirement that states conduct default enrollments in a manner that takes existing provider-individual relationships into consideration.[83] We further support CMS's proposal that, to the extent this approach is not possible, states would be required to equitably distribute individuals among the participating health plans based on criteria such as geographic location of the beneficiary, enrollment preferences of family members, previous plan assignment of the beneficiary, quality assurance and improvement performance, procurement evaluation elements, and other reasonable criteria that support to the goal of the Medicaid program.

B. BIO Supports the Proposed Beneficiary Protections Related to Coverage and Authorization of Services and Continuation of Benefits While the MCO Appeal and State Fair Hearing are Pending.

[77] Id. at 31.134; 42 C.F.R. §§ 438.54(c)(2) & (d)(2) (proposed).
[78] Id. at 31,135.
[79] Id. at 31,135; 42 C.F.R. §§ 438.54(c)(3) & (d)(3) (proposed).
[80] Id. at 31,136; 42 C.F.R. § 438.71 (proposed).
[81] Id. at 31.136; 42 C.F.R. § 438.71 (proposed).
[82] 42 C.F.R. § 438.54(c)(8) (proposed).
[83] 42 C.F.R. §§ 438.54(c)(6)-(7) & (d)(6)-(7) (proposed).

BIO supports CMS's proposals to modernize the Agency's regulations regarding coverage and authorization of services and the established standards to ensure that utilization management strategies used by managed care plans adequately support individuals with ongoing or chronic conditions, as well as those needing access to the benefits of community living. In particular, as proposed, each state would have to ensure that service utilization standards used by plans do not disadvantage those with ongoing chronic conditions or needing long-term services and supports (LTSS).[84] We support this proposal and agree that these services should be authorized in a manner that reflects the beneficiary's continual need for such services and supports. So, for example, a plan should not be permitted to discontinue services pending a re-authorization. Moreover, plans should not impose re-authorization requirements that are unduly burdensome in either their frequency or scope. We further support CMS's expectation that states will monitor managed care plan compliance with setting reasonable authorization periods, as well as the proposed standard for monitoring plans' utilization management.[85] BIO also supports CMS's proposals to:

- Revise the criteria for defining medically necessary services to include Early and Periodic Screening, Diagnosis and Treatment (EPSDT) services for beneficiaries under age 21.[86] *We agree that this change is necessary to ensure that state definitions of medical necessity comply with federal laws requiring the provision of important EPSDT services to this population.*

- Broaden the criteria for defining medically necessary services to refer to "[t]he prevention, diagnosis, and treatment of <u>an enrollee's disease, condition, and/or disorder that results in health impairments and/or disability</u>."[87] *BIO supports this proposal, which we believe aligns with CMS's intent to modernize its regulations to better accommodate medical management, as opposed to solely an acute-care model.*

- Require that managed care plans continue to provide benefits without interruption through the conclusion of the SFH process if the enrollee appeals the managed care plans' adverse benefit determination.[88] *We agree that this is a "critical beneficiary protection" and strongly urge CMS to adopt a similar requirement with respect to managed care plans offered in the CHIP program, contrary to CMS's current proposal.*

C. BIO Supports the Proposed Beneficiary Protections Related to Continued Services to Beneficiaries and Coordination and Continuity of Care.

First, BIO supports CMS's proposals that relate to enrollee transitions between Medicaid delivery systems. Specifically, CMS proposes to require states to establish transition of care standards for certain high-risk Medicaid beneficiaries moving to

[84] 80 Fed. Reg. at 31,138; 42 C.F.R. § 438.210(a)(4)(ii)(B) (proposed).
[85] <u>Id.</u> at 31,138; 42 C.F.R. § 438.66 (proposed).
[86] <u>Id.</u> at 31,138; 42 C.F.R. § 438.210(a)(5)(ii) (proposed).
[87] <u>Id.</u> at 31,138; 42 C.F.R. § 438.210(a)(5)(iii)(A) (proposed) (emphasis added).
[88] <u>Id.</u> at 31,139 (proposing to delete 42 C.F.R. § 438.420(c)(4)).

managed care from fee-for-service (or between two Medicaid managed care plans), which would be a required standard in state contracts with Medicaid managed care entities.[89] Among other things, this requirement would permit an enrollee to continue to receive services they are currently receiving from their current provider—including prescription drugs, if covered under the contract—for a specified period. Additional transition policies would include: referring the enrollee to an appropriate participating provider; assuring that the state or MCO comply with requests for historical utilization data; and assuring that the enrollee's new provider is able to obtain appropriate medical records. We believe that each of these policies is critically important to ensure continuity of care for enrollees that are undergoing a transition in coverage.

