

October 30, 2020

VIA E-MAIL: 340B@help.senate.gov and 340B@mail.house.gov

The Honorable Lamar Alexander
Chairman
U.S. Senate Committee on Health, Education, Labor & Pensions
428 Senate Dirksen Office Building
Washington, D.C. 20460

The Honorable Greg Walden
Ranking Member
U.S. House Committee on Energy and Commerce
2322 Rayburn House Office Building
Washington, DC 20515

Re: Request for Input on Modernizing 340B Drug Pricing Program

Dear Senator Alexander and Representative Walden:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the invitation by Senator Lamar Alexander and Congressman Greg Walden to comment on your *Request for Input on Modernizing 340B Drug Pricing Program* (RFI). PhRMA represents the country's leading innovative biopharmaceutical research companies devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Since 2000, PhRMA member companies have invested nearly \$1 trillion in the search for new treatments and cures, including an estimated \$83 billion in 2019 alone.

America's biopharmaceutical companies are committed to developing solutions to help diagnose and treat those with COVID-19, a disease caused by a novel strain of coronavirus. In addition to applying their scientific expertise to find ways to diagnose, treat, and prevent infections from the virus, the biopharmaceutical industry is providing financial support and in-kind donations to organizations and collaborating with U.S. and global health authorities to combat this global public health emergency. Most PhRMA members have research and development efforts underway and are providing donations of medicines and critical medical supplies to support patients and first responders in addressing this evolving crisis.

PhRMA is pleased to provide input on how the 340B Drug Pricing Program (340B) can be strengthened to better support our nation's most vulnerable patients. We look forward to continuing our conversations on meaningful improvements that can be made to ensure the 340B program is overseen and operated in a way that sustains the program for the long-term so that patients more directly benefit from the discounts provided by biopharmaceutical manufacturers.

PhRMA and our member companies have long supported the 340B program and the critical safety-net role it was intended to play in our nation's health care system. The program was enacted to help make prescription medicines more accessible to uninsured or vulnerable patients, but the 340B program has veered off course, and as noted in the RFI, "changes are long overdue." Today, it is no longer accurate to characterize the 340B program as a *safety-net* program primarily focused on *vulnerable patient care*. Increasingly, the 340B program has become a *revenue stream* for certain stakeholders decoupled from the medical and pharmaceutical access needs of vulnerable patients.

The lack of meaningful program transparency, integrity, eligibility, and sustainability standards have contributed to a program that has strayed far from focusing on vulnerable, needy patients as originally intended. A mounting body of evidence from independent watchdogs—Congressional oversight hearings, audits by the Health Resources and Services Administration (HRSA), government reports, and academic research—reinforces the need for changes.¹

Program realignment must more directly benefit vulnerable patients. The program's intent has always been to support patients; therefore, any program realignment emerging from your efforts must advantage vulnerable patients and not serve as a revenue-maximizing enterprise for hospitals, contract pharmacies, or for-profit vendors. To ensure the 340B program fulfills its purpose of providing discounts on covered outpatient drugs to true safety-net providers that serve low-income, uninsured, and other vulnerable patients, policymakers should address several critical shortcomings in the current program by:

- **Providing broader program accountability and transparency.** Requiring fundamental transparency in the 340B program is the first essential step in ensuring the program delivers for patients. Program standards should include clear rules for how all covered entities must use savings from 340B drug discounts to benefit eligible patients. Improvements to the reporting standards will enable policymakers to ensure that all 340B covered entities are consistently and systematically serving the needs of low-income, uninsured, and other vulnerable patients. Transparency standards in previously introduced legislation—the *Helping Ensure Low-income Patients have Access to Care and Treatment* (HELP Act) S.2312 and *Protecting Access for the Underserved and Safety-Net Entities Act* (340B PAUSE Act) H.R. 4710—are a sound starting point for aligning the program to meet its intended purpose and serve more vulnerable patients, and should be expanded to account for all 340B covered entities.
- **Ensuring clarity for all stakeholders on which patients are eligible for the program.** Without a clear definition of which individuals are deemed "patients" of 340B covered entities, it remains difficult to ensure the program is serving the patients for whom it was designed and is not being used in ways that divert funds from these patients. Many stakeholders have expressed concern over the lack of clarity for this fundamental element of the program, which also poses significant program integrity risks. HRSA has yet to address this, and changes are long overdue. Meaningful patient eligibility criteria should ensure that the program is focused on ensuring vulnerable patients with demonstrated need can benefit from the program.

¹ Government Accountability Office, "340 Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement," GAO-20-212, January 2020; Government Accountability Office, *Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements*, December 11, 2019; Government Accountability Office, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, GAO-18-480: Jun 28, 2018; Government Accountability Office, *Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals*. GAO-15-442. June 2015; Government Accountability Office, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*. September 23, 2011.

- **Addressing the asymmetry between contract pharmacies' growth and patient benefit.** While the 340B program has grown exponentially over the past decade, there is limited evidence that there has been a commensurate improvement in patient benefits. The current unlimited use of contract pharmacy arrangements is unsustainable and diverts savings meant for 340B patients to for-profit pharmacies and other middlemen. Program realignment must address the misuse of the 340B program by for-profit contract pharmacies and create consistent processes to prevent prohibited behavior.
- **Establishing more meaningful linkages between care for vulnerable patients and program eligibility standards.** Policymakers should reconsider and revise flawed hospital and child-site eligibility standards. Current standards are not correlated with the level of care delivered to vulnerable patients or the level of charity care at 340B hospitals. This misalignment calls into question whether the program is focused on fully benefiting low-income patients and other vulnerable patient groups. Updating eligibility metrics should account for the degree to which 340B covered entities continue to serve a meaningful and measurable safety-net function relative to typical non-340B providers. The Government Accountability Office (GAO) has cited inadequate oversight of covered entity and child site eligibility, including providers whose eligibility is based on a "contract with a state or local government." Furthermore, the proliferation of child sites under the 340B program should not be permitted to continue without better oversight. Instead, specific criteria should be established to set clear requirements for such sites to demonstrate their ability to address unmet medical needs in rural, medically underserved, and shortage areas, thereby bringing them in line with broader public health priorities.
- **Improving audits and program violation enforcement to prevent diversion and duplicate discount violations.** A growing body of evidence from HRSA audits, government reports, and academic research demonstrates repeated examples of diversion and duplicate discount abuses that exist among covered entities. There are persistent problems with diversion and duplicate discounts that have gone unaddressed due to HRSA's insufficient and inconsistent guidance. Failure to ensure compliance with basic program requirements, which are intended to direct program resources and benefits to eligible patients at safety-net facilities, further erodes confidence that the program is serving those patients most in need of support.

