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**BY ELECTRONIC DELIVERY**

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Children and Adults Health Programs Groups  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Mail Stop S2-01-06  
Baltimore, MD 21244-1850

**Re: Path to Transformation: Illinois 1115 Waiver Proposal**

Dear Ms. Gerrits:

The Biotechnology Industry Organization (BIO) and the Illinois Biotechnology Industry Organization (iBIO) are pleased to submit comments on the *Path to Transformation: Illinois 1115 Waiver Proposal* (the "Waiver Proposal") submitted to the Centers for Medicare & Medicaid Services (CMS) on June 4, 2014.<sup>1</sup>

BIO represents more than 1,000 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. In Illinois, BIO works in collaboration with iBIO, the state's champion for the life sciences, whose membership includes strong representation from the bio-pharmaceutical sector. This sector accounts for a large portion of the \$98 billion in biotech annual economic output and 369,000 directly and indirectly-created jobs in the state.<sup>2</sup>

BIO represents an industry that is devoted to discovering new treatments and ensuring patient access to them. Accordingly, we closely monitor payment policies for their potential impact on innovation and patient access to drugs and biologicals. With respect to the Waiver Proposal, BIO believes that integrated delivery models—such as "care coordination entities" (CCEs) and "accountable care entities" (ACEs)—have great potential to provide better care for individuals, better health for populations, and lower growth in overall

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<sup>1</sup> Illinois Department of Healthcare and Family Services, *Path to Transformation: Illinois 1115 Waiver Proposal* (June 4, 2014), available at: <http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/il-il-path-transformation-pa.pdf>.

<sup>2</sup> See *The Economic Engine of Biotechnology in Illinois*, Ernst & Young. For additional information about iBIO, please visit: <http://www.ibio.org/>.

expenditures—a three-part aim that BIO fully supports. That said, risk-based models such as these create incentives to undersupply services to control spending, to the potential detriment of patients. BIO is particularly sensitive to the fact that one area in which care is limited and services undersupplied is with regard to new technologies because the savings associated with these technologies are not realized within the relevant window of time and their costs are not included in the benchmark.

**I. Incentive Payments Should be Based on Evidence-Based Performance Standards Selected by a Diverse Group of Stakeholders**

Under the Waiver Proposal, Illinois proposes to “establish a Health System Integration and Transformation Performance Program to allow participating hospitals and health systems to earn incentive payments by meeting specific performance objectives.”<sup>3</sup> The state also proposes to “appoint an advisory committee to review and recommend three to five performance standards based on potential return on investment, impact on quality of care, and other factors.”<sup>4</sup> We believe that the establishment of robust, evidence-based performance standards can mitigate the inherent disincentives caused by a risk-sharing reimbursement system and thus urge the state to implement certain guardrails around the standard-selection process.

As an initial matter, we believe that the performance standards adopted for purposes of this demonstration should address the unique and diverse medical needs of Medicaid patients, many of whom have one or more chronic conditions that are managed by prescription medications. A transparent and inclusive process with stakeholder collaboration will ensure the inclusion of measures that are scientifically and clinically relevant. Thus, in addition to “experts from hospitals, accountable care entities (ACEs), [and] experts in health care performance/outcomes measurement and evaluation,”<sup>5</sup> we urge CMS to require the state to include other stakeholders, such as healthcare professionals (including medical specialists), patients, and pharmaceutical manufacturers on the advisory committee appointed to select the applicable performance standards. Broader involvement in the selection of measures also is important to ensure that the measures chosen can be feasibly collected without significant burden to providers or patients.

BIO also believes that it is especially important that the state require the advisory committee to adopt standards that are endorsed by a national organization, such as the National Quality Forum (NQF), or a disease or provider specialty society. Furthermore, to ensure that CCEs and ACEs are not required to adhere to outdated standards, the state should also institute a process for the committee to review existing standards and for updating or removing standards that are outdated on a timely basis, and in no event later than six months after the measure becomes obsolete. CMS may also want to consider requiring the state to create an exception process for providers who follow new guidelines or measures so as to not hinder patient care when performance measures lag behind changes in treatment.

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<sup>3</sup> Supra note 1 at 21-22.

<sup>4</sup> Id. at 21.

<sup>5</sup> Id. at 21.