However, we urge the Agency to consider adding greater specificity to these transition-of-care requirements for beneficiaries who move between managed care plans and from fee-for-service to managed care coverage. At a minimum, we ask CMS to consider aligning such requirements with those in the Medicare Part D program with respect to transition supplies of prescription drugs. Specifically, within the first 90 days of coverage under a new plan, Part D plans must provide a temporary fill of a non-formulary drug (or a drug on formulary, but that requires prior authorization or step therapy) when requested by a beneficiary. The fill must be for at least 30 days in the outpatient setting, and at least 90 days in the long-term care setting.[90] CMS should consider requiring states to include at least these transition-fill standards in their contracts with Medicaid managed care plans.

We also urge CMS to expand applicability of this requirement apply to all beneficiaries transitioning between FFS and managed care (and between managed care plans), rather than merely to situations in which "an enrollee without continued services would experience serious detriment to their health or put them at risk of hospitalization or institutionalization."[91] We believe that all individuals undergoing a transition in coverage would benefit from appropriate transition-of-care policies, even if the absence of such policies would not result in a "serious detriment to their health or put them at risk of hospitalization or institutionalization" in every instance. To illustrate, it is especially important for serious mental illness patients that their transition to different providers occurs at the appropriate time, although such patients would not always qualify for transition-of-care assistance under the burdensome standard that CMS has proposed.

Second, in several places in the proposed rule, including in this section, CMS removes explicit references to "primary care."[92] We believe that these changes explicitly require transition coverage for specialists, in addition to primary care providers, and urge CMS to clarify the Agency's intent with regard to the deletion of "primary care."

Finally, CMS proposes standards related to care coordination activities. Specifically, CMS proposes to make changes to the care coordination activity requirements to align with requirements applicable to plans offered through Medicare

[89] Id. at 31,139; 42 C.F.R. § 438.62(b) (proposed).
[90] 42 C.F.R. § 423.120(b)(3).
[91] 80 Fed. Reg. at 31,139.
[92] Id. at 31,140.

Advantage and the Exchanges, which "seek to ensure that the needs of enrollees are assessed, and that care is coordinated across settings and with services delivered inside and outside the health plans."[93] BIO supports this approach. We also support CMS's proposal to require Medicaid managed care entities to conduct a primary health assessment within 90 days of an enrollees' effective date of enrollment.[94]

VIII. BIO urges CMS to highlight the need for state-level enforcement of the important patient protections available to Medicaid managed care plan enrollees, including those added by the Proposed Rule.

As discussed throughout this letter, BIO supports many of CMS's proposals to enhance Medicaid managed care beneficiary protections throughout the Proposed Rule, including changes to the grievance and appeals process, prior authorization process for covered outpatient drugs, coordination and continuity of care, network adequacy and provider and medication formulary listings. We believe these types of protections can help prevent discriminatory practices such as adverse tiering and exclusionary formularies that have been reported in other public programs and that can have significant implications on health outcomes and adherence.[95]

However, we note that the success of these patient-centered improvements will likely depend on the ability of states and CMS to monitor and enforce these protections. Implementation of key Medicaid reforms included in the Affordable Care Act have presented numerous challenges to states, as outlined in a recent GAO report published in 2012. According to the report, CMS has issued regulations and guidance on a range of topics regarding Medicaid expansion; however, several implementation gaps exist, particularly related to new technical and operational requirements pursuant to the ACA.[96] Similarly, implementation of these proposed regulations will likely require clarifying guidance to ensure that states are prepared to enforce the new regulations in a consistent manner. We therefore request that CMS continue to provide states with the necessary resources, rules, and guidance to enable them to implement and enforce new patient protections effectively. Appropriate oversight and enforcement of these enrollee protections is a vital role for states, with the federal government as a backstop to ensure that states are following through. Concerted and cooperative efforts on the part of CMS and the states will be critical to supporting CMS's efforts to modernize the Medicaid program.