Policymakers should examine problems that have been identified by GAO, HHS Office of Inspector General (OIG), and others related to hospital eligibility criteria, transparency, and requirements for patient benefit, all of which provide opportunities to ensure the 340B program is serving its intended purpose for patients. Program improvements should adopt an integrity architecture that creates sustainability and certainty for patients, prevents program abuses, and assures covered entity compliance.

The 340B program has strayed far from its focus of serving low-income, vulnerable patients and safety-net providers as originally intended.

Congress created the 340B program in 1992 to restore the voluntary drug discounts for uninsured or vulnerable patients that manufacturers provided before the passage of the Medicaid drug rebate statute. A lot has changed in the healthcare landscape since the 340B program was enacted, including new legislative mandates requiring manufacturers to pay Part D coverage gap discounts and statutory rebates on Medicaid managed care claims. As part of the 340B program, manufacturers provide steep discounts averaging about 60 percent² on most outpatient medicines to certain types of clinics

² Berkeley Research Group, Measuring the Relative Size of the 340B Program, 2018 Update. May 2020.

(known as “grantees”) and qualifying hospitals as a condition of their medicines being covered in Medicaid. Some safety-net clinics have federal grant requirements that ensure they reinvest profits into care for the uninsured or vulnerable patients they treat. In contrast, the current 340B program rules lack standards for how covered entities, including DSH hospitals, should use these discounts. For sales through Apexus, hospitals comprise 87 percent of all 340B sales,³ with the use of the 340B program most concentrated in the disproportionate share (DSH) hospitals.⁴

Today, it is no longer accurate to characterize the program as primarily focused on vulnerable patient care by safety-net providers. Instead, much of the 340B program is increasingly dominated by a complex web of financial transactions and proprietary, contractual relationships that have evolved to benefit hospitals and middlemen, leaving vulnerable patients to fend for themselves. Even as hospitals’ 340B drug purchases have grown dramatically, hospitals’ uncompensated care has dropped.⁵ Based on evidence from GAO, OIG, analysis in the *New England Journal of Medicine*, *JAMA*, and others,⁶ immediate changes are needed in each of the following areas to help refocus the program to its intended purpose.

Broader program accountability and transparency are needed to put the program back on track for the patients it was intended to serve.

An essential step in ensuring that the 340B program provides measurable patient benefit is adopting fundamental improvements in transparency. Currently, standards are highly variable, and in some instances woefully inadequate, across the range of providers participating in the 340B program. As a result, policymakers and stakeholders are unable to evaluate the program, quantify its benefit to patients, or objectively confirm that patients fully benefit from the program discounts. Current 340B program rules do not provide adequate standards for how covered entities should use 340B discounts, how much covered entities can keep in 340B profits, how much 340B profit can be made by marking up prices charged to vulnerable and uninsured patients, or how the program has helped improve patient affordability. In this way, the 340B program creates incentives that can increase costs for patients, insurers, and the government^{7, 8, 9} without any evidence to support claims that eligible patients are benefiting from program discounts.

At a minimum, all covered entities should have similar reporting requirements to ensure that vulnerable patients benefit from the program. Specific data are needed to quantify patient benefit in terms of the number of vulnerable patients who benefit from the 340B program and covered entities use the discounts they receive to help patients. Commonsense reporting requirements should be focused on basic information hospitals are likely already collecting for other purposes. For example, the data on the insurance status of patients is already needed for payment purposes.

³ Government Accountability Office. Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements, December 11, 2019.

⁴ Apexus, 340B Health Summer Conference, July 2016; Apexus, 340B Health Summer Conference, July 2016

⁵ Fein A. Exclusive: The 340B Program Reached \$19.3 Billion in 2017 – As Hospitals’ Charity Care Has Dropped

⁶ HHS Office of Inspector General. Contract Pharmacy Arrangements in the 340B Program. February 2014; Government Accountability Office, Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals. GAO-15-442. June 2015; Desai S, McWilliams JM. Consequences of the 340B Drug Pricing Program. *N Engl J Med*. 2018; Conti R, Bach P. Cost Consequences of the 340B Drug Discount Program. *JAMA*. 2013;309(19):1995-1996; Hirsch BR, Balu S, Schulman KA. The Impact Of Specialty Pharmaceuticals As Drivers Of Health Care Costs. *Health Affairs*. 2014;33(10):1714-1720.

⁷ 8 S. Desai and J.M. McWilliams, "Consequences of the 340B Drug Pricing Program," *N Engl J Med* 2018.

⁸ R. Conti, P. Bach, “Cost Consequences of the 340B Drug Discount Program,” *JAMA: The Journal of the American Medical Association*, 2013;309(19):1995-1996. doi:10.1001/jama.2013.4156.

⁹ Government Accountability Office, Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals, GAO-15-442, June 2015.

There are several examples of how these policies might be developed.¹⁰ Two prior legislative proposals offer a sound starting point. S. 2312, the *Helping Ensure Low-income Patients have Access to Care and Treatment* (HELP Act),¹¹ introduced by Senator Cassidy and H.R. 4570, the *Protecting Access for the Underserved and Safety-Net Entities Act* (340B PAUSE Act), introduced by Representatives Larry Bucshon and Scott Peters. The HELP Act included many essential and commonsense reporting and accountability measures that could help all stakeholders better understand how DSH hospitals are using the 340B program and which patients have access to 340B discounts. This legislation also included much-needed standards for how DSH hospitals and their child sites qualify for the 340B program. The 340B PAUSE Act would have required similar steps to increase understanding of how 340B hospitals qualify for the program and which patients receive 340B prescriptions.

