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VIA ELECTRONIC DELIVERY to: www.regulations.gov

February 13, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–4201–P
Baltimore, MD 21244–1850

Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications [CMS–4201–P]

Dear Administrator Brooks-LaSure:

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to comment on the Center for Medicare and Medicaid Services' (CMS's/the Agency's) Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications [CMS–4201–P] (Proposed Rule).[1]

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 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 membership includes biologics and vaccine manufacturers and developers who have worked closely with stakeholders across the spectrum, including the public health and advocacy communities, to support policies that help ensure access to innovative and life-saving medicines and vaccines for all individuals.

Our comments on specific aspects of the CY 2024 Proposed Rule are presented below. We thank the Agency for its consideration of our comments.

Medication Therapy Management (MTM) Program (§ 423.153) p. 79453
After an extensive analysis to identify potential disparities in MTM program eligibility and access, CMS is proposing changes to the MTM targeting criteria at § 423.153(d)(2) to

1 Federal Register, Vol. 87, No. 247. P. 79452, December 27, 2022

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promote consistent, equitable, and expanded access to MTM services. The combination of proposed changes includes:

(1) requiring plan sponsors to target all core chronic diseases identified by CMS, codifying the current 9 core chronic diseases in regulation, and adding HIV/AIDS for a total of 10 core chronic diseases;
(2) lowering the maximum number of covered Part D drugs a sponsor may require from 8 to 5 drugs and requiring sponsors to include all Part D maintenance drugs in their targeting criteria; and
(3) revising the methodology for calculating the cost threshold ($4,935 in 2023) to be commensurate with the average annual cost of 5 generic drugs ($1,004 in 2020).

According to CMS, the proposed changes would reduce eligibility gaps so that more Part D enrollees with complex drug regimens at increased risk of medication therapy problems would be eligible for MTM services. They would also better align MTM eligibility criteria with statutory goals to reduce medication errors and optimize therapeutic outcomes for beneficiaries with multiple chronic conditions and taking multiple Part D drugs, while maintaining a reasonable cost criterion.

In this rule, CMS also proposes to codify longstanding CMS guidance that a beneficiary is unable to accept an offer to participate in the comprehensive medication review (CMR) only when the beneficiary is cognitively impaired and cannot make decisions regarding their medical needs. CMS is also proposing other technical changes to clarify that the CMR must include an interactive consultation that is conducted in real time, regardless of whether it is done in person or via telehealth.

BIO Comment: BIO notes the documented successes of MTM in a number of situations, but recognizes room for improvement in the program. For example, among people over the age of 65, 44 percent of men and 57 percent of women take five or more medications. This heavily increases the risk of drug-drug interactions, medication misuse, and medication noncompliance. Medication errors can be harmful or even lethal, and missed doses can increase preventable patient morbidity, mortality, and healthcare expenditures.

To take one example, older patients with Alzheimer's disease (AD) are challenged with adhering to complex medication regimens. A recent study examined Comprehensive Medication Review (CMR), a required Medicare Part D Medication Therapy Management (MTM) program component, on medication adherence among AD patients. Researchers examining 100% of two years of Medicare claims covering the entire United States found the likelihood of nonadherence in the intervention group was respectively reduced by 38%, 46%, and 50% more than the comparison group for diabetes, hypertension and hyperlipidemia.[2] This provides evidence that

2 Xiaobei Dong, Chi Chun Steve Tsang, Shirong Zhao, Jamie A. Browning, Jim Y. Wan, Marie A. Chisholm-Burns, Christopher K. Finch, Jack W. Tsao, Lisa E. Hines & Junling Wang (2021) Effects of the Medicare Part D

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the MTM program can be effective for a population with unique medication adherence challenges.

The enhanced MTM program can be a counter to alarming trends towards medication underuse and overuse. According to one large Part D sponsor, two years of data show that targeted medication reviews met unmet patient needs.[3] The results indicate:

- Significant reductions in acute inpatient admissions
- Increases in medication adherence
- Reductions in emergency department visits

Thus, in many cases, MTM benefits patients directly and can decrease the burden of healthcare costs, but according to researchers at the National Board of Medication Therapy Management, results are not consistent across the board,[4] suggesting a need to increase the overall quality of MTM evaluations. In conducting a review of MTM literature, they found studies have multiple factors that explain the inconsistency of results, including study size, study quality, and consistency MTM delivery methods. Several of the studies in the review had a relatively small sample size, sometimes including less than one hundred study subjects, and some were at a single site. BIO concurs with these researchers in recommending that future studies should consider increasing study size and incorporating multiple sites to bolster the reliability of the results.[5] We believe the Agency can use its authority to influence these changes in further MTM studies.

