Massa, Cody

From: Jack Geisser <jgeisser@bio.org>
Sent: Friday, June 3, 2022 2:12 PM
To: solicitation.questions
Cc: Ben Chandhok
Subject: SMMC RFI, AHCA RFI 014-21/22
Attachments: BIO_Medicaid MCO RFI Comments Permission to release6-30-22.FINAL.docx; BIO_Medicaid MCO RFI Comments 06_03_2022.FINAL.pdf

Importance: High

Dear Mr. Massa:

Please accept the attached copy of the Biotechnology Innovation Organization's (BIO's) comments regarding the Medicaid Managed Care Organization Request for Information **(AHCA RFI 014-21/22)**. I have also attached a letter indicating that they are suitable for release unredacted since they do not contain any confidential or proprietary information.

Thank you for the opportunity to comment.

Regards,
Jack Geisser

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BY ELECTRONIC DELIVERY

June 3, 2022

Mr. Cody Massa
Procurement Officer
Agency for Health Care Administration (AHCA)
solicitation.questions@ahca.myflorida.com

RE: Request for Information, RFI 014-21/22 Re-Procurement of the Statewide Medicaid Managed Care Program

Dear Mr. Massa:

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to comment on the AHCA's recent Request for Information regarding the Re-Procurement of the Statewide Medicaid Managed Care Program. Our comments contain no confidential or proprietary information, and therefore, we have no need to redact the document. Our letter is appropriate for release.

Thank you for the opportunity to submit comments on this Request for Information. Should you have any questions, please do not hesitate to contact me at (202) 962-9200 or at jgeisser@bio.org.

Sincerely,

/s/

Jack Geisser
Sr. Director, Healthcare Policy, Medicaid, & State Initiatives

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RE: Request for Information, RFI 014-21/22 Re-Procurement of the Statewide Medicaid Managed Care Program

Dear Mr. Massa:

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to comment on the AHCA's recent Request for Information regarding the Re-Procurement of the Statewide Medicaid Managed Care Program. Our comments will focus mostly on the integration of value-based agreements in a state's pharmacy program.

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 thirty 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 yield not only improved health outcomes, but also reduced health care expenditures due to fewer physician office visits, hospitalizations, and surgical interventions.

Value-based payment arrangements can increase patient access and quality while also reducing overall healthcare costs.

In the RFI, the Agency seeks comments on, "[u]tiliz[ing] value-based payment designs to simultaneously increase quality and reduce costs." For years, BIO and our members have expressed great interest in value-based arrangements (VBAs) under which payment for a prescription drug or biologic could vary depending on its outcome for any particular patient. We view these arrangements as an important tool that can promote patient access to innovative therapies and encouraging investment in research and development for rare and hard-to-treat diseases, while simultaneously balancing the need for payers to have avenues to spread risk and to associate payments with the value provided to any individual patient. Our industry has sought to partner with payers and health care providers to structure a variety of innovative payment arrangements that have proven valuable for patient access.

The Centers for Medicare and Medicaid Services (CMS) saw fit previously to allow state plan amendments[1] and promulgate regulations due to take effect on July 1, 2022, permitting manufacturers to negotiate voluntary value-based purchasing agreements and report multiple Best Prices. Florida could pursue its stated interest in aligning payment to value under this regulatory structure or seek voluntary agreements under a state plan amendment that ensure coverage of transformative therapies, when appropriate. A state plan amendment provides the state the maximum flexibility to negotiate agreements that are tailored to its own population.

The success of a VBP arrangement is directly tied to the selection of the "right" outcome measure(s) to use in the contract arrangement. The ease or difficulty in implementing VBP outcomes-based arrangements, generally, will be driven by the nature of the disease and treatment, including whether outcome measures can be readily identified that will be straightforward; objective; reliable to measure and interpret; easy to collect; and, ultimately, simple to operationalize. Overlaying an outcome selection in a rare disease with variable disease progression is complex and not all disease areas may be amenable to a VBP arrangement. Providing flexibility will be critical to promoting tailored use of VBP arrangements where they can make the most difference in facilitating patient access while balancing health care system sustainability over time.