Whether Congress adopts these policy options or seeks another legislative route, essential transparency and reporting requirements should be applied consistently across the 340B program, so the public and policymakers have the assurance that eligible patients are fully benefiting from 340B drug discounts. These data are essential to guaranteeing low-income, uninsured patients benefit more directly from discounts on 340B medicines and helping to ensure program sustainability. Importantly, in its January 2018 report on the 340B program, the House Committee on Energy and Commerce Subcommittee on Oversight and Investigations questioned numerous HRSA grantees about their additional reporting requirements under their HRSA grants. Grantees told the Committee, “they found the additional program requirements manageable.”¹²

To ensure the 340B program delivers fully on its promise for patients, policymakers must clearly define the population of “patients” to whom benefits must be delivered.

The 340B program was created to provide manufacturer discounts on covered outpatient drugs to safety-net facilities that serve low-income, uninsured, and other vulnerable patients. Under the 340B law, a covered entity has access to a 340B discount if the medicine is used for the covered entity’s own “patient.”¹³ The 340B law prohibits covered entities from reselling or otherwise transferring medicines purchased under the 340B program to anyone but a “patient” of the covered entity (a practice known as “diversion”).¹⁴

Despite this centrality of “patient” to defining the program’s scope and assuring that statutory program integrity requirements are met, it has been a quarter of a century since the 340B program was created, and the patient definition has yet to be more clearly defined.¹⁵ As a result, there is broad consensus that the lack of specificity in the current (1996) patient definition invites abuse. For example:

- “[S]ome 340B covered entities may have interpreted the [patient] definition too broadly, resulting in the potential for diversion of medications purchased under the 340B Program.... This [never finalized] clarification provides covered

¹⁰ 8 S. Desai and J.M. McWilliams, “Consequences of the 340B Drug Pricing Program,” *N Engl J Med* 2018.

¹¹ R. Conti, P. Bach, “Cost Consequences of the 340B Drug Discount Program,” *JAMA: The Journal of the American Medical Association*, 2013;309(19):1995-1996. doi:10.1001/jama.2013.4156.”

¹² Government Accountability Office, Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals, GAO-15-442, June 2015

¹³ House Energy and Commerce Subcommittee on Oversight and Investigations, Review of the 340B Drug Pricing Program, January 10, 2018. Available at:

https://energycommerce.house.gov/wpcontent/uploads/2018/01/20180110Review_of_the_340B_Drug_Pricing_Program.pdf

¹⁴ 42 U.S.C. § 256b(a)(5)(b).

¹⁵ 42 U.S.C. § 256b(a)(5)(B).

¹⁶ We support the general approach to defining a 340B “patient” reflected in HRSA’s proposed (now withdrawn) omnibus guidance, taking into account considerations for HRSA grantees in the 340B program. 80 Fed. Reg. 52300 (Aug. 28, 2015).

entities with more explicit guidance regarding the relationship between a covered entity and an individual that makes that individual a 'patient' of the covered entity." (HRSA, 2007.)¹⁶

- "HRSA officials told us that the [patient] definition currently includes individuals receiving health care services from providers affiliated with covered entities through 'other arrangements' as long as the responsibility for care provided remains with the entity. However, HRSA does not define 'other arrangements,' and officials told us what is meant by responsibility for care also needs to be clarified. As a result of the lack of specificity in the guidance, HRSA has become concerned that some covered entities may be broadly interpreting the definition to include individuals such as those seen by providers who are only loosely affiliated with a covered entity and thus ... for whom the entity does not actually have the responsibility for care." (GAO, 2011)¹⁷
- "[C]overed entities ... use different methods to identify 340B-eligible [patients and] prescriptions to prevent diversion in their contract pharmacy arrangements. In some cases, these different methods lead to differing determinations of 340B eligibility.... [T]wo covered entities may categorize similar types of prescriptions differently (i.e., 340B-eligible versus not 340B-eligible) [T]here is inconsistency within the 340B program as to which prescriptions filled at contract pharmacies are treated as 340B-eligible." (HHS OIG, 2014)¹⁸
- "HRSA has outlined three criteria for who is an eligible patient, but some of these criteria are not clearly defined." (MedPAC, 2015)¹⁹
- "HRSA's guidance addresses patient eligibility but leaves room for interpretation as to which of the patient's prescriptions might be eligible in a retail pharmacy setting. In these retail settings, we found that providers, in fact, are making different determinations of what prescriptions are eligible for the 340B discounts." (Oral Testimony of Ann Maxwell, Assistant Inspector General, OIG, Senate Health, Education, Labor & Pensions (HELP) Committee, May 15, 2018.)
- "HRSA's current patient definition guidance does not account for the complexity of contract pharmacy arrangements...In its 2014 report, OIG found wide variation in these [340B] eligibility determinations. Different determinations of 340B eligibility appear to stem from the application of the patient definition by 340B providers and their contract pharmacies to a wide variety of prescription-level scenarios. Depending on the interpretation of HRSA's patient definition, some 340B provider eligibility determinations would be considered diversion and others would not." (Testimony of Ann Maxwell, Assistant Inspector General, OIG, Senate HELP Committee, May 15, 2018)²⁰

As highlighted by HRSA, GAO, OIG, and others, the 1996 patient definition is vague and lacks the specificity needed to provide clear direction to covered entities and manufacturers about who qualifies as a patient for 340B discount purposes.²¹ This has encouraged covered entities to take broad interpretations of the patient definition guidance and use 340B medicines for many individuals Congress never intended the program to serve. This behavior is even more aggressive with DSH

¹⁶ 72 Fed. Reg. 1543, 1544 (Jan. 12, 2007).

¹⁷ Government Accountability Office. Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement. September 23, 2011.

¹⁸ HHS Office of Inspector General. Contract Pharmacy Arrangements in the 340B Program. February 5, 2014.

¹⁹ MedPAC. Report to the Congress: Overview of the 340B Drug Pricing Program. May 2015.

²⁰ Ann Maxwell, HHS OIG, Testimony Before the United States Senate Committee on Health, Education, Labor and Pensions: Examining Oversight Reports on the 340B Drug Pricing Program, May 15, 2018.

