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LD 1938 – AN ACT TO PROHIBIT DISCRIMINATORY PRACTICES RELATED TO THE 340B DRUG PRICING PROGRAM

TESTIMONY IN OPPOSITION
Of
CIGNA

February 15, 2022

Senator Sanborn, Representative Tepler and Honorable members of the Health Coverage, Insurance and Financial Services Committee, I am Charlie Soltan, of Winthrop, ME, a partner in the law firm of Soltan Bass, LLC and I appear today on behalf of Cigna in opposition to LD 1938.

Cigna Corporation is a global health service company dedicated to improving the health, well-being and peace of mind of those they serve. Cigna delivers choice, predictability, affordability and access to quality care through integrated capabilities and connected, personalized solutions that advance whole person health. All products and services are provided exclusively by or through operating subsidiaries of Cigna Corporation, including Cigna Health and Life Insurance Company, Connecticut General Life Insurance Company, Evernorth companies or their affiliates, and Express Scripts companies or their affiliates. Such products and services include an integrated suite of health services, such as medical, dental, behavioral health, pharmacy, vision, supplemental benefits, and other related products. Cigna maintains sales capability in over 30 countries and jurisdictions, and has more than 175 million customer relationships throughout the world.

Cigna appreciates Senator Claxon bringing the bill forward. It is well understood that the federal 340B drug pricing program, as it has matured, has grown increasingly complex and has developed many challenges for its participants. But LD 1938 does not address 340B challenges in a manner that is consistent with federal law. Nor is LD 1938 confined to 340B matters. It is drafted in such a manner that we believe the bill is fatally flawed and, thus, we respectfully ask that you do not pass the bill.

Just this past November 30th, 2021, the Justices of the United States Supreme Court described the 340B statute as one of the most complex federal laws they had ever tried to interpret in a case argued before them where Maine's own Northern Light

was a lead plaintiff against the US Dept. of Health and Human Services.[1] Because of this case, and numerous other federal cases challenging provisions of 340B provisions, Cigna urges the Committee to forego any state attempt to interfere in this federal program while the United States Supreme Court and other federal courts interpret provisions of the federal statute. Cigna believes these current pending cases will bring greater clarity to the program.

Attached with this testimony is a concise overview of the 340B drug pricing program. We hope you find this overview useful in understanding the 340B program and some of its challenges. Cigna, through its health services business, Evernorth, plays 2 roles within 340B, as a PBM and a contract pharmacy:

1. Express Scripts Pharmacy home delivery and Accredo specialty pharmacy, both Evernorth companies, are contract pharmacies for 340B covered entities.
2. Express Scripts PBM needs notification when a prescription is processed for a 340B patient at one of its retail network pharmacies to help ensure rebates connected to those prescriptions are accounted for, and ultimately removed from, rebate reporting provided by Express Scripts to its clients. This process enables us to accurately administer rebates according to client contracts, as well as manufacturer rebate arrangements.
   – Express Scripts requires network pharmacies to identify all 340B claims (not just Medicaid). In an effort to reduce administrative burden on pharmacies, Express Scripts adopted usage of the National Council for Prescription Drug Programs (NCPDP) N1 transaction in March 2021. This standard was created specifically to support the exchange of 340B information between trading partners in one transaction, as opposed to pharmacies using a reverse-and-rekey process (two transactions) to provide the same data.
   ♣ <u>The updated reporting requirement has no impact on a provider's reimbursement or participation in Express Scripts' networks.</u>

Therefore, it is vitally important to be able to identify a 340B claim in order to preserve transparency when a prescription claim is processed by one of our network pharmacies for a 340B patient to ensure accurate administration of rebates according to our client contracts, as well as manufacturer rebate arrangements.

LD 1938, among many other flaws, would eliminate this transparency through the operation of the addition of §2699-A(3)(A)(5) that prohibits 3rd parties requiring a billing claim to indicate that the claim is a 340B drug pricing claim unless it is being billed under the Medicaid program on a fee-for-service basis (p. 2, line 22-24 of the bill) as well as trying to apparently make a pharmacy claim processed by a pharmacy as final. (page 3, lines 7-8).