## **II. Innovative Technologies Should Be Carved Out of the Shared Savings Benchmark**

To ensure that patients continue to have access to innovative medical technologies, BIO strongly urges CMS to require Illinois to create a carve-out for new, innovative medical technologies from the shared savings calculations for CCEs and ACEs. With such a carve-out, the decision to use promising new therapies will not affect the calculation of expenditures by the CCEs and ACEs for purposes of determining whether they generated shared savings. We also believe that there should be a similar carve-out from the capitated rate paid to Medicaid managed care organizations (MCOs) under the demonstration, such that the MCOs are not penalized when a new technology is approved mid-year that was not contemplated in the calculation of its capitated rate.

## **III. The Waiver Proposal Should Incorporate Beneficiary Protections to Ensure Robust Patient Access to Medically Appropriate Care**

BIO is very concerned that the transition to a risk-based payment methodology will incentivize CCEs and ACEs to “cherry-pick” the healthiest patient populations and restrict patients from obtaining the most appropriate care. To mitigate these incentives, we believe that CCEs and ACEs should be required to comply with all applicable federal and state laws that pertain to beneficiary rights, including those applicable to Medicaid MCOs.<sup>6</sup> These include, for example:

- The right of beneficiaries to receive information on available treatment options and alternatives, to participate in decisions regarding their health care, and to access services rendered by both primary care providers and medical specialists.<sup>7</sup>
- A prohibition on restricting healthcare professionals from acting within their scope of practice, or from advising or advocating on behalf of a beneficiary who is their patient.<sup>8</sup>
- The requirement to operate a robust beneficiary grievance process.<sup>9</sup>

We also believe that these entities should incorporate certain protections that apply to other integrated delivery systems, including Accountable Care Organizations participating in the Medicare Shared Savings Program, such as:

- The requirement to consult with participating healthcare providers regarding the entities’ medical policy, quality improvement programs, and medical management procedures.<sup>10</sup>
- The prohibition on making shared savings payments to physicians as an inducement to reduce or limit medically necessary services.<sup>11</sup>

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<sup>6</sup> See 42 C.F.R. § 438.100, et seq.

<sup>7</sup> See 42 C.F.R. §§ 438.100; 439.206-210.

<sup>8</sup> See 42 C.F.R. § 438.102.

<sup>9</sup> See 42 C.F.R. § 438.228. See also 42 C.F.R. § 438.400, et seq.

<sup>10</sup> See 42 C.F.R. §§ 425.106; 425.108; 425.112.

- The imposition of tough sanctions for the avoidance of at-risk beneficiaries.<sup>12</sup>

Moreover, because CCEs and ACEs, as well as MCOs, will be “held accountable for the health outcomes of individual patients within their networks as well as for their overall patient population,”<sup>13</sup> Illinois should adopt a robust risk-adjustment methodology to ensure that entities that attract more high-cost beneficiaries will not be penalized based solely on the nature of their underlying patient population. There are two basic measures to assess health risk for purposes of risk adjustment: demographic and medical. BIO strongly urges Illinois to adopt a risk-adjustment methodology that is based on medical factors, as risk adjustment based on demographic factors alone is insufficient.<sup>14</sup> Moreover, using encounter-based diagnostic information for this purpose is generally feasible for all types of health plans.<sup>15</sup> An added benefit of such a system is that collecting these data may assist CCEs, ACEs, and MCOs in better coordinating care and tracking performance on quality measures.

Given the importance of these patient protections and risk-adjustment methodologies for ensuring patient access to appropriate care, we urge CMS to refrain from approving this Waiver Proposal until these protections have been added and stakeholders have had a meaningful opportunity to comment on them.

#### **IV. Behavioral Health Care Integration Must Protect Patients’ Access to Needed Therapies**

BIO applauds Illinois for its particular attention in the Waiver Proposal to improved care coordination for patients with behavioral health needs.<sup>16</sup> We agree that the challenges presented by fragmented care or gaps in needed care, especially during (or immediately following) transitions in care, are compounded in this vulnerable patient population. We further support the goal of the proposed “health homes” to streamline access to the myriad of services available in Illinois for patients with serious mental illness and comorbid health conditions. However, we caution that a focus on utilization management of the therapies

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<sup>11</sup> See 42 C.F.R. § 425.208(b)(4) (citing 42 U.S.C. § 1320a-7, which, among other things, prohibits hospitals from making payments to physicians “as an inducement to reduce or limit services provided with respect to individuals” who are entitled to benefits under a Medicaid state plan).