IX. CMS Should Take Additional Steps to Advance Electronic Health Information Exchange.

In the Proposed Rule, CMS encourages states, managed care plans, and other stakeholders to use health information exchange and certified health information technology to effectively and efficiently help providers to improve care delivery practices,

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[93] Id. at 31,140; 42 C.F.R. § 438.208(b)(2) (proposed).
[94] Id. at 31,140; 42 C.F.R. § 438.208(b)(3); (5) (proposed).
[95] Douglas B. Jacobs & Benjamin D. Sommers, Using Drugs to Discriminate — Adverse Selection in the Insurance Marketplace, N. Engl. J. Med. 372;5 (January 29, 2015).
[96] United States Government Accountability Office; Medicaid Expansion, States' Implementation of the Patient Protection and Affordable Care Act, GAO-12-821 (August 2012).

support management of care across the continuum, enable electronic quality reporting, improve efficiencies, and reduce unnecessary costs.[97] BIO supports this general statement, but urges CMS to do more to advance electronic health information exchange.

The growth of the information captured in, and the number of providers utilizing, electronic health records (EHRs) has created a unique opportunity to better characterize outcomes associated with a specific medical intervention or therapy in a given patient population. In the context of drugs and biologics specifically, EHRs present significant promise in linking specific clinical outcomes, including adverse events, to a specific product, lot number, and manufacturer. To ensure that EHRs contain the most relevant data to improve care delivery practices, support management of care across the continuum, enable electronic quality reporting, improve efficiencies, and reduce unnecessary costs, we ask CMS to convene stakeholders to specifically discuss: what EHR standards should be in place; whether specific identifiers should be required for inclusion in all EHRs; how to encourage uptake of these identifiers in EHRs and of EHRs more generally (especially among specialists and rural providers) either through, or outside of, the existing CMS programs;[98] how to balance the need for sufficient detail within the EHR fields to be useful in drawing conclusions with the practical need to minimize reporting burdens to providers; how to aggregate this information on a product-level; and how to make the information available to interested stakeholders—including manufacturers—while protecting patient confidentiality. It will also be important to ensure that these data are interpreted holistically with the goal of better tailoring care to individual patients' circumstances and not used to limit appropriate care.

X. Modernize Regulatory Requirements

A. BIO Appreciates CMS's Focus on Network Adequacy Standards for Managed Care, Including by Establishing Standards for Availability of Services, Assurances of Adequate Capacity and Services, and Network Adequacy Standards, and Urges the Agency to Implement BIO's Recommendations to Build Upon these Protections.

BIO appreciates CMS's focus on network adequacy standards for Medicaid managed care plans in the Proposed Rule.[99] BIO is a consistent advocate that more must be done to ensure that all forms of insurance coverage provide timely, accessible and reliable access to all necessary and appropriate care.[100] Patients must be able to access

[97] 80 Fed. Reg. at 31,141.
[98] The CMS-governed Medicare and Medicaid Electronic Health Care Record (EHR) Incentive Programs provide incentive payments to eligible professionals, eligible hospitals, and critical access hospitals (CAHs) as they adopt, implement, upgrade or demonstrate meaningful use of certified EHR technology. More information on participants, incentives, and standard-setting is available at: http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index.html?redirect=/ehrincentiveprograms/.
[99] 80 Fed. Reg. at 31,271.
[100] See BIO. 2015. Comments Regarding DRAFT 2016 Letter to Issuers in the Federally-facilitated Marketplaces, available here: https://www.bio.org/advocacy/letters/bio-submits-comments-regarding-draft-2016-letter-issuers-federally-facilitated-mark; *also see* BIO. 2015. Comments Regarding Health Benefit Plan Network Access and Adequacy Model Act, available here: https://www.bio.org/advocacy/letters/bio-submits-comments-regarding-health-benefit-plan-network-access-and-adequacy-mode; *also see* BIO. 2015. Comments Regarding HHS Notice of Benefit and Payment Parameters for 2016 Proposed Rule, available at:

the providers most appropriate for them, namely, those with the expertise to provide highly-specialized care if needed, those in sufficient proximity to patients, and those who can provide essential care in a timely manner in settings where patients may already seek care. Access to appropriate providers can be influenced directly by a number of factors, including the robustness of network adequacy standards in place, and indirectly by additional factors, including, but not limited to, provider reimbursement rates.[101] Our comments in this section are limited to the former, given the scope of the provisions in the Proposed Rule. However, we urge the Agency not to ignore the latter when considering additional reforms to the program moving forward since this array of factors, taken together, are integral to ensuring meaningful coverage for all medically necessary care.