[1] American Hospital Association v. Becerra.

Other questionable features of the bill attempt to make its provisions have a far greater reach than merely over the 340B program. For example, the definition of "patient" on page 1, line 9 is far more expansive than the type of "patients" that qualify under 340B rules. The definition of "Pharmacy" on page 1, line 10 is also far broader than that allowed under the 340B program since not all pharmacies may be qualified under 340B. Moreover, the definition of "provider" on page 1, lines 13-14 is confusing at best since the 340B program defines eligible pharmacies rather than the more granular pharmacist. These definitions alone make the bill confusing as to its intent and have an impact that is far greater than the title of the bill describes.

The provisions described in sub-§2 of §2699-A, beginning on page 1, line 23 of the bill are mostly provisions that have no relevance to a 340B program as well as are confounding. 340B has its own rules on dispensing medications to eligible patients in order to appropriately track 340B discounted medications. The provisions in this section cannot interfere with these federal requirements and the way they are drafted thus apply to situations outside of the program. Further, they seem to not take into consideration already mandated pharmacy choice for patients under state law. And the provision regarding "pharmacy claims" on page 4, lines 7-8, is very problematic since all claims should be subject to review to prevent fraud, confirm appropriate billing and prescription practices let alone conform to agreed upon contractual terms between the parties.

And the proposed rulemaking section on page 3, lines 9-11 of the bill is also odd. The bill proposes to give the Superintendent of Insurance rulemaking authority yet the bill's placement is in Title 22. Title 22 is the operational statute for the Maine Department of Health and Human Services. The Superintendent of Insurance does not possess any authority over title 22 provisions.

In summary, Cigna understands the unique role that 340B covered entities and their contract pharmacies perform in providing affordable access to health care for America's most vulnerable populations. As such, we support minimizing administrative burden to the 340B Program and the patients it serves. As a PBM, we require transparency when a prescription claim is processed by one of our network pharmacies for a 340B patient to ensure rebates are appropriately adjusted. We support clear guidance regarding the use of 340B contract pharmacies. As a PBM, we do not lower reimbursement amounts because a drug was purchased through the 340B program. We also do not change network participation standards or limit a pharmacy's ability to serve as a contract pharmacy for 340B covered entities. This ensures the 340B benefit is not diminished for 340B covered entities or their contract pharmacies.

Unfortunately, LD 1938 does not address any of these principles and is flawed in so many ways that we urge you to vote it "ought not to pass."

ISSUE OVERVIEW: 340B DRUG PRICING PROGRAM

An overview of the federal program which enables covered entities serving low-income patients to obtain covered outpatient drugs from manufacturers at significant discount

Background

340B is a drug pricing program established by the Veterans Health Care Act of 1992, which added Section 340B to the Public Health Service Act. The intent of the program is to allow providers serving vulnerable populations "to stretch scarce Federal Resources as far as possible, reaching more eligible patients and providing more comprehensive services." As a condition of participation in Medicaid, drug manufacturers agree to provide highly discounted prices on covered outpatient drugs to certain health care providers, known as covered entities. The program is overseen by the Health Resources and Services Administration (HRSA), an agency of the U.S. Department of Health and Human Services (HHS).

Covered entities include two categories of providers:

- **Eligible hospitals:** Hospitals which are owned by a state or local government, a non-profit that has been delegated governmental powers, or are under contract with a state or local government to provide services to low-income patients who do not qualify for Medicare or Medicaid are eligible to participate in 340B. These covered entities include critical access hospitals, disproportionate share (DSH) hospitals, children's hospitals, and rural referral centers. Eligible hospitals must meet specified DSH percentages by treating a disproportionate share of low-income Medicaid and Medicare patients to qualify for participation in 340B. Critical access hospitals do not need to meet the DSH thresholds.
- **Federal grantees:** Certain entities are eligible to participate in 340B by virtue of receiving some type of federal support. Eligible federal grantees include Federally Qualified Health Centers (FQHCs), Ryan White programs, family planning clinics and sexually transmitted disease clinics.