²¹ Debra Draper, GAO, Testimony Before the Committee on Health, Education, Labor & Pensions, U.S. Senate, May 15, 2018.; Testimony of Ann Maxwell, OIG, Testimony Before the Committee on Health, Education, Labor & Pensions, U.S. Senate, May 15, 2018.

hospitals that often develop a web of complex arrangements that appear to have the goal of growing revenue by capturing as many “patients” as possible, rather than more fully serving uninsured, low-income patients.

The lapse in guidance defining 340B eligible patients is glaring given the 340B statute creates an absolute prohibition on covered entities transferring or selling 340B drugs to individuals *who are not patients* of the covered entity. Therefore, a clear definition of “patient” is a crucial element of the program and critical to the integrity and long-term sustainability of the 340B program. We believe a new definition of 340B patients could make significant strides in resolving many of the inconsistencies in the way stakeholders have interpreted this key term.

A sound patient definition in the 340B program should address several key issues, including, at a minimum: clarifying the relationship between the 340B provider seeing the patient (including the need for in-person visits to maintain the provider-patient relationship); specifying child site criteria for patient receipt of outpatient care at a covered entities’ facilities, and delineating hospital eligibility standards for the 340B program as a result of a state government contract (defining criteria for patients receiving care within the scope of the contract). This clarification is an essential building block in putting the 340B program on a firm footing – a clear definition of “340B patient” is needed urgently to ensure that the program is fully serving the vulnerable, low-income patients for whom it was designed.

Improve hospital eligibility standards to provide a stronger linkage between 340B eligibility and the extra help provided to uninsured, low-income, and other vulnerable patients.

Current hospital eligibility standards for the 340B program are woefully outdated and not serving safety-net patients well. As a result, one of the program’s primary failings over the past several decades has been explosive program growth driven by hospitals (including many large health systems) that appears largely focused on expanding revenue and is disconnected increasingly from benefiting patients. Consequently, the program’s significant growth in recent years has not been matched by a commensurate, demonstrable increase in benefits to the uninsured and other vulnerable patients for whom the program was designed.

For example, the DSH metric – one of the requirements for 340B hospital eligibility does not target the 340B program’s intended patient population or even represent outpatient care, raising questions about whether the program is helping those in medically underserved areas who disproportionately lack access to primary care. According to a *Health Affairs* study on the 340B program, the program has evolved “from [a program] that serves vulnerable communities to one that enriches hospitals,”²² with the majority of DSH hospitals participating in the 340B program providing below national average levels of free and reduced cost treatment to uninsured or vulnerable patients, when compared to all hospitals.²³

In 2004, more than a decade after enactment, federal grantees accounted for 55 percent of 340B sales, and hospitals accounted for 45 percent. By 2016, grantees’ share of sales had dropped to just 13 percent while hospitals’ share of 340B sales increased to 87 percent.²⁴ Based on Apexus sales data, the clear majority of 340B sales to hospitals are to DSH hospitals, accounting for about 80 percent of 340B hospital sales.²⁵ With 45 percent of acute care hospitals participating in a

²² R. Conti, P. Bach. “The 340B Drug Discount Program: Hospitals Generate Profits by Expanding to Reach More Affluent Communities,” *Health Affairs* 33, no. 10 (2014): 1786-1792.

²³ *Ibid*

²⁴ Mathematica, *The PHS340B Drug Pricing Program: Results of a Survey of Eligible Entities*, August 2004. Apexus, 340B Health Summer Conference, July 2016; Apexus, 340B Health Summer Conference, July 2016.

²⁵ Chris Hatwig, Apexus Update, 340B Health Summer Conference, 2016

program intended for true safety-net facilities,²⁶ the eligibility criteria for DSH hospitals must be reexamined. DSH hospitals qualify for the 340B program based, in part, on their DSH adjustment percentage,²⁷ which relates to the number of Medicaid and low-income Medicare patients treated in a hospital's *inpatient* unit. MedPAC reported that it had found little correlation between hospitals' DSH adjustment percentages and whether they had high percentages of uninsured patients.²⁸

Another important issue is ensuring that 340B-eligible hospitals are true safety-net facilities. The statute requires that for private nonprofit hospitals to participate in the 340B program they must either have been formally granted governmental powers by a state or local government or have entered into a contract with a state or local government to provide health care services to low-income individuals who are not Medicare or Medicaid eligible. Meaningful eligibility standards are needed for both types of eligibility, and significantly more oversight is needed to ensure discounts are going to hospitals serving a truly indigent or vulnerable population.

Unfortunately, there is little guidance, transparency, or oversight to enforce these requirements. A recent GAO report on private hospitals' participation in the 340B program concluded, "Given the weaknesses in HRSA's oversight, some hospitals that do not appear to meet the statutory requirements for program eligibility are participating in the 340B program and receiving discounted prices for drugs for which they may not be eligible. Although HRSA has initiated some efforts to strengthen its processes for assessing hospitals' eligibility, continued growth in the number of participating hospitals and 340B-purchased drugs highlights the need for HRSA to improve its oversight processes. Assessing hospitals' eligibility is critical to safeguarding the integrity of the 340B Program."²⁹

This lack of oversight makes it difficult to ensure that these hospital contracts meet Congressional intent to serve a low-income and vulnerable patient population. The legislative history states that a private nonprofit hospital that had "a minor contract to provide indigent care which represents an insignificant portion of its operating revenues" could not qualify for the 340B program under the state and local government contract test.³⁰ Yet this requirement is not currently being enforced, an issue highlighted by GAO³¹ when it found "weaknesses in the Health Resources and Services Administration's (HRSA) oversight that may result in some hospitals receiving discounts for which they are not eligible."³²

The current eligibility criteria for hospitals' satellite facilities (so-called "child sites") further weaken the link between 340B drug discounts and delivery of benefits to needy patients.

The current 340B hospital "child site" policy is outdated, increases costs, and drives consolidation that can negatively impact patient access to care. At a minimum, 340B hospitals should be required to report how discounts are used at each of these child sites. In addition, as policymakers consider broader restructuring of hospital 340B eligibility standards to deliver more benefit to patients, the appropriate role of child sites must be addressed.