Further, several state Medicaid programs—including Alabama, Arizona, Colorado, Louisiana, Massachusetts, Michigan, North Carolina, Oklahoma, Texas, and Washington— have all been approved by CMS for Medicaid supplemental rebate agreements (SRAs) that allow for value-based agreements (VBAs) and alternative payment models with pharmaceutical manufacturers for a variety of treatments. Legislation, similar to what passed in Texas in 2019[2], is pending in multiple states. The Texas law gave the Department of Health and Human Services the authority to apply for a state plan amendment[3] with CMS to enter into a broad array of outcomes-based arrangements. BIO strongly supported passage of this law. BIO believes this legislative approach would give the State and the Department the broad flexibility that is necessary to explore the wide range of contracting opportunities available under the state plan amendment and the ability to work with manufacturers to tailor arrangements to the state population for which they are intended.

An important factor to consider in developing value-based arrangements is that their potential savings should be viewed holistically to a patient's overall health care costs and outcomes, not just narrowly within the pharmacy budget. The benefits of an outcomes-based arrangement or another type of arrangement, may be embedded in the structure of the contracting strategy. For example, while spending within the pharmacy benefit may increase due to the cost of a specific therapy,

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[1] Value-based State Plan Amendments approved in: Alabama, Arizona, Colorado, Louisiana, Massachusetts, Michigan, Oklahoma, Texas, and Washington. (Several other states are reportedly considering.)
[2] SB 1780, https://capitol.texas.gov/tlodocs/86R/billtext/pdf/SB01780F.pdf#navpanes=0
[3] Texas State Plan Amendment, Approval Document, CMS, September 28, 2020. https://www.medicaid.gov/medicaid/spa/downloads/tx-20-0010.pdf Accessed: June 3, 2022.

there may be significant savings in one of the metrics chosen for the contract, such as hospital admissions for that disease that could outweigh net increases in the pharmacy budget.[4] This could mean fewer hospital admissions for heart disease or other chronic diseases. It some cases it could mean a complete cure and resolution of a lifetime of exorbitant medical costs or simply better outcomes through improved condition and quality of life. Savings may not always be the goal of an innovative payment arrangement. In some cases, spreading risk or the predictability of financing may be the major concerns.

Access to innovative biopharmaceuticals can improve outcomes for complex chronic diseases.

The RFI also seeks comment on "[d]ecreas[ing] mortality rates for recipients with complex chronic diseases and address[ing] payment strategies for high-cost therapies and prescription drugs in development." Chronic disease accounts for approximately 67% of all deaths in the United States,[5] placing a severe economic toll on the health care system. According to the U.S. Centers for Disease Control and Prevention (CDC) heart disease, kills approximately 878,000 people per year, costing the health care system $216 billion annually. Cancer kills 600,000 people per year and the cost of cancer care will rise to almost $240 billion per year by 2030.[6] However, there has been great progress in treating chronic disease and many other diseases thanks in large part to development of innovative medicines.

According to the Manhattan Institute, "age-adjusted mortality per 100,000 from heart disease in the U.S. fell from 543 in 1965 to 169 in 2015, and for stroke from 166.4 to 37.6 over the same period. Though lifestyle changes account for just under half this decline, medications such as statins, beta-blockers, and ACE inhibitors explain most of the decline in heart disease mortality."[7]

The American Cancer Society points out that cancer death rates have dropped significantly in most types of common cancers.[8] The steepest decline in death rates has been for patients with melanoma skin cancer. After a new immunotherapy drug was approved in 2011, death rates began dropping 7% per year between 2013 and 2017.[9] Furthermore, the five-year survival rates for chronic myeloid leukemia increased from 22% in the 1970s to 70% for those diagnosed between 2009 to 2015. Today, those taking tyrosine kinase inhibitors can have a near normal life