HRSA has established three criteria for defining which individuals are considered patients of a covered entity:

- The covered entity maintains records of the individual's health care; and
- The health care professional providing services to the individual is an employee of, or contracted with, the covered entity, so that responsibility for care remains with the covered entity.
- For non-hospital covered entities, the health care services received by the individual must be services for which federal grant funding is provided.

Individuals do not qualify as patients if the only health care service provided by a covered entity is dispensing prescription drugs.

340B Drug Delivery Models

Patients may receive 340B drugs through contract pharmacies, a covered entity's outpatient pharmacy, or a covered entity's clinic. When the program began, covered entities were only permitted to use a single point for pharmacy services, either an in-house pharmacy or an individual contract pharmacy, unless a waiver was received. In 2010, HRSA issued guidance to allow covered entities to contract with multiple pharmacies to help address concerns regarding patient access and transportation challenges. As a result, between 2010 and 2020, the number of participating contract

pharmacies increased nearly 15 times to more than 28,000 pharmacies with approximately 120,000 distinct contract relationships with covered entities.

Duplicate Discounts Prohibited in Medicaid

A duplicate discount (sometimes referred to as "double dipping") occurs when drug manufacturers provide a discounted 340B price to a covered entity at the time of purchase while also paying a rebate to a Medicaid agency. Federal law prohibits duplicate discounts in Medicaid and covered entities must have mechanisms in place to prevent them from happening. No similar prohibition exists for commercial or Medicare coverage.

The growth in Medicaid Managed Care Organizations (MCOs) and 340B contract pharmacies has resulted in increased compliance challenges which led the Centers for Medicare & Medicaid Services (CMS) to issue new guidance in 2020 to avoid 340B duplicate discounts. This guidance outlines best practices to avoid 340B duplicate discounts, including: requiring claims modifiers; using HRSA's Medicaid Exclusion File (limited to Medicaid Fee-for-Service); providing claims level detail to manufacturers; developing strategies with contract pharmacies; and using specific Medicaid MCO BIN/PCN numbers on patient identification cards.

340B Program Challenges

The 340B Program has faced numerous challenges since its inception. These challenges are complicated by the fact that HRSA's regulatory authority for the program is limited to three areas:

- Establishing and implementing a binding Administrative Dispute Resolution (ADR) process for certain disputes involving compliance with program requirements;
- Imposing civil monetary penalties against manufacturers who knowingly and intentionally overcharge a covered entity for a 340B drug; and
- Issuing precisely defined standards of methodology for calculating 340B ceiling prices.

In addition to a narrow regulatory framework, the program's statutory guardrails are also limited. For example, there are no specified requirements for how covered entities must utilize 340B revenue to fulfill the program's intent, nor are there limitations on patient eligibility outside of the factors previously mentioned. Covered entities can provide 340B drugs to all eligible patients, regardless of payer status.

In 2020, drug manufacturers raised their own concerns about the 340B Program. In response to the increase in contract pharmacies, several manufacturers, including Sanofi, AstraZeneca, Novartis, and Eli Lilly, announced plans to limit 340B discounts available to contract pharmacies. Manufacturers also took action to increase disclosure of contract pharmacy claims information through a data sharing platform. Given HRSA's lack of authority to regulate contract pharmacies, many stakeholders and Congress have called on HHS to address this issue. Several parties, ranging from drug manufacturers to hospital groups, have filed lawsuits regarding the program as well.