²⁶ MedPAC. Report to the Congress: Overview of the 340B Drug Pricing Program. May 2015.

²⁷ See 42 U.S.C. § 256b(a)(4)(L)-(O).

²⁸ MedPAC. Report to the Congress: Medicare Payment Policy. March 2007.

²⁹ Government Accountability Office, *340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements*, GAO-20-108, 23 (Dec. 2019).

³⁰ U.S. House of Representatives Report accompanying H.R. Rep. 102-384 (II) (1992).

³¹ Government Accountability Office. *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*. September 23, 2011.

³² Government Accountability Office. *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*. September 23, 2011.

The 340B law defines the types of hospitals that can participate in the program with particular specificity³³ but never mentions the participation of off-campus outpatient facilities associated with these hospitals. Although there is no basis in the statute for including these sites, in 1994, HRSA unilaterally issued guidance dramatically expanding 340B by permitting child sites to participate—even if they are only loosely connected to the parent hospital and without regard for whether they serve a disadvantaged population.³⁴ Child sites have become a significant source of program growth and inducement for that growth. In 1994, there were 34 child sites. By 2016, this had increased to over 15,000.³⁵

In addition to accounting for much of the 340B program’s explosive growth, the policy on hospital child sites has shifted the program away from its original goal of helping make discounted medicines more accessible for uninsured and vulnerable patients.³⁶ The authors of a 2018 *New England Journal of Medicine* Perspective on the 340B program state, “hospitals have purchased community practices in part ... to expand their footprint into wealthier neighborhoods to ‘profit’ from the 340B program.”³⁷

Evidence suggests that growth and abuse of the 340B program are creating distorted market incentives that result in shifts in care to more expensive and less convenient settings (as 340B hospitals buy up smaller facilities to generate more revenue), increases costs to commercial payers and patients (as hospitals leverage market power to demand higher prices), and ultimately raises premiums. Government reports reinforce this concern, indicating that hospitals frequently exploit the guidance on child site eligibility that has not been revisited since 1994, allowing hospitals to obtain more 340B discounts by buying community-based physician practices so that prescriptions written by those physicians then qualify for 340B discounts.

³⁸

The rampant growth in the number of 340B hospital child sites, the lack of any meaningful requirement that these clinics are a part of the parent hospital, and lack of HRSA oversight in this area are a major reason why the 340B program has become increasingly disconnected from a mission focused on serving vulnerable patients. Eligibility standards must be strengthened to focus the 340B program on this mission and should include: tightening the eligibility criteria to assess when these outpatient facilities are considered a part of a covered entity for 340B program purposes. Child sites should also be subject to the same requirements applied to the parent hospital, such as serving low-income and vulnerable patients, providing a broad range of services (not just dispensing of a drug), and if applicable, offering the same parent hospital sliding fee scale that shares 340B discounts with low-income patients. In addition, any newly considered reporting and transparency requirements should apply to both the parent hospital and individual child sites.

Rampant growth of contract pharmacy arrangements not aligned with patient benefit.

PhRMA appreciates the call for stakeholder feedback on improvements that can strengthen the 340B program, including how “contract pharmacies are an important part of the continued discussion around 340B modernization.” While contract pharmacies can help provide improved access to medicines, their role and unchecked growth in the 340B program continues to raise troubling concerns about the unfettered expansion of the 340B program. Researchers, economists, thought leaders, and Members of Congress have documented how contract pharmacy arrangements’ growth contributes to the

³³ 42 U.S.C. § 256b(a)(4)(L)-(O).

³⁴ 59 Fed. Reg. 47884, 47885 (September 19, 1994).

³⁵ HRSA OPA Database, October 2016.

³⁶ Vandervelde A, Blalock E. *340B Program Sales Forecast: 2016 – 2021*. 2016. Available at: <http://340breform.org/userfiles/December%202016%20BRG%20Growth%20Study.pdf>.

³⁷ Gellad, WF, James AE. Discounted drugs for needy patients and hospitals—understanding the 340B Debate. *New England Journal of Medicine*. 2018;378(6):501-503.

³⁸ Government Accountability Office. Medicare Part B Drugs: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals. GAO-15-442, June 2015; 59 Federal Register 47884, 47885 (September 19, 1994).

program's ballooning size without any accompanying guarantee of patient benefit.^{39,40} As respected health economist and 340B expert Rena Conti of Boston University has noted, "Here's a policy that is maximizing revenue for hospitals and contract pharmacies and perversely going against the intent of the program, which is to provide accessible and affordable health care for vulnerable people."⁴¹

Most alarming is that repeatedly, these reports show that 340B covered entities and their contract pharmacies share in 340B profits but, in most cases, do not share 340B discounts with uninsured patients at contract pharmacies.⁴² These same reports have also raised significant concerns about program integrity. Independent agencies such as the OIG and GAO have found that this vast expansion increases the risk of 340B law violations, noting that contract pharmacy arrangements create complications in preventing diversion and duplicate discounts, two practices prohibited by the 340B law. In fact, two-thirds of the diversion findings in HRSA audits for non-compliance involved drugs distributed at contract pharmacies.^{43,44}

Without providing a clear benefit to needy patients, as the 340B program was intended to do, the dramatic expansion of contract pharmacy arrangements into the for-profit, retail pharmacy sector represents an unreasonable and unnecessary risk to program compliance. Any potential policy discussions must seriously examine the role contract pharmacies should play in a program that has grown significantly over the past ten years without any accountability for helping patients access the medicines they need.

Promulgated under HRSA guidance, contract pharmacy arrangements lack the force and effect of law.

Under the 340B law, manufacturers must offer each qualifying covered entity "covered outpatient drugs" for purchase at or below a deeply discounted price (statutorily defined as the "340B ceiling price"). When the program began, covered entity providers were able to access the discounts for medicines used to treat their patients. However, certain entities may have lacked the operational capacity to provide retail medicines through an on-site pharmacy – such as not having adequate inventory space to store the medicines or the staff and pharmacy license to dispense the 340B purchased medications to the vulnerable patients they served.