<sup>12</sup> See 42 C.F.R. § 425.316(b).

<sup>13</sup> Supra note 1 at 14.

<sup>14</sup> Indeed, a study conducted by Jonathan Weiner of Johns Hopkins University found that the best diagnosis-based adjuster is about five times more accurate than demographic adjustment. This study randomly assigned 50,000 members to 25 hypothetical health plans to determine which risk-adjuster (medical v. demographic) would overpay the lowest-risk plan or underpay the highest-risk plan. See Weiner JP, Dobson A, Maxwell SL, et al., Risk-Adjusted Medicare Capitation Rates Using Ambulatory and Inpatient Diagnoses, *Health Care Fin. Rev.*, Spring 1996 17(3):77-99.

<sup>15</sup> For instance, risk adjustment based on medical factors is used for all Medicare Advantage and many Medicaid patients nationwide. See, e.g., Pope GC, Kautter J, Ellis RP, et al., Risk Adjustment of Medicare Capitation Payments Using the CMS-HCC Model, *Health Care Fin. Rev.*, Summer 2004 25(4):119-41, available at: <http://www.cms.gov/Research-Statistics-Data-and-Systems/Research/HealthCareFinancingReview/downloads/04Summerpg119.pdf>; Winkelman & Damler R, Risk Adjustment in State Medicaid Programs (Jan. 2008), available at: <http://www.soa.org/library/newsletters/health-watch-newsletter/2008/january/hsn-2008-iss57-damler-winkelman.pdf>.

<sup>16</sup> See supra note 1 at 41-42.

needed by these patients may not achieve, but in fact may countermand, the goal of ensuring “the right service, to the right individual, at the time of need.”<sup>17</sup>

In the treatment of mental illness, it is critical that patients have access to the therapies that are most appropriate for them and that they are able to switch between treatments based on changes in their condition. Broad access is also critical to long-term adherence because it allows patients, in conjunction with their providers, to find the most effective therapy or combination of therapies while minimizing side effects. Adherence to treatment, in turn, can be directly correlated to positive behavioral health outcomes, as well as improved outcomes of treatment for comorbid health conditions. Therefore, BIO urges CMS to ensure that any effort to integrate the delivery of care for these patients preserves or expands their access to available therapies and adequately provides for the highly-individualized treatment needs of this patient population in accordance with the protections set forth in the Medicaid Drug Rebate Statute,<sup>18</sup> the requirements of which are not proposed to be waived here.

#### **V. BIO Supports Illinois’ Efforts to Increase Access to Specialists for Medicaid Patients**

BIO strongly supports Illinois’ efforts throughout the Waiver Proposal to increase access to providers for Medicaid patients—particularly medical specialists—including through the state’s planned collaborations with the University of Illinois Hospital and Health Sciences System and the Cook County Health and Hospital System, as well as the state’s proposed Graduate Medical Education (GME) pilot program.<sup>19</sup> Medicaid patients face numerous barriers to care, including that many healthcare providers do not accept new Medicaid patients.<sup>20</sup> This is especially pronounced with respect to specialty care.<sup>21</sup> Lack of timely specialty care can result in adverse medical outcomes and potentially higher costs from avoidable emergency room visits and hospitalizations.<sup>22</sup> Access to medical specialists is particularly critical for patients with rare diseases, who face challenges finding appropriate medical care during the many years it takes to receive a correct rare-disease diagnosis, as well as locating specialty care post-diagnosis.<sup>23</sup> We encourage CMS to work with Illinois to build on the state’s proposals to ensure that Medicaid patients throughout Illinois have access to the specialty care they need.

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<sup>17</sup> Id.

<sup>18</sup> 42 U.S.C. § 1396r-8.

<sup>19</sup> Supra note 1 at 18, 20, 30, 89.

<sup>20</sup> Decker SL, Two-Thirds Of Primary Care Physicians Accepted New Medicaid Patients In 2011–12: A Baseline To Measure Future Acceptance Rates. *Health Aff.* July 2013. 32(7):1183-1187.