i. Provider-Specific Network Adequacy Standards

To address the issue of network adequacy in Medicaid managed care, CMS proposes to require that states develop time and distance standards for specific types of providers, namely: primary care, adult and pediatric; obstetrics and gynecology; behavioral health; specialist, adult and pediatric; hospital; pharmacy; pediatric dental; and additional provider types "when it promotes the objectives of the Medicaid program, as determined by CMS."[102] The Agency would require states to develop separate standards for LTSS that take into account the time and distance an enrollee must travel to the provider to receive services.

BIO strongly supports the identification of specific provider types for the purposes of state requirements to establish network adequacy standards. The implementation of this requirement will ensure Medicaid managed care patients have timely, meaningful access to covered healthcare services. We also support the separate identification of standards for access to pediatric services, as it reflects the clinical reality that pediatric care is a physician specialty and can require specific training and expertise. In the same vein, we urge CMS to recognize other medical specialties as in need of specific network adequacy standards in the Final Rule. We interpret that the intent of identifying specific provider specialties was to ensure that standards for timely access to the most appropriate provider are in place for enrollees of Medicaid managed care plans. However, BIO is concerned that, without identifying certain specific specialties within the proposed "specialist, adult, pediatric" category, this intent will not be achieved in practice, since a managed care plan may meet a state's network adequacy standards by including an abundance of one specialty provider type while excluding other specialty provider types

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https://www.bio.org/advocacy/letters/bio-submits-comments-regarding-hhs-notice-benefit-and-payment-parameters-2016-propo.

[101] For example, California's Medicaid program, Medi-Cal, maintains some of the lowest physician reimbursement rates in the country (the fourth lowest in the country according to one estimate, *see* Tatum, A. 2013 (July 16). Diagnosing Medi-Cal: A Deeper Look into California's Medicaid Program. *California Common Sense*, Executive Summary, p.3, available at: http://cacs.org/pdf/37.pdf), implementing a 10 percent cut to reimbursement rates in 2011. Recent studies also have found that Medi-Cal beneficiaries report higher rates of delaying needed care because of difficulty getting an appointment and more limited access to specialists than Medicaid beneficiaries in other states when controlling for healthcare needs and socioeconomic status (*see* California Healthcare Foundation. 2015. *Medi-Cal Versus Medicaid In Other States: Comparing Access to Care*, p. 18, available at: http://www.chcf.org/~/media/MEDIA%20LIBRARY%20Files/PDF/M/PDF%20MediCalAccessComparedUrban.pdf.

[102] 80 Fed. Reg. at 31,145.

entirely, or nearly entirely. Not only would this practice jeopardize patients' access to the most appropriate provider for their care, with potential ramifications for health outcomes, but this situation also can lead to discrimination against individuals with certain diseases or conditions, effectively dissuading individuals with these conditions from joining a particular plan. Thus, we ask CMS in the Final Rule to require states to establish network adequacy standards for at least the following specific types of specialty care (for adults and, where appropriate, pediatrics): gastroenterologists, hematologists, hepatologists, neurologists, oncologists, ophthalmologists, rheumatologists, pain specialists, and rare disease specialists.

Moreover, CMS also should consider the potential to include provider subspecialties on the list of providers for which states must establish specific network adequacy requirements. For example, while we urge plans' inclusion of oncologists be specifically assessed—given the importance of timely and convenient access to this type of specialist 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 ensuring patients obtain expert and individualized care. Thus, we ask the Agency to consider including the subspecialties of the five most prevalent cancers by incidence—breast, prostate, lung, colorectal, and melanoma—in the Final Rule.

ii. Metrics of Network Adequacy

While the Proposed Rule identifies "time and distance" as the metric for the proposed network adequacy standards that states must develop for certain provider types, CMS, nonetheless, requests comments on whether a different standard—using the example of provider-to-enrollee ratios—would be more appropriate. In considering this request, BIO asks CMS to allow states to use different metrics for different provider types in different geographic locations. In fact, CMS already proposes that states would be permitted to have varying standards for the same provider type based on geographic areas. The intent of allowing states to apply different network adequacy metrics based on provider type and geographic area would be to maximize the number of appropriate providers to whom patients have timely access. For example, in a metropolitan city served by a robust public transportation system (e.g., New York City), time and distance standards may be less meaningful than provider-to-enrollee ratios since wait times and the lack of providers seeing new patients may be greater barriers to patient access than physical distance from a provider's practice. Alternatively, provider-to-enrollee ratios may not be appropriate metrics for service areas that include rural or frontier geographies, since, in this case, the time it takes to traverse the distance between a patient's home and the provider's office is likely to be more limiting to patient access.