In response, HHS has taken several steps to address ongoing challenges:

- **Administrative Dispute Resolution:** In Dec. 2020, HHS published a final rule implementing an ADR Process for the 340B Program. The Affordable Care Act required implementation of such a process within 180 days after enactment in 2010; however, the rulemaking process was significantly delayed. HHS issued an Advanced Notice of Proposed Rulemaking in 2010, a Notice of Proposed Rulemaking in 2016, and then ultimately the final rule in 2020. Members were nominated to the ADR Panel in Jan. 2021 by the Trump Administration; but, the Biden Administration pulled those nominees and announced its own nominees on June 24, 2021. The intent of the ADR process is to provide a forum for adjudicating disputes between manufacturers and covered entities. HHS has not historically had the authority to regulate contract pharmacies, so it is unclear if the ADR panel will have more authority. Lawsuits challenging the authority of the ADR panel, as well as the rulemaking process establishing the panel, are ongoing.
- **Office of the General Counsel (OGC) Advisory Opinion on Contract Pharmacies:** In response to Congressional and stakeholder calls for HHS to address recent manufacturers' actions, the HHS OGC published an advisory opinion on Dec. 30, 2020, stating that "covered entities under the 340B Program are entitled to purchase covered outpatient drugs at no more than the 340B ceiling price…even if those covered entities use contract pharmacies." The

document was careful to note that the opinion lacks the force of law, and HHS withdrew this advisory opinion on June 22, 2021 to "avoid confusion and unnecessary litigation."

- **Civil Monetary Penalties:** In May 2021, HRSA sent letters to six drug manufacturers and threatened to impose civil monetary penalties if they refused to supply 340B discounts to contract pharmacies associated with covered entities. In response, several manufacturers have filed suit challenging the authority of HRSA to impose those penalties.
- **Access to Affordable Life-Saving Medications Rule:** Following an executive order issued in July 2020, the Trump Administration finalized a rule requiring FQHCs to provide insulin and epinephrine at the price they pay for these drugs (plus a nominal administration fee) to patients with incomes below 350% of the Federal Poverty Level. HHS stopped short of saying these sales would have to bypass payers which would have excluded these sales from current rebate obligations. The Biden Administration delayed the final rule twice and has since issued a proposed rule in June 2021 to permanently rescind the policy.

Recent developments suggest there should be significantly more clarity regarding the use of contract pharmacies in the 340B Program in the next 12-18 months, but that clarity is likely to come through the courts, rather than Congress or HHS.

Our Participation in 340B

Evernorth, Cigna's health services business, plays two roles – a PBM and a contract pharmacy – in 340B:

- Express Scripts Pharmacy home delivery and Accredo specialty pharmacy, both Evernorth companies, are contract pharmacies for 340B covered entities.
- Express Scripts PBM needs notification when a prescription is processed for a 340B patient at one of its retail network pharmacies to help ensure rebates connected to those prescriptions are accounted for, and ultimately removed from, rebate reporting provided by Express Scripts to its clients. This process enables us to accurately administer rebates according to client contracts, as well as manufacturer rebate arrangements.
  - Express Scripts requires network pharmacies to identify all 340B claims (not just Medicaid). In an effort to reduce administrative burden on pharmacies, Express Scripts adopted usage of the National Council for Prescription Drug Programs (NCPDP) N1 transaction in March 2021. This standard was created specifically to support the exchange of 340B information between trading partners in one transaction, as opposed to pharmacies using a reverse-and-rekey process (two transactions) to provide the same data.
    - The updated reporting requirement has no impact on a provider's reimbursement or participation in Express Scripts' networks.

Policy Principles

- We understand the unique role that 340B covered entities and their contract pharmacies perform in providing affordable access to health care for America's most vulnerable populations. As such, we support minimizing administrative burden to the 340B Program and the patients it serves.
- As a PBM, we require transparency when a prescription claim is processed by one of our network pharmacies for a 340B patient to ensure rebates are appropriately adjusted.
- We support clear guidance regarding the use of 340B contract pharmacies.
- As a PBM, we do not lower reimbursement amounts because a drug was purchased through the 340B program. We also do not change network participation standards or limit a pharmacy's ability to serve as a contract pharmacy for 340B covered entities. This ensures the 340B benefit is not diminished for 340B covered entities or their contract pharmacies.