<sup>21</sup> Skinner A & M Mayer, Effects of Insurance Status on Children’s Access to Specialty Care: A Systematic Review of the Literature, *BMC Health Servs Res.* 2007. 7(194), available at: <http://www.biomedcentral.com/1472-6963/7/194>; Asplin B et al., Insurance Status and Access to Urgent Ambulatory Care Follow-up Appointments, *J. of the Am. Med. Ass’n.* 2005 Sep 14; 294(10):1248-54.

<sup>22</sup> The Commonwealth Fund, Improving Access To Specialty Care For Medicaid Patients: Policy Issues And Options at 9 (June 2013), available at: [http://www.commonwealthfund.org/~media/files/publications/fund-report/2013/jun/1691\\_felland\\_improving\\_access\\_specialty\\_care\\_medicaid\\_v2.pdf](http://www.commonwealthfund.org/~media/files/publications/fund-report/2013/jun/1691_felland_improving_access_specialty_care_medicaid_v2.pdf).

<sup>23</sup> Shire, Rare Disease Impact Report at 9 (April 2013), available at: <http://www.geneticalliance.org.uk/docs/e-update/rare-disease-impact-report.pdf>.

## **VI. CMS Should Not Approve any Waiver Modifications that Impose Excessive Beneficiary Cost-Sharing**

Under the original version of the Waiver Proposal, Illinois proposed to “waive the requirement that Illinois must track each family’s incurred cost sharing through an effective mechanism that does not rely on beneficiary documentation.”<sup>24</sup> BIO expressed strong concerns regarding this proposal in comments submitted to the state. While Illinois has eliminated this proposal in the draft waiver submitted to CMS,<sup>25</sup> the state nonetheless notes that it “will follow up with stakeholders and may modify this request pending those discussions.”<sup>26</sup> BIO strongly urges CMS not to approve any such modifications that do not conform to applicable federal cost-sharing requirements.<sup>27</sup> Moreover, the public should be provided with an ample opportunity to comment regarding any such proposed modifications prior to their inclusion in the waiver.

## **VII. CMS and Illinois Should Take Steps to Avoid Duplicate Discounts and Diversion of 340B Drugs**

As you are likely aware, pharmaceutical manufacturers that want their products to be reimbursed with federal funds under Medicaid are required to participate in the 340B Program and charge a deeply discounted price for their covered outpatient drugs to 340B “covered entities”. This program was originally put into place to improve access to prescription drugs for uninsured low-income patients. To safeguard against the potential for diversion of drugs purchased with such discounts, Congress specifically prohibited resale of drugs purchased by these covered entities “to a person who is not a patient of the entity.”<sup>28</sup>

BIO has previously expressed concerns that existing challenges with enforcement of the 340B program requirements—identified on numerous occasions by the Government Accountability Office and the Department of Health and Human Services Office of Inspector General<sup>29</sup>—may be compounded in integrated delivery models, such as Illinois’ proposed CCEs and ACEs, if significant precautions and oversight are not employed. While many of these challenges stem from the lack of a robust patient definition under the 340B program, which is administered at the federal level by the Health Resources and Services Administration (HRSA), we believe the state has a critical role to play in ensuring that its proposed CCEs and ACEs comply with existing requirements.

One specific concern is that the CCE and ACE arrangements may make it more difficult for the state to identify and exclude 340B utilization from their rebate claims, resulting in potential violations of the federal “duplicate discount” prohibition. Specifically, the 340B

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<sup>24</sup> Illinois Department of Healthcare and Family Services, Path To Transformation: Illinois 1115 Waiver Proposal at 46 (Feb. 10, 2014), available at: <http://www2.illinois.gov/gov/healthcarereform/Pages/1115waiver.aspx>.

<sup>25</sup> *Supra* note 1 at 47.

<sup>26</sup> *Id.* at 50.

<sup>27</sup> *See* 42 C.F.R. §§ 447.50, et seq.; 447.62, et seq.

<sup>28</sup> 42 U.S.C. § 256b(a)(5)(B).