However, it is crucial to ensure that this approach maximizes, rather than minimizes, patient access. In identifying which metric will be used for specific provider types and geographic areas, CMS should require states to submit, as part of the proposed publication requirements, an explanation as to why the state's proposed metric will ensure the most timely, meaningful patient access to appropriate providers (see

comment section (v) on publication requirements, below).[103] This approach also would allow states to consider metrics other than time, distance, and provider-to-enrollee ratios that may better evaluate patient access to appropriate providers in specific circumstances.

As to whether CMS should define network adequacy metrics, as opposed to individual states, BIO recommends that CMS finalize the proposal to allow individual states this opportunity given the need to 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, we urge the Agency to establish an internal process to comprehensively review the impact of the implementation of these requirements on patient access to appropriate providers no longer than three years after the effective date of the Final Rule. This assessment will provide an opportunity for CMS, along with stakeholders, to reevaluate the need to establish national standards of network adequacy within the Medicaid managed care program to act as the minimum standards applicable in each state.

iii. Foundational Elements of State Network Adequacy Standards

BIO strongly supports the minimum criteria CMS proposes as the basis for network adequacy standards set by states. We agree that a more thorough understanding of the context of the Medicaid managed care population and available providers will improve individual states' abilities to establish standards that are relevant and meaningful to enrolled individuals. In addition to these criteria, BIO recommends that CMS also require states to consider the range of services offered by providers and facilities within the geographic areas served by Medicaid managed care plans. This is an important piece of context insofar as these standards must reflect the services available (e.g., for geographic service areas that include tertiary cancer care facilities, network adequacy standards should reflect the availability of these services). We also urge CMS, as articulated in section V of this letter, to establish standards for provider payment that support the network adequacy standards outlined in the Proposed Rule. Including these additional criteria, BIO urges CMS to finalize this proposal.

iv. Exceptions Process

In the Proposed Rule, CMS notes that states may permit exceptions to any of the provider-specific network adequacy standard it develops. We agree with the need to identify specific standards for these exceptions, but BIO is concerned that the two requirements CMS proposes are not sufficient to ensure that any such exceptions do not discriminate against patients with specific conditions or unduly limit access to appropriate providers. BIO therefore urges CMS to additionally require states to evaluate and approve exceptions based on a written strategy, provided by the plan, which identifies how the plan will promote adequate access to providers for the affected enrollees nonetheless. BIO urges CMS to include this criterion in the Final Rule so that it will provide a minimum patient protection for all Medicaid enrollees.

[103] Id. at 31,272.

CMS also proposes state oversight of the implementation of these exceptions processes. We very much agree with the need for state and Agency oversight, and ask that CMS further commit to establishing procedures to review required state reports in a timely fashion and work with states to identify and implement relevant recommendations to improve access to the provider types included under an exception, if warranted by the report findings. CMS also should work with states to ensure the monitoring processes in place are robust and able to identify access issues that can negatively impact patient care.

v. Publication of Network Adequacy Standards

CMS proposes to require states to publish the state-developed network adequacy standards online, and to provide them in alternate formats at no cost to enrollees with disabilities.[104] BIO agrees that state network adequacy should be made easily available to the public, and asks CMS to finalize this requirement. However, it is equally important that states consider public input in developing standards in compliance with the proposed requirements, and thus urge CMS to require states to establish network adequacy standards through a public notice-and-comment process. As discussed above, the list of specific providers for which network adequacy standards must be in place should be part of this notice-and-comment process, and states should consider updating all network adequacy standards required by the Proposed Rule at least every two years to capture shifts in the provider and enrollee population.