To accommodate those entities that could not house an on-site pharmacy HRSA issued guidance in 1996 allowing a covered entity *without* their own in-house pharmacy to enter into an agreement with *one* contract pharmacy ("contract pharmacy arrangement") to dispense covered outpatient drugs to the 340B patient on behalf of the covered entity.⁴⁵ This is referred to as a 'ship-to-bill-to' model, whereby the covered entity is invoiced for the 340B medicine, but the manufacturer is directed by the covered entity to ship the drug to a designated contract pharmacy for dispensing to an eligible patient.

In 2010, through updated guidance, HRSA dramatically expanded the use of contract pharmacies by allowing any covered entity (including covered entities *with* an in-house pharmacy) to contract with an *unlimited* number of contract

³⁹ Hayes, Tara. Market Distortions Caused by the 340B Program. American Action Forum. November 2017.

⁴⁰ Energy and Commerce Committee. Report of the 340B Drug Pricing Program. January 2018. https://republicans-energycommerce.house.gov/wp-content/uploads/2018/01/20180110Review_of_the_340B_Drug_Pricing_Program.pdf

⁴¹ Karlin-Smith, Sarah. Perverse Incentives? Why some 340B pharmacies are opting for branded drugs. July 2018. <https://www.politico.com/newsletters/prescription-pulse/2018/07/02/perverse-incentives-why-some-340b-pharmacies-are-opting-for-branded-drugs-268802>

⁴² Government Accountability Office. "Drug Pricing: Manufacturing Discounts In The 340B Program Offer Benefits, But Federal Oversight Needs Improvements", GAO-11-836, September 2011.

⁴³ HHS Office of Inspector General, "Contract Pharmacy Arrangements in the 340B Program," February 2014.

⁴⁴ Government Accountability Office, "Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement," GAO-18-480: Jun 28, 2018.

⁴⁵ 61 FR 43549, August 23, 1996

pharmacies,⁴⁶ regardless of whether the “covered entity” had an in-house pharmacy. Today, there are well over 100,000 contract pharmacy arrangements⁴⁷, but this change did nothing to ensure that 340B patients benefit from this expansion. A 2014 OIG report found that most covered entities in their study *did not* ensure that they passed 340B discounts back to uninsured patients who filled their prescriptions at a contract pharmacy.⁴⁸ That same report noted it is not uncommon that “uninsured patients pay the full non-340B price for their prescription drugs at contract pharmacies.” This means such uninsured or vulnerable patients did not benefit from manufacturer discounts on 340B drugs dispensed at contract pharmacies.

Instead, the 2010 guidance has raised significant concerns from multiple stakeholders that the exponential growth of contract pharmacies without appropriate safeguards creates complications in preventing diversion and duplicate discounts, in which manufacturers pay twice on the same prescription claim (a 340B discount and a rebate).^{49, 50} It is important to note that the term “contract pharmacy” is not mentioned in the 340B law or in any regulations. Agency guidance such as the 2010 contract pharmacy guidance cannot impose any binding requirements on the public and lacks the force and effect of law.

Growth of contract pharmacy arrangements without appropriate safeguards has contributed to a lack of clear patient benefit.

Since HRSA updated its guidance in 2010, contract pharmacy participation has skyrocketed, growing by more than 4,000%.⁵¹ This growth rate may not necessarily cause concern if the growth correlated with an expansion in discounted medicines for vulnerable and indigent patients. However, despite the explosion in contract pharmacy arrangements, there is little evidence to suggest patients have benefited from contract pharmacy growth—in fact, contract pharmacies may often charge patients a drug’s full retail price.⁵² There are no HRSA requirements that covered entities reinvest any portion of their 340B-generated revenue into patient care or report how these profits are used to benefit uninsured or vulnerable patients. As a result, there is little to no insight into whether those profits are invested in caring for underserved patients or whether 340B patients are actually receiving the benefit of the 340B discount at contract pharmacies today.

Without standardized requirements for a specific designation of a 340B-eligible prescription or some clear patient identifier, contract pharmacies generally do not know which individuals are 340B patients when they fill their prescriptions. Unlike at a covered entity’s on-site pharmacy, a prescription filled at a contract pharmacy oftentimes is not identified as being eligible for 340B discounts until after the prescription is filled.⁵³ In such cases, it is difficult, if not impossible, for uninsured or vulnerable patients to benefit directly from the discounts. In addition, this lack of identifier creates a large risk of diversion and duplicate discounts. The OIG has confirmed that contract pharmacies are typically unable to determine who is eligible for 340B discounts at the time a prescription is filled.⁵⁴

Current unlimited use of contract pharmacies diverts savings from the 340B program to for-profit pharmacies and other middlemen, threatening the safety-net.

⁴⁶ 75 FR 10272, March 5, 2010

⁴⁷ BRG Analysis of HRSA OPA Database, August 2020.

⁴⁸ HHS Office of Inspector General, “Contract Pharmacy Arrangements in the 340B Program,” Feb. 2014.

⁴⁹ Government Accountability Office. “*Drug Pricing: Manufacturing Discounts In The 340B Program Offer Benefits, But Federal Oversight Needs Improvements*”, GAO-11-836, September 2011.

⁵⁰ Government Accountability Office. “*340 Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement*,” GAO-20-212, January 2020.

⁵¹ Berkeley Research Group: For-Profit Pharmacy Participation in the 340B Program. October 2020. https://media.thinkbrg.com/wp-content/uploads/2020/10/06150726/BRG-ForProfitPharmacyParticipation340B_2020.pdf

⁵² Conti, Rena M., and Peter B. Bach. “Cost consequences of the 340B drug discount program.” *JAMA* 309.19 (2013): 1995-1996.

⁵³ Ibid.

⁵⁴ HHS Office of Inspector General, “*State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates*”, June 2016.