<sup>29</sup> *See e.g.*, Government Accountability Office, Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement (2011), available at: <http://www.gao.gov/products/GAO-11-836>; Department of Health and Human Services Office of Inspector General (OIG), Contract Pharmacy Agreements in the 340B Program (2014), available at: <https://oig.hhs.gov/oei/reports/oei-05-13-00431.asp>.

statute prohibits obtaining a Medicaid drug rebate for a drug purchased through the 340B program.<sup>30</sup> Accordingly, states must exclude 340B utilization from the Medicaid rebate invoices they submit to manufacturers. This is relatively easy in the fee-for-service context, where the state receives claims directly from Medicaid providers and can thus identify whether each Medicaid provider is also a 340B covered entity. It becomes much more difficult for the state to comply with this requirement in the context of managed care plans and integrated delivery models, however, because the plan/integrated delivery system acts as an intermediary between the state and the covered entity. Accordingly, we urge CMS to require Illinois to ensure that CCEs, ACEs, and MCOs identify utilization by 340B covered entities—including through the use of 340B-specific identifiers—and pass this information on to the state so that the state can exclude this utilization from its rebate invoices.

We are also concerned that the requirement that the CCEs and ACEs coordinate and integrate care will lead the CCE or ACE and a 340B covered entity to conclude that a patient of the CCE or ACE is a patient of the 340B covered entity, even if the patient does not otherwise meet the definition of a 340B patient, for purposes of obtaining discounted drug pricing. The potential for such abuse undermines the integrity of the 340B program and threatens the goals it is intended to achieve, as well as those of the proposed Illinois demonstration. We thus urge both CMS and the state of Illinois to coordinate with HRSA to ensure that CCEs and ACEs that affiliate with 340B covered entities are prevented from diverting products under the 340B Program in this manner.<sup>31</sup> This request aligns with 2012 HRSA guidance that prohibits such diversion for Accountable Care Organizations, the CCE and ACE equivalents in federal demonstration projects.<sup>32</sup> BIO also encourages both CMS and Illinois to work with HRSA to provide the additional guidance necessary to minimize the opportunity for product diversion and to ensure that the 340B covered entities that enable product diversion, including the CCE or ACE in which they participate, are held accountable.

#### **VIII. Any Efforts to Establish Multi-Payer Programs Should Comply with Applicable Federal Guidance.**

As part of the Waiver Proposal, Illinois proposes to establish new multi-payer models that “enable people covered by Medicaid to remain with their providers if they shift from Medicaid to subsidized coverage under the Illinois Marketplace.”<sup>33</sup> While we support this proposal in principal, we urge CMS to ensure that any such programs comply with federal guidance regarding Medicaid “Bridge Plans,” including that such plans are in compliance with

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<sup>30</sup> 42 U.S.C. § 256b(a)(5)(A).

<sup>31</sup> This is especially important given the concerns recently raised by the HHS Office of Inspector General that: a lack of clarity on HRSA’s definition of a 340B-eligible “patient” has led to the inconsistent assessment of eligibility at the contract pharmacy level; and that most covered entities do not employ oversight activities in compliance with HRSA’s recommendations. With the rise in the number of covered entities that employ contract pharmacies, and the sheer number of contract pharmacies emerging, coordination between CMMI and HRSA will be crucial to ensure the integrity of the interaction between ACOs and the 340B program. See HHS Office of Inspector General (OIG). 2014. Contract Pharmacy Agreements in the 340B Program. Washington, DC: HHS OIG, Available at: <https://oig.hhs.gov/oei/reports/oei-05-13-00431.asp>.

<sup>32</sup> HRSA, 340B Drug Pricing Program Notice Release No. 2012-2 (May 23, 2012).

<sup>33</sup> *Supra* note 1 at 16.

the requirements applicable to both Medicaid MCOs and Qualified Health Plans, and that they are in the interest of consumers.<sup>34</sup>

## **IX. Conclusion**

BIO appreciates the opportunity to comment on the Waiver Proposal. We look forward to continuing to work with both CMS and Illinois to address these critical issues in the future. Please feel free to contact me at (202) 962-9200 if you have any questions or if we can be of further assistance. Thank you for your attention to this very important matter.

Sincerely,

/s/

Patrick Plues  
Senior Director  
State Government Relations

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<sup>34</sup> See Center for Consumer Information and Insurance Oversight, Frequently Asked Questions on Exchanges, Market Reforms, and Medicaid at 6 (Dec. 10, 2012), available at: <https://www.cms.gov/CCIIO/Resources/Files/Downloads/exchanges-faqs-12-10-2012.pdf>.