vi. Additional Triggers for Submission of Documentation

BIO supports CMS's proposal to add to the list of events that trigger the requirement that a plan resubmit documentation of compliance with network adequacy standards. We agree that the additional trigger event is an important addition because changes in the composition of a network—for example, the discontinuing of a contract with a large, academic medical center—can have a dramatic impact of patients' timely access to appropriate providers. We ask CMS to finalize this proposal, adding this event to existing triggers such as enrollment of a new population and changes in benefits, service area, or payment.

vii. Oversight of Network Adequacy Standards Implementation

The specificity and robustness of the network adequacy requirements CMS finalizes will determine whether they result in improved patient access to necessary providers, and in turn, services covered by Medicaid managed care plans; BIO's recommendations in the preceding subsections are aimed at further strengthening CMS's proposals. We believe that, in addition to these requirements, an equally robust oversight strategy must be in place to monitor compliance and quickly identify and rectify issues that may arise. CMS identifies the important role of oversight in the Proposed Rule where the Agency requests stakeholder input on measuring enrollees' timely access to covered

[104] Id. at 31,272.

services and evaluating plan coverage with the network adequacy standards set by states to fulfill the proposed requirements. We urge CMS to require states to submit, as part of the publication requirement described in proposed section 438.68(e), an oversight strategy describing the protocols and procedures they intend to have in place. At a minimum, states should be required to have criteria in place to identify potentially at-risk plans (e.g., those that serve a high percentage of vulnerable populations) and assess such plans' compliance with network adequacy standards. In particular, we urge CMS to require states to conduct and assess enrollee surveys, or utilize existing surveys, that specifically require responses related to network adequacy.

Moreover, BIO urges CMS to assess the ability of different state oversight strategies to identify potential noncompliance and facilitate the sharing of best practices between and among states. Finally, BIO urges CMS to consider requiring states to report findings of noncompliance to help the Agency identify patterns of discriminatory network design. With improved information on how the final regulations are being operationalized, and their impact on patient access to appropriate providers, CMS will be better able to determine whether modifications should be considered in the future.

B. BIO Supports CMS's Efforts to Establish Quality Assessment and Performance Improvement Programs, and Urges the Agency to Consider Certain Recommendations to Enhance These Requirements.

As basic elements of quality assessment and performance improvement programs, CMS proposes that states must ensure that Medicaid managed care plans comply with specific requirements, including to: collect and submit performance measurement data that comply with certain requirements; conduct performance improvement projects (PIPs) that comply with certain requirements; and have in effect mechanisms to detect both under- and over-utilization of services.[105] BIO supports what we believe to be the intent underlying these proposals: to strengthen the data and assessment infrastructure to improve efficient, timely access to covered services. To enhance the requirements CMS proposes, BIO urges CMS to adopt the following three recommendations.

- We encourage CMS to consider performance measures that reflect patient access to efficient, quality care in a timely fashion. The Agency also should consider the suitability of existing performance measures used by states for plans operating in other insurance markets, including the private market, to minimize reporting burdens for providers participating in Medicaid managed care plans. While the current proposal would allow CMS to establish these performance measures, reporting by plans appears to stop at the state-level. To empower the Agency to identify best practices as well as patterns of inconsistent or poor performance, CMS should require states to share these data with CMS for the purposes of broader analyses and to inform future policymaking activities.

[105] Id. at 31,150.

- In reviewing plans' PIPs, states should consider whether the quality indicators being reported are not only objective, as directed in the Proposed Rule, but also whether they reflect outcomes of clinical care that are meaningful to patients and providers. Plans should be required to utilize quality indicators that are specific to patient subgroups and provider specialties, where such indicators exist. Additionally, to contribute to the overall assessment of the objectivity of any reported quality-of-care indicators, states should require plans to use only those indicators that have been endorsed by a consensus-based process that allows public comment and employs a rigorous evaluation of the methodology support the indicator (e.g., that used by the National Quality Forum).

- CMS should require not just the detection of under- and over-utilization of care, but also require that, when identified, such issues be addressed in a manner that is consistent with accepted clinical practice. Plans should report systemic under- and over-utilization of care to states, as well as strategies to address this, as part of their annual quality assessment and performance improvement program, as required by section 438.330(e)(1). States, in turn, should exercise oversight with regard to whether the plan-identified strategies adhere to accepted standards of clinical care and mitigate the under- or over-utilization of care they were meant to address.