Contract pharmacies are dominated mainly by for-profit, retail pharmacies with whom covered entities partner to dispense 340B medicines. The contract pharmacy and the covered entity may share the profit generated from the “spread” between a drug’s third-party reimbursement and the covered entity’s 340B acquisition cost^{55,56} with no guarantee that patients benefit from the 340B discount. Depending on their agreements with covered entities, contract pharmacies can also generate higher returns by dispensing more 340B prescriptions compared to non-340B prescriptions. The average profit margin on 340B medicines commonly dispensed through contract pharmacies (i.e., reimbursement rate for the drug minus its acquisition cost to the covered entity) is an estimated 72% compared with a margin of 22% for non-340B medicines dispensed through independent pharmacies.⁵⁷

Although there are more than 27,000 distinct pharmacy locations that participate in the 340B program, over half of the 340B profits retained by contract pharmacies are estimated to be concentrated in just three pharmacy chains – Walgreens, Walmart, and CVS Health -- and Cigna’s Accredo specialty pharmacy.⁵⁸ An entire cottage industry of 340B supply chain “middlemen” consisting of for-profit pharmacies, covered entities’ third-party administrators (TPAs), and consultants that seek to maximize 340B dispensing has also come into existence since 2010.⁵⁹ They financially benefit from 340B drug utilization and the 340B “spread,” with no obligation to report what they do with the revenue. For example, one vendor that provides 340B software states in its education materials for pharmacies that “the covered entities are allowed to use the benefit of these substantial [340B] savings in any way they choose. There is no requirement to pass the savings on to patients directly.”⁶⁰ The fact that large chain pharmacies (which may be owned by health plans or PBMs) often serve as contract pharmacies raises questions about whether these “middlemen” are diverting resources from the 340B program’s intended purpose of assisting low-income or vulnerable patients.

Policymakers are correct to be concerned about the rampant growth of contract pharmacies. We strongly encourage a deep and thorough examination by an independent agency that could inform future policy discussions. Any new policy must consider what role contract pharmacies should play in a program that has grown significantly over the past ten years and with little to no guaranteed benefit to patients.

Current mechanisms to identify and prevent duplicate discounts and diversion are ineffective.

The 340B law creates an absolute prohibition on duplicate discounts, which prohibits covered entities from purchasing a drug at a 340B discount that also generates a Medicaid rebate.⁶¹ Despite this straightforward statutory imperative, current prevention methods are insufficient to address the duplicate discounts that persist throughout the 340B program. HRSA covered entity audit data from FY2017 show that two-thirds of all DSH hospitals audited were non-compliant

⁵⁵ MedPAC Report to Congress. Overview of the 340B Drug Pricing Program. May 2015.

⁵⁶ Fein, A. How Hospitals and PBMs Profit – and Patients Lose – from 340B Contract Pharmacies. July 2020. Available at: <https://www.drugchannels.net/2020/07/how-hospitals-and-pbms-profitand.html>

⁵⁷ Berkeley Research Group: For-Profit Pharmacy Participation in the 340B Program. October 2020. https://media.thinkbrg.com/wp-content/uploads/2020/10/06150726/BRG-ForProfitPharmacyParticipation340B_2020.pdf

⁵⁸ Berkeley Research Group: For-Profit Pharmacy Participation in the 340B Program. October 2020. https://media.thinkbrg.com/wp-content/uploads/2020/10/06150726/BRG-ForProfitPharmacyParticipation340B_2020.pdf

⁵⁹ The link has been taken down, but it was previously at <http://www.linkedin.com/pub/timothy-hong/28/651/511>; Senator Charles Grassley, Letter to Walgreens CEO Gregory Watson, July 21, 2013. Available at: http://www.pembrokeconsulting.com/pdfs/Grassley_340B_Letter_to_Walgreens_31July2013.pdf; http://www.talyst.com/wp-content/uploads/Talyst_White_Paper_Benefit_Becoming_Contract_Pharmacy.pdf

⁶⁰ Talyst, “Benefits to Becoming a Contract Pharmacy: Answering the pharmacist’s questions regarding 340B Contract Pharmacy,” available at: http://www.talyst.com/wp-content/uploads/Talyst_White_Paper_Benefit_Becoming_Contract_Pharmacy.pdf (accessed August 2020).

⁶¹ Sec. 340B PHSA(a)(5)(i).

in at least one area, and many were non-compliant in multiple areas, including duplicate discounts and diversion.⁶² However, it does not appear that HRSA uses audit violations as the basis for enforcement actions against covered entities. At least one Congressional committee found little evidence of strong agency oversight, citing that “HRSA rarely terminates covered entities from 340B through the audit process.”⁶³

Although 340B/Medicaid duplicate discounts are statutorily prohibited, a drug with a negotiated commercial or Medicare Part D rebate can also be subject to a 340B discount due to the lack of appropriate mechanisms to identify 340B-eligible claims. As a result, manufacturers could end up paying a 340B discount and a plan/PBM rebate on the same claim. While some manufacturers may include provisions in their contracts with commercial plans that drugs purchased through the 340B program are not eligible for rebates to the health plan, in practice, these contract terms are difficult to operationalize and enforce without a 340B claims identifier required to be tagged consistently throughout claims processing and rebate invoicing. The 340B program is already growing; if manufacturers are forced to pay a rebate on a medicine that was already purchased at a large discount, this likely compounds the distortive impact that economists say that 340B discounts already have on prescription medicine prices.⁶⁴

There are no program requirements on PBMs or contract pharmacies to identify 340B claims properly, and some of the profit-driven motives previously mentioned could have unintended affordability consequences for patients.⁶⁵ Complications with duplicate discounts are magnified by a convergence of lax agency oversight and marketplace dynamics related to the expansion of Medicaid rebates for medicines used by Medicaid Managed Care Organization (MCO) enrollees since 2010. Today, Medicaid rebates cover an even larger population due to Medicaid expansion and the extension of rebates to Medicaid MCO enrollees. However, to date, the only mechanism HRSA has developed to prevent duplicate discounts (the Medicaid Exclusion File) expressly excludes Medicaid managed care utilization. HRSA has stated that it “recognizes the need to address covered entities’ role in preventing duplicate discounts under Medicaid Managed Care and is working with CMS to develop policy in this regard.”⁶⁶ However, neither HRSA nor CMS has developed mechanisms to address this issue despite what the statute requires.⁶⁷

A 2018 GAO report found that because HRSA only assesses the potential for duplicate discounts in fee-for-service and not MCOs, “[u]ntil HRSA develops guidance and includes an assessment of the potential for duplicate discounts in Medicaid managed care as part of its audits, the agency does not have an assurance that covered entities’ efforts are effectively preventing non-compliance). This lack of guidance leaves a critical gap in enforcing the law’s duplicate discount ban as about 56 million Americans are covered by Medicaid managed care plans. Half of all Medicaid spending on prescription medicines was through MCOs in 2014,⁶⁸ and that share has likely increased in recent years.