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[4] Chatterjee, Arnaub, et al., "Innovative phrma contracts: When do value-based arrangements work?," Mckinsey & Company, October 2017.
[5] "Reducing the Burden of Chronic Disease: A Report of the Aspen Health Strategy Group," the Aspen Institute Health Strategy Group, 2019. Accessed: May 27, 2022. https://www.aspeninstitute.org/wp-content/uploads/2019/02/AHSG-Chronic-Disease-Report-2019.pdf
[6] https://www.cdc.gov/chronicdisease/about/costs/index.htm
[7] "Issues 2020: Drug Spending is Reducing Health Care Costs," Manhattan Institute, 2020. Accessed: 5/27/2022. https://www.manhattan-institute.org/issues-2020-drug-prices-account-for-minimal-healthcare-spending#notes
[8] https://www.cancer.org/latest-news/facts-and-figures-2020.html#:~:text=The%205%2Dyear%20relative%20survival%20rate%20for%20all%20cancers%20combined,except%20cervical%20and%20endometrial%20cancers.
[9] Ibid.

expectancy.[10] "Among women diagnosed with invasive breast cancer between 1975 and 1977, 74.8% survived for five years. In the period from 2003 to 2009, five-year survival reached 90.3%."[11]

In addition, other innovation has resulted in peopled being cured of disease. For example, in Hepatitis C, patients are now cured rather than suffer a chronic, debilitating disease that ultimately results in costly liver transplants.[12]

Furthermore, many chronic diseases are rare diseases for which there are few treatments available. Indeed, of the 7,000 known rare diseases, approximately 5% have FDA-approved treatments.[13] Moreover, 80% of all rare diseases are considered genetic. Fifty percent of all rare diseases affect children, while 30% die before the age of 5 years.[14] Fortunately, there is great progress has been made in cell and gene therapy that is making strides towards treatment of many rare and genetic diseases, including many rare cancers. BIO strongly supports timely, appropriate, and equitable access to all FDA-approved medicines, but particularly for transformative medicines for diseases for which there are few or no treatments available.

However, this progress does not come without heavy investment, years of research and development, and significant risk. According to the US Government Accountability Office (GAO), it can take 10 to 15 years to bring a drug to market, and only 1 in 10,000 chemical compounds that enters clinical testing makes through FDA approval.[15] The average cost to bring a drug from clinical development to market is estimated to be $2.9 billion.[16] It is important that the cost of innovative medicines reflect the investment in bringing therapies to market and also the value they bring to the patient and the health care system overall.

BIO continues to advocate for policies that seek to eliminate barriers to coverage and access established by public and private payers and third-party administrators. Specifically, Medicaid managed care organizations should not be allowed to establish blanket policies that hinder patient access to transformative therapies, such as developing coverage policies that are inconsistent with the FDA-approved

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[10] https://www.cancer.org/latest-news/facts-and-figures-2020.html#:~:text=The%205%2Dyear%20relative%20survival%20rate%20for%20all%20cancers%20combined,except%20cervical%20and%20endometrial%20cancers

[11] "Breast Cancer by the Numbers," *Pharmacy and Therapeutics*, March 2014. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4005124/#:~:text=Still%2C%20the%20war%20on%20cancer,identify%20as%20women's%20most%20feared.&text=Among%20women%20diagnosed%20with%20invasive,%2Dyear%20survival%20reached%2090.3%25.

[12] Manhattan Institute, 2020.

[13] Kaufman, Petra, et al., "From Scientific Discovery to Treatments for Rare Diseases—A View from the National Center for Advancing Translational Sciences—Office of Rare Diseases Research," Orphanet Journal of Rare Diseases, November 6, 2018. https://ojrd.biomedcentral.com/articles/10.1186/s13023-018-0936-x Accessed: May 27, 2022.

[14] National Institutes of Health, https://www.nichd.nih.gov/newsroom/resources/spotlight/020116-rare-disease-day. Accessed: December 1, 2019.

[15] "Artificial Intelligence in Health Care: Benefits and Challenges of Machine Learning in Drug Development,"US. Government Accountability Office (GAO). [Reissued: January 31, 2020].