Health Equity in Medicare Advantage (§§ 422.111 and 422.112) p. 79479

CMS says it is committed to advancing health equity for all, including those who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality.[1] CMS proposes further clarification of a current requirement for MA plans to provide culturally competent care by expanding the list of populations that MA organizations must provide services to in a culturally competent manner. This includes people: (1) with limited English proficiency or reading skills; (2) of ethnic, cultural, racial, or religious minority groups; (3) with disabilities; (4) who identify as lesbian, gay, bisexual, or other diverse sexual orientations; (5) who identify as transgender, nonbinary, and other diverse gender identities, or people who were born intersex; (6) who live in rural areas and other areas with high levels of deprivation; and (7) otherwise adversely affected by persistent poverty or inequality.

Studies demonstrate that low digital health literacy, especially among populations experiencing health disparities, continues to impede telehealth access and worsen care gaps

comprehensive medication review on medication adherence among patients with Alzheimer's disease, Current Medical Research and Opinion, 37:9, 1581-1588,

3 https://press.humana.com/news/news-details/2019/health-benefits-tailored-medication-approach/default.aspx#gsc.tab=0

4 https://www.nbmtm.org/mtm-reference/significant-research-mtm-associated-cost-savings/

5 Ibid.

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particularly among older adults. CMS proposes requiring MA organizations to develop and maintain procedures to offer digital health education to enrollees to improve access to medically necessary covered telehealth benefits. In addition, CMS proposes building on current best practices by requiring MA organizations to include providers' cultural and linguistic capabilities in provider directories. If finalized, this change would improve the quality and usability of provider directories, particularly for non-English speakers, limited English proficient individuals, and enrollees who use American Sign Language. Finally, CMS is proposing that MA organizations must address health disparities as part of existing requirements to develop and maintain quality improvement programs.

BIO Comment: BIO commends CMS for this effort to promote health equity by improving the delivery of culturally competent care. In this vein, BIO has committed itself to a detailed plan of change to promote health equity; invest in the current and next generation of scientists; and expand opportunity for underrepresented populations.[6] BIO and its member companies stand ready to assist the Agency in any such efforts to eliminate disparities and promote health equity.

Utilization Management Requirements: Clarifications of Coverage Criteria for Basic Benefits and Use of Prior Authorization, Additional Continuity of Care Requirements, and Annual Review of Utilization Management Tools (§§ 422.101, 422.112, 422.137, 422.138, and 422.202) p. 79497

CMS says it has received numerous inquiries regarding concerns about the use of prior authorization by Medicare Advantage (MA) plans and the effect on beneficiary access to care, including recommendations from the Office of the Inspector General (OIG). In the rule, CMS proposes impactful changes to address these concerns to ensure enrollees have timely access to medically necessary care.

The proposed rule proposes clarifications and revisions to the regulations governing when and how Medicare Advantage plans develop and use coverage criteria and utilization management policies to ensure that MA enrollees receive the same access to medically necessary care they would receive in Traditional Medicare. CMS proposes that in situations when no applicable Medicare statute, regulation, National Coverage Determinations (NCD), or Local Coverage Determinations (LCD) establishes when an item or service must be covered, MA organizations must include current evidence in widely used treatment guidelines or clinical literature made publicly available to CMS, enrollees, and providers when creating internal clinical coverage criteria. These and other related proposed changes, including requiring that the physician or other health care professional used by the MA plan have expertise in the field of medicine that is appropriate for the service be involved before the MA plan can deny coverage, would help ensure enrollees have consistent access to medically necessary care.

6 See: https://www.bio.org/bioequality-agenda

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The proposed rule also would streamline prior authorization requirements, including adding continuity of care requirements and reducing disruption in ongoing care for beneficiaries by requiring that when an enrollee is granted prior authorization approval it will remain valid for the full course of treatment. First, CMS proposes that prior authorization policies for coordinated care plans may only be used to confirm the presence of diagnoses or other clinical criteria and/or ensure that an item or service is medically necessary. Second, CMS proposes that plans must provide a minimum 90-day transition period when an enrollee currently undergoing treatment switches to a new MA plan. Third, to ensure prior authorization is being used appropriately, CMS proposes to require that all MA plans establish a Utilization Management Committee to review policies annually and ensure consistency with Traditional Medicare's national and local coverage decisions and guidelines.