Additionally, BIO supports CMS's proposal to require that, as a condition of contracting with the state, a Medicaid MCO must undergo a review on the basis of performance in accordance with standards that are at least as stringent as the standards used by a private accreditation entity approved or recognized by CMS for purposes of accrediting MA plans and QHPs. We agree with the Agency that Medicaid MCOs should be held to performance standards at least as stringent as those set by private accreditation and ask CMS to finalize this proposal.

C. BIO Strongly Supports CMS's Proposal to Establish a Medicaid Managed Care Quality Rating System.

CMS proposes to establish minimum standards that all states contracting with Medicaid managed care plans would use to develop and implement a Medicaid managed care quality rating system. Specifically, CMS proposes to use the same three summary indicators currently used to frame the QHP quality rating system: clinical quality management; member experience; and plan efficiency, affordability, and management.[106] Additionally, CMS proposes to use the same performance measures identified above under section 438.330(a)(2)—on which each Medicaid managed plan must report its performance to the state as part of its quality assessment and performance improvement program—as the basis for calculating a quality rating for each plan. Each state will be required to apply a CMS-established methodology to the reported performance data to determine the quality rating for each plan. While elements of this methodology will be standardized nationally, CMS proposes to allow states to report on additional measures as part of a plan's quality rating. States also may request, and CMS may grant, authority to utilize an alternative quality rating system entirely. For Medicaid

[106] Id. at 31,152.

managed care plans serving only dual-eligible populations, CMS proposes to allow the state to utilize the MA five-star rating. No matter what quality rating system is utilized, states must aggregate the ratings for all plans and display them prominently online.

BIO strongly supports CMS's proposals to implement a standard quality rating system for Medicaid managed care plans. Quality ratings provide important information to individuals before they enroll in a plan, and thus, act as incentives for plans to improve the access to quality covered services. Evidence of the important role quality measures play in the MA program can be seen in a recent Avalere analysis: in 2015, Avalere found a significant shift in enrollment in plans with at least four (out of five) stars. In fact, the proportion of MA beneficiaries enrolled in MA plans with four or more stars reached 60 percent in 2015, up from just 38 percent in 2014.[107] However, the prominent role quality ratings can play in decisions around enrollment also conveys a substantial expectation that the ratings reflect aspects of access to care that are meaningful to patients. Affordability, for example, must be measured from the perspective of patients' out-of-pocket costs, which can have a direct impact on patient health outcomes and overall expenditures.[108] Thus, given the importance of the underlying performance measures to the robustness of the proposed quality rating system, BIO looks forward to participating in CMS's public notice-and-comment process, as proposed. BIO also recommends that CMS work with states to establish procedures by which CMS can obtain access to the performance data from states in order to assess the robustness of the quality rating system not more than two years after the effective date of the final regulations to consider whether the proposed performance measures and ratings methodology is working or should be reevaluated.

We also urge CMS, as it is developing the system to create incentives for states to develop robust subcategories under the clinical measures, to ensure that the working poor now covered under Medicaid are first, appropriately treated for any existing comorbidities to prevent permanent disability (and subsequent Medicare coverage), and for appropriate treatment of common comorbidities (such as asthma) to prevent readmissions and emergency department visits.

D. BIO Supports CMS's Proposal to Establish Comprehensive State Quality Strategy and External Quality Review (EQR) Requirements.

CMS proposes to extend the comprehensive quality strategy to all state Medicaid programs, currently in place for Medicaid managed care plans, identifies additional requirements related to network adequacy that must be addressed by the quality strategy, and requires an additional, network-adequacy-specific mandatory EQR-related activity.

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[107] Avalere. 2015. Sixty Percent of Medicare Advantage Enrollees Now in Plans with Four or More Stars, available at: http://avalere.com/expertise/managed-care/insights/sixty-percent-of-medicare-advantage-enrollees-now-in-plans-with-four-or-mor.

[108] A robust literature base supports the link between adherence and out-of-pocket (OOP) costs for patients: as cost-sharing for patients increases, adherence to medications decreases, which can result in poorer health outcomes, for example, *see* Eaddy, M. T., C. L. Cook, K. O'Day, S. P. Burch, and C. R. Cantrell. 2012. How Patient Cost-Sharing Trends Affect Adherence and Outcomes: A Literature Review. *Pharmacy & Therapeutics* 37(1):45-44.