[16] Joseph A. DiMasi, Henry G. Grabowski, and Ronald W. Hansen, "Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs," *Journal of Health Economics*, 47 (May 2016): 20–33. Accessed: May 27, 2022.

labeling. Medicaid managed care programs should conduct clinical reviews and provide equitable access and reimbursement for all innovative therapies. Following review, clear documentation of access parameters and reimbursement policies, consistent with their FDA-approved labeling, should be transparent and easily found in policy manuals and posted on a website. Medicaid is legally required to cover drug therapies consistent with the FDA-approved labeling per Section 1927 of the Social Security Act when the manufacturer has entered into a Medicaid Drug Rebate Agreement. CMS requires that Medicaid MCOs provide coverage according to requirements of the Medicaid rebate statute.[17]

Furthermore, BIO supports the use of alternative payment models (APMs), when appropriate, to ensure access to all innovative therapies in Medicaid. BIO strongly encourages the State of Florida to work with CMS and biopharmaceutical manufacturers on voluntary, alternative payment strategies that balance patient care, the potential for health care system savings, and positive health outcomes against the needs and limitations of the state's finite resources and budgetary requirements. It is imperative that state policymakers understand the variety of arrangement opportunities that are available, including arrangements based on outcomes or paying overtime. Moreover, policymakers must provide flexibility to ensure that new payment models can be developed as health care evolves and new medications are approved.

The Need for Medicaid MCO Contracts to Include a 340B Claims Modifier

Another prominent issue that BIO believes should be mentioned is the importance of including a claims modifier that identifies 340B claims in the contract for Medicaid MCOs to protect against duplicate discounts, which as prohibited by federal statute. For years, the GAO and the HHS Office of Inspector General have been making recommendations to HHS, Congress, and states on the need to address duplicate discounts The CMS issued a bulletin in January 2020, that made "best practice" recommendations to states on minimizing duplicate discounts.[18] One of the "best practices" included by CMS was for states to require Medicaid MCOs to have a means to identify 340B drug claims. This is consistent with CMS regulations[19] that dictate states include a provision within their Medicaid MCO contracts to identify 340B claims.[20] The purpose is to make it easier for MCOs to identify 340B claims for reporting Medicaid MCO utilization data to the state, which must exclude 340B claims data. Furthermore, states are required to report data excluding 340B claims to CMS for the purposes of billing manufacturers for Medicaid drug rebates. Without a claims modifier, it would be extremely difficult for plans and the state to identify such claims. As required by the Medicaid Managed Care Final Rule, 42 CFR §438.3(s)(3), "claims for 340B drugs that are the responsibility of the Medicaid managed care plan must

[17] 81 *Federal Register* at 27857
[18] Lynch, Calder, "Best Practices for Avoiding 340B Duplicate Discounts in Medicaid," *CMS Information Bulletin*, Centers for Medicare and Medicaid Services, January 8, 2020.
[19] 42 CFR §438.3(s)(3), Medicaid Managed Care Final Rule, CMS.
[20] 42 CFR §438.3(s)(3), Medicaid Managed Care Final Rule, CMS.

be identified and excluded from the general managed care utilization data reported to the state for purposes of billing manufacturers for Medicaid rebates."[21] Furthermore, the CMS Bulletin also notes that "HRSA encourages 340B covered entities to work with the [applicable] state to develop strategies to prevent duplicate discounts on drugs covered by Medicaid managed care plans."[22] Leaving out a requirement to identify 340B claims in the Medicaid MCO contracts runs counter to federal regulations and CMS' and HRSA's recommendations, and increases the likelihood for diversion and duplicate discounts.

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Thank you for the opportunity to submit comments on this Request for Information. Should you have any questions, please do not hesitate to contact me at (202) 962-9200 or at jgeisser@bio.org.

Sincerely,

/s/

Jack Geisser
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[21] Best Practices, January 8, 2020.
[22] Ibid.