Amid proposed changes to UM criteria, however, the Agency states, it is "not proposing to revise § 422.136, which authorizes MA plans to use step therapy policies for Part B drugs under certain circumstances…"). CMS continues, by way of background, to state, "In…2018, CMS announced that under certain conditions beginning in contract year 2019, MA plans may use utilization management tools such as step therapy for Part B drugs. In a May 2019 final rule (84 FR 23832), we codified MA organizations' ability to use step therapy for Part B drugs under certain conditions that protect beneficiaries and acknowledged that utilization management tools, such as step therapy, can provide the means for MA plans to better manage and negotiate the costs of providing Part B drugs."

> **BIO Comment:** BIO expresses its general support for the Agency's proposal to require MA plans to have a patient-centered and/or medical basis for applying UM.
>
> For many conditions, treatments must be carefully tailored to a patient's individual needs and many patients try multiple therapies before finding one that works best for them. Utilization management actions such as fail first/step therapy and prior authorization will often unnecessarily drag out this process by requiring patients to try older, less expensive treatments that may not only be ineffective but could also lead to pain and adverse side effects. Furthermore, it undermines the clinical judgement of healthcare providers and puts insurance companies in control of treatment decisions.
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> BIO believes policies that sacrifice the health of patients in the hope of cutting program costs undermine the promise Medicare represents for so many individuals. We strongly encourage the Agency to move forward with alternative solutions like those described in this Proposed Rule, to require clinically appropriate utilization management, that utilizes current evidence-based guidelines designed with the input of medical practitioners, patients, and advocates relying on published peer-reviewed evidence or and real-world evidence.
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> Further, sharing the Agency's concerns that enrollees may be facing unreasonable barriers to needed care, BIO supports the Agency's proposal to require MA sponsors to establish utilization management committees, to operate similar to a Pharmacy and Therapeutics, or P&T, committee. Additionally, we request that CMS specifically

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state that these Committees must detail how proposed plan UM policies comply with formulary coverage requirements for USP categories and classes and for the six protected class requirements. Further, committees should have specific timeframes for meetings so that proposed UM tools are approved or disapproved for a given plan year and do not delay patient treatments. Moreover, as also raised in the preamble, BIO believes the proposed UM Committees should include a specialist on the therapy being reviewed.

While we are happy to express our support for positive proposals for patients in this section, we must continue to express opposition to CMS's continued permission of step therapy for drugs in Part B. BIO maintains its opposition to plans' use of step therapy for Part B drugs, as we previously articulated to the Agency in a January 25, 2019 letter. Indeed, Part B drug step therapy continues in MA plans, even as it remains prohibited for non-drug treatments, as an arbitrary, unfounded distinction.

We continue to believe step therapy is not appropriate for patients taking Part B medicines and urge CMS to reinstate rules or guidance to prohibit this practice. In 2018, CMS noted that it believes step therapy will "better enable MA organizations to ensure that…enrollees pay less overall or per unit for Part B drugs."[7] In actuality, the savings generated from such a policy accrue only to the MA plans themselves, who bid on a benchmark of estimated costs for Part A and Part B services to provide coverage for beneficiaries. It is unclear how any savings from step therapy policies are being passed on to beneficiaries if a plan is theoretically spending less on Part B services under a step therapy policy. Moreover, requiring a non-indicated drug prior to an indicated drug for any diagnosis is inappropriate in a step edit scenario. Using a non-indicated generic over a branded drug with the labeled indication should not be permitted.

Again, while we share the Agency's goal of reducing OOP costs for patients, we do not believe step therapy for Part B drugs is an appropriately targeted solution and urge the Agency to reverse its current stance.

Behavioral Health in Medicare Advantage (MA) (§§ 422.112 and 422.116) p. 79488

CMS proposes policies to strengthen network adequacy requirements and reaffirming MA organizations' responsibilities to provide behavioral health services. Specifically, CMS proposes to: (1) add Clinical Psychologists, Licensed Clinical Social Workers, and Prescribers of Medication for Opioid Use Disorder as specialty types for which CMS sets specific minimum standards and on which CMS evaluates MA networks, and make these specialty types eligible for the existing 10 percentage point telehealth credit; (2) amend general access to services standards to explicitly include behavioral health services; (3) codify standards for appointment wait times for both primary care and behavioral health services;

7 83 Fed. Reg., No. 231, p. 62169 (November 30, 2018).