BIO supports the proposal to extend the comprehensive quality strategy to all state Medicaid programs. We believe, if implemented, this will allow states to take a streamlined approach to improving quality for Medicaid enrollees across the board. As proposed, the comprehensive quality strategy would have to address, among other issues, state-defined Medicaid managed care network-adequacy and availability-of-services standards, as well as examples of evidence-based clinical practice guidelines the state requires its Medicaid managed care plans to adopt. While we support the inclusion of network adequacy standards as part of the comprehensive state quality strategy, BIO reiterates concerns we have expressed to CMS that a focus on adherence to clinical guidelines may not foster the best care for individual patients. This is because clinical guidelines may only address treatment options based on the most likely clinical circumstances, whereas patients suffering from complex, chronic conditions may require highly individualized care. Thus, we continue to urge CMS and states not to rely on adherence to treatment guidelines as a measure of quality care for all patients.

Additionally, in the Proposed Rule CMS notes that EQR is already a requirement for elements of the state comprehensive quality strategy. However, CMS proposes to add a fourth mandatory EQR-related activity: validate that Medicaid managed care plans' network adequacy during the preceding 12 months complies with the state standards developed in accordance with the requirements of the Proposed Rule. Moreover, CMS proposes to release a new EQR protocol identifying specific measures, of which several potential options are identified in the preamble of the Proposed Rule. BIO strongly supports this proposal and urges CMS to finalize it.

CMS also identifies criteria that would exempt a Medicaid managed care plan from the EQR requirement: the plan must have a current MA contact; the two contracts (Medicaid and MA) must cover all or part of the same geographic area within the state; and the Medicaid contract must have been in effect for at least two consecutive years before the effective date of the exemption, and as such, have been subject to two EQR evaluation periods and been found to have performed acceptably during both.[109] While BIO is sympathetic to the reporting burdens associated with the EQR, we, nonetheless, ask that CMS not allow more than two consecutive exemption periods for a plan. We make this recommendation to balance the goal of aligning requirements across MA and Medicaid managed care—a goal stated by CMS throughout the Proposed Rule, and one which BIO generally supports—and the goal of ensuring the specific healthcare needs of the Medicaid managed care population are being effectively met.

E. BIO Supports CMS's Clarification in the Program Integrity Section of the Proposed Rule that Managed Care Plans May Not Discriminate Against Certain Providers.

CMS proposes to add new provider enrollment and screening requirements.[110] In making this proposal, CMS expressly notes that these new requirements would not alter Medicaid managed care plans' responsibility under section 438.214(c) to operate a

[109] 80 Fed. Reg. at 31,282.
[110] Id. at 31,127.

provider selection process that does not discriminate against providers that serve high-risk populations or that specialize in costly treatments. BIO appreciates this express clarification restating the nondiscrimination requirement, especially in light of evidence that narrow provider networks are increasingly employed across the insurance spectrum. For example, a 2014 analysis found that coverage through the health insurance Marketplaces of the specialists needed by patients suffering from cardiovascular disease (i.e., cardiologists, neurologists, and diagnostic radiologists) can be as low as 8 percent of all such physicians in some cities.[111] Given these data, it appears that narrow networks are being used as an extension of utilization management techniques without sufficient attention to the resulting impact on patient access to necessary providers. Thus, we urge CMS to reiterate this clarification in the preamble to the Final Rule to the extent that the Agency finalizes the proposed provider enrollment and screening requirements.

XI. Conclusion

BIO appreciates the opportunity to comment on the Proposed Rule. We appreciate the efforts that CMS has made to align the beneficiary protections applicable to Medicaid managed care entities to those applicable in Medicare and the private insurance market. We also support CMS's efforts to address the expansion of Medicaid drug rebates—as well as the related duplicate discount prohibition—to Medicaid managed care utilization. We look forward to continuing to work with CMS to address these critical issues in the future, including to provide further guidance with respect to these proposed new requirements. Please feel free to contact me at (202) 449-6384 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/

Erin Estey Hertzog, J.D., M.P.H.
Director, Health Law & Policy

Attachment

[111] Avalere. 2014. Access to Comprehensive Stroke Centers & Specialty Physicians in Exchange Plans, available at: http://www.heart.org/idc/groups/public/@wcm/@adv/documents/downloadable/ucm_468318.pdf.