⁶² HRSA OPA Database Program Integrity FY17 Audit Results. March 6, 2018.

⁶³ Energy & Commerce Committee’s “Review of the 340B Drug Pricing Program.”

⁶⁴ Conti R, Rosenthal M. Pharmaceutical Policy Reform — Balancing Affordability with Incentives for Innovation. *N Engl J Med*. 2016;374:703-706.; Conti R, Bach P. Cost Consequences of the 340B Drug Discount Program. *JAMA*. 2013;309(19):1995-1996.

⁶⁵ Drug Channels. How Hospitals and PBMs profit – and Patients lose - from 340B Contract Pharmacies. July 23, 2020. <https://www.drugchannels.net/2020/07/how-hospitals-and-pbms-profitand.html>

⁶⁶ HRSA, 340B Drug Pricing Program Release No. 2014-1 (Dec. 12, 2014). The Medicaid Exclusion File mechanism requires that 340B covered entities either “carve in” (provide 340B drugs to Medicaid patients and report this practice to HRSA, so that these entities are listed on the Exclusion File and State Medicaid programs do not bill manufacturers for rebates on drugs furnished by these entities) or “carve out” (do not provide 340B drugs to Medicaid beneficiaries, so that drugs supplied by a 340B entity to a Medicaid patient triggers a Medicaid rebate, but not a 340B discount). Under the 2014 guidance, this mechanism no longer applies to prevent double discounts on 340B drugs provided to MCO beneficiaries.

⁶⁷ 42 USC 256b(a)(5)(A)(ii) and 256b(d)(2)(B)(iii).

⁶⁸ KFF, “Total Medicaid Managed Care Enrollment, 2014” available at: <https://www.kff.org/medicaid/state-indicator/total-medicaid-mc-enrollment/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D> (accessed March 11,

In January 2020, the Centers for Medicare & Medicaid Services (CMS) issued an information bulletin to states to encourage them to consider best practices to avoid duplicate discount violations in state Medicaid programs. In that informational bulletin, CMS notes, “340B duplicate discounts can often best be identified from a review of claims level data by manufacturers.”⁶⁹ While this is an encouraging development, neither HRSA nor CMS has developed effective policies nor required covered entities to adopt practices to prevent these statutory violations in the 340B program. The result can be lengthy and costly audits and disputes for both manufacturers, state Medicaid agencies, and covered entities.

In identifying the top unimplemented recommendations to reduce fraud and abuse in HHS programs, OIG has stated, “CMS and HRSA should ensure that States can pay correctly for 340B-purchased drugs billed to Medicaid, by requiring claim-level methods to identify 340B drugs and sharing the official 340B ceiling prices”.⁷⁰ The sharing of basic claims level data can help ensure 340B discounts are being properly applied, ensuring all stakeholders are operating in a compliant manner, and patients are able to benefit in the way the program is intended. PhRMA appreciates that the Energy and Commerce Committee has identified the prevention of duplicate discounts, particularly in Medicaid Managed Care, as a priority area that HRSA and CMS need to address.⁷¹ We look forward to working with stakeholders on identifying solutions to prevent duplicate discounts, strengthen the 340B program, and reduce market distortions exacerbated by manufacturer rebates paid on commercial or Part D drugs that also received 340B discounts.

340B program improvements in several key areas are needed to ensure the program fully benefits vulnerable patients.

PhRMA appreciates your leadership in advancing a broad assessment of the 340B program and the degree to which it could achieve the goal of delivering clinical and affordability benefits to vulnerable patients. Better oversight and administration of the program are foundational for ensuring that it can serve the patients for whom it was created. Failures in program transparency, integrity, eligibility, and sustainability standards have contributed to the lack of focus on the vulnerable, needy patients the program was created to serve. Insufficient guidance, historically weak program oversight, and other areas of insufficient program administration have led to dramatic program growth without a commensurate delivery of benefits to low-income and vulnerable patients.

PhRMA believes that the significant discounts biopharmaceutical manufacturers provide under the 340B program should serve a targeted purpose—helping low-income uninsured and other vulnerable patients obtain the outpatient medicines they need—and all covered entities qualifying for the program should be accountable for using its benefits properly. However, changes in critical areas of the program would help provide the integrity, oversight, and transparency that are urgently needed to put it on a sustainable footing for the long-term and, most importantly, ensure it is doing all it can to support patients most in need. For these reasons, we agree that “changes are long overdue,” and meaningful program realignment must be pursued to increase transparency and accountability in the 340B program.

2018); MACPAC, “Medicaid Spending for Prescription Drugs,” January 2016. Available at: <https://www.macpac.gov/wp-content/uploads/2016/01/Medicaid-Spending-for-Prescription-Drugs.pdf>.

⁶⁹ CMCS Informational Bulletin. “Best Practices for Avoiding 340B Duplicate Discounts in Medicaid.” January 2020. Available at: <https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/cib010820.pdf>

⁷⁰ HHS Office of Inspector General. OIG’s Top Unimplemented Recommendations: Solutions to Reduce Fraud, Waste and Abuse in HHS Programs. August 2020. <https://oig.hhs.gov/reports-and-publications/compendium/files/compendium2020.pdf>

⁷¹ Energy and Commerce Committee. Review of the 340B Drug Pricing Program. January 2018. https://republicans-energycommerce.house.gov/wp-content/uploads/2018/01/20180110Review_of_the_340B_Drug_Pricing_Program.pdf

PhRMA reiterates our support for the 340B program. We are committed to working with Congress, the Administration, and other program stakeholders to develop patient-focused policy solutions for the sustainability and success of this essential safety-net program. Thank you for the opportunity to comment.

Sincerely,

A handwritten signature in cursive script, appearing to read "Stephen J. Ubl".

Stephen J. Ubl
President & Chief Executive Officer