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(4) clarify that emergency medical services that must not be subject to prior authorization include behavioral health services to evaluate and stabilize an emergency medical condition; (5) require that MA organizations notify enrollees when the enrollee's behavioral health or primary care provider(s) are dropped midyear from networks; and (6) require MA organizations to establish care coordination programs, including coordination of community, social, and behavioral health services to help move towards parity between behavioral health and physical health services and advance whole-person care.

> **BIO Comment:** BIO applauds CMS for the efforts listed above to increase access to behavioral health services for MA enrollees. CDC estimates 20% of older adults in the US experience some type of mental health concern[8], making behavioral health particularly important for the Medicare population. The most common conditions include anxiety, severe cognitive impairment, and mood disorders, such as depression or bipolar disorder. In particular, depression is the most prevalent mental health problem among older adults.[9] It is associated with distress and suffering and can lead to impairments in physical, mental, and social functioning. Moreover, the presence of depressive disorders often adversely affects the course and complicates the treatment of other chronic diseases.[10]
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> Older adults with depression visit the doctor and emergency room more often, use more medication, incur higher outpatient charges, and stay longer in the hospital.[11] Although the rate of older adults with depressive symptoms tends to increase with age depression is not a normal part of growing older.[12] Rather, in 80% of cases it is a treatable condition. Unfortunately, according to CDC, depressive disorders are a widely under-recognized condition and often are untreated or undertreated among older adults.[13]
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> Taken together, these findings underscore the importance of diagnosing and treating behavioral health disorders for Medicare beneficiaries. We therefore thank the Agency for these changes designed to increase access.

Section 1876 Cost Contract Plans and Cost-Sharing for the COVID-19 Vaccine and its Administration (§ 417.454), p. 79409

In the proposed rule, CMS proposes to amend § 417.454(e)(4) of its regulations to make permanent the requirement that section 1876 cost contract plans (cost plans) cover COVID-19 vaccines and their administration with zero cost-sharing by removing the existing language limiting such coverage to the duration of the PHE, and instead referencing the Medicare fee-for-service coverage standard under section 1861(s)(10)(A) of the Act.

8 https://www.cdc.gov/aging/pdf/mental_health.pdf
9 Ibid.
10 Ibid.
11 Ibid.
12 Ibid.
13 Ibid,

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BIO Comment: BIO supports CMS's proposal to make permanent coverage of the COVID-19 vaccine and its administration by Medicare cost plans. Section 3713 of The Coronavirus Aid, Relief, and Economic Security (CARES) Act (2020) (Pub. L. 116–136) compelled such coverage for Medicare fee-for-service and Medicare Advantage. While such coverage was not similarly compelled for cost plans, BIO supports CMS's use of its authority under section 1876(i)(3)(D) of the Act to ensure more equitable access to care, and that cost is not a barrier to access COVID-19 vaccines across all Medicare populations.

BIO also encourages CMS to continue supporting and implementing payment policies that reduce immunization access barriers and drive uptake, for both COVID-19 vaccines and other recommended preventive vaccines more broadly. While CMS has made great strides in improving vaccine access in recent years, immunizations are a high-value service that remains underutilized.14 It is therefore important for CMS to continue to ensure that all Medicare beneficiaries have equitable access to recommended vaccines, especially as COVID-19 is likely to remain a public health concern for the foreseeable future.

Changes to an Approved Part D Formulary – Immediate Substitutions (§§ 423.4, 423.100, 423.104, 423.120, and 423.128) p. 79536

Current regulations permit Part D sponsors to immediately remove from the formulary a brand name drug and substitute its newly released generic equivalent. Part D sponsors meeting the requirements can provide notice of specific changes, including direct notice to affected beneficiaries, after they take place; do not need to provide a transition supply of the substituted drug; and can make these changes at any time including in advance of the plan year.

The proposed rule states CMS proposes to codify in regulation longstanding sub-regulatory guidance and terminology (such as classification of changes as either maintenance or non-maintenance) that specify when and how Part D sponsors obtain approval to make negative formulary changes and the enrollees to whom these changes would apply.

The Agency proposes to permit Part D sponsors to immediately substitute: (i) a new interchangeable biological product for its corresponding reference product; (ii) a new "unbranded biological product" for its corresponding brand name biological product; and (iii) a new authorized generic for its corresponding brand name equivalent.

BIO Comment: BIO notes that Section 351(i) of the Public Health Service Act defines an interchangeable biological product as one that "may be substituted **for**

14 *See, e.g.*, Michele Kohli et al., The potential public health and economic value of a hypothetical COVID-19 vaccine in the United States: Use of cost-effectiveness modeling to inform vaccination prioritization, 39 VACCINE 1157–1164 (Feb. 12, 2021) (finding that a two-dose vaccine course costing $84 in product and administration generates net cost savings in the over 65 population—i.e., no net expenditures for the health system for each life-year saved).

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the reference product without the intervention of the health care provider who prescribed the reference product." (emphasis added) BIO urges the Agency to align with the scope of this definition as articulated in law. Consistent with the statutory definition of interchangeability, the regulatory assessment and determination of interchangeability for a proposed interchangeable biosimilar product considers only data and information to demonstrate that the product may be substituted for the reference product, not another interchangeable product or biosimilar. As such, BIO encourages the Agency to clearly incorporate into their policies that a biosimilar judged by FDA to be interchangeable with a reference product may only be substituted for such reference product and not substituted, for example, for another biologic even if judged to be biosimilar to the same reference product.

BIO is encouraged that the Agency states in the preamble, "[w]e are not proposing to permit Part D sponsors to immediately substitute biosimilar products. Biosimilar products have not met additional requirements to support a demonstration of interchangeability based on further evaluation and testing of the product, as outlined by the Biologics Price Competition and Innovation (BPCI) Act." BIO encourages the Agency to promulgate this language, or language to this effect, to Part D sponsors in its instructions for compiling Part D formularies and in Part D enrollee literature. BIO believes that confusion still exists among stakeholders regarding the distinct concepts of physician-mediated switching of biosimilar products and pharmacy-level substitution of interchangeable products. Such language can help to clear up this confusion.

Further, achieving stability on a medicine can be challenging for patients and any change in medicine could disrupt the that achieved stability. BIO therefore believes patients should be afforded notice and sufficient opportunity to find alternative prescription drug coverage if a product prescribed to them is proposed to be substituted by a pharmacy. A retroactive direct notice requirement deprives them of this opportunity.

We believe a better approach would be to add new biologics to the formulary and allow patients to continue on the biologic of choice, as prescribed by, and in consultation with, their provider for the remainder of the plan year. Patients would then be able to choose a prescription drug plan with a formulary that covers their chosen therapy at the beginning of the next plan year. At the very least, we believe a 30-day transition fill requirement should apply, consistent with Part D formulary change rules elsewhere.

Finally, BIO notes that under the policies described in this proposed rule, upon market entry of a new, interchangeable biosimilar, a Part D plan would be permitted to place the given biologic reference product on a higher formulary tier as a negative midyear change, without CMS permission. Notwithstanding this new exception, BIO encourages the Agency to continue to promulgate to Part D sponsors and to Part D enrollees that the beneficiary protections generally forbidding negative midyear

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formulary changes, as outlined in Section 30.3.3 of Chapter 6 of the Medicare Prescription Drug Benefit Manual, remain in force.

Gross Covered Prescription Drug Costs (§ 423.308) p. 79611

The Agency states that "[c]onsistent with the language of section 1860D–15(b) of the Act, policy, including the current reporting requirements, and operations, including how the industry tracks and reports costs (that is, industry practice), we propose to amend the definition of ''gross covered prescription drug costs'' at § 423.308 to remove the two references to ''actually paid'' to clarify that GCPDC are not net of all DIR.

BIO Comment: As BIO has previously stated, CMS should ensure that the negotiation process under the Inflation Reduction Act (IRA) is predictable, transparent, and that the factors it considers focus on clinical benefit to patients. A key element of a predictable and transparent process includes ensuring that draft guidance is released as soon as possible and that companies have sufficient opportunity to comment.

To that end, we appreciate CMS's clarification in this proposed rule regarding the definition of "gross prescription drug costs." We further urge CMS to set forth all components of its proposed negotiation methodology and process and explain how its proposed approach would ensure predictable and reasonable pricing. Further, we request that CMS clarify key methodological issues as soon as possible, such as the data CMS will be using to identify the top spend drugs in Medicare and how CMS will consider different drug formulations, dosage forms, and strengths.

Conclusion

BIO Comment: BIO appreciates the opportunity to provide feedback to CMS through this NPRM for comment. We look forward to continuing to work with the Agency to ensure Medicare enrollees can access care in an efficient and timely manner. Should you have any questions, please do not hesitate to contact us at 202-962-9200.

Sincerely,

/s/
Crystal Kuntz
Vice President
Healthcare Policy & Research
Biotechnology Innovation Organization

/s/
Andy Cosgrove
Senior Director
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