NATIONAL ASSOCIATION OF Community Health Centers

August 7, 2020

Mr. Phillip Rinnander
Executive Director, Finance
Customer Contract Management
Merck Sharpe & Dohme Corp.

Dear Mr. Rinnander,

On behalf of our nation's 1400 Federal Qualified Health Centers (FQHCs, or health centers) and the nearly 30 million medically-underserved patients they serve, I am writing to express my serious concerns about your request for data on 340B-priced drugs dispensed to health center patients via contract pharmacies. I am also requesting a meeting to discuss alternative approaches for avoiding duplicate discounts, as well as strategies to prevent third parties from accessing the financial benefits of the 340B discounts intended for health centers.

Background on FQHCs and 340B Program Integrity:

FQHCs are the backbone of the nation's primary care safety net. As mission-driven organizations, FQHCs intentionally seek to care for medically-underserved and vulnerable populations, and to ensure that these individuals can access affordable, high-quality health care regardless of their ability to pay. With roughly 14,000 sites nationally, FQHCs care for nearly 30 million vulnerable individuals, including persons experiencing homelessness, migrant and seasonal farmworkers, and resident of public housing. Nationally, one of every three persons living in poverty and one of every five persons in rural areas receives care from their local FQHC.

Each FQHC is governed by its own patients. Almost 70% of FQHC patients have incomes below the Federal Poverty Level (FPL); if uninsured or underinsured, these individuals pay no more than a nominal fee for health care services. Another 23% of FQHC patients have incomes between 101% and 200% FPL; if uninsured or underinsured, they are charged based on a sliding fee scale. Almost one-quarter of FQHC patients have no insurance, and almost half have Medicaid. As small, community-based organizations, FQHCs lack the negotiating power possessed by many other entities involved the health care. As a result, the discounts provided by the 340B program are critical to FQHCs' ability to offer their patients access to affordable pharmaceuticals and other services.

Across the nation, FQHCs are committed to being good stewards of the 340B program. By law, regulation, and mission, every penny that health centers save through 340B discounts is used either to make medication affordable for low-income patients, or to support other activities that expand access to care for their medically-underserved patient population. Members of

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Congress from both parties have repeatedly highlighted FQHCs as excellent stewards of the 340B program, praising them for using 340B savings as Congress intended — "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." We cannot overstate how vitally important such discounts are to FQHCs' efforts as health centers battle COVID-19 on the frontlines of hot zones across America.

As part of their stewardship of this critical program, FQHCs are committed to avoiding both diversion and duplicate Medicaid discounts. Their proactive efforts to prevent diversion and duplicate Medicaid discounts from ever occurring include:

- Implementing policies and procedures designed to prevent diversion and duplicate Medicaid discounts, based on guidance from Apexus.
- Collaborating with State Medicaid agencies, managed care organizations, and contract pharmacies to develop and adopt measure to avoid duplicate Medicaid discounts.
- Hiring third-party administrators with expertise in avoiding diversion and duplicate discounts to administer their 340B programs. For example, TPAs can block all Medicaid claims unless the state has provided guidance on avoiding duplicate discounts.
- Training staff on compliance information provided by HRSA, Apexus, and NACHC (e.g., the NACHC 340B Manual for Health Centers)
- Participating in monthly national webinars on 340B compliance, and/or in-person compliance trainings held at least four times a year at the national level.

In addition to these proactive measures, FQHCs also engage in several retrospective activities to identify and correct any diversion or duplicate discounts that may have occurred. These efforts include:

- Regular self-audits (either monthly or quarterly, depending on the health center)
- Annual external audits.
- Making good faith efforts to voluntarily collaborate with state and private (e.g., Kalderos) efforts to identify duplicate Medicaid discounts.

As an added layer of program integrity, FQHCs are also subject to:

- HRSA 340B audits
- Manufacturer audits, provided that the manufacturer has demonstrated reasonable cause and received HRSA prior approval of their audit work plan.

With this background about FQHCs' on-going commitment to 340B program integrity, we will now outline our concerns about your data requests, first addressing Medicaid and then Medicare and commercial insurance.

Data on Drugs Dispensed to Medicaid Patients

As good stewards of the 340B program, FQHCs are committed to doing their part to prevent duplicate discounts on drugs dispensed to Medicaid patients. As outlined above, FQHCs currently engage in a range of efforts designed to prevent and rectify such duplicate discounts, including – but not limited to -- making good faith efforts to cooperate with outside organizations who share the same program integrity goal. However, Merck's recent request for data on Medicaid drugs would require much more than a "good faith effort" on the part of FQHCs, for the following reasons:

1. **Merck is placing the same expectations on all 340B providers, without consideration of providers' commitment to program integrity or specific evidence of duplicate discounts.** Merck is making the identical request of every 340B provider in the country, regardless of what types of program integrity protections they have in place, or whether they have ever been found to have been involved in duplicate discounts. To the extent that duplicate discounts with Medicaid might be occurring, they are likely to be concentrated among specific providers, provider types, and/or states. Merck's one-size-fits-all approach is unfair to FQHCs and other providers who have strong histories of compliance and who utilize rigorous systems to ensure program integrity.

2. **The amount of data being requested is massive, and would constitute a significant administrative burden for FQHCs.** Merck's request for Medicaid data far exceeds what can be considered a "good faith effort". As you know, Merck is requesting bi-weekly reports on every 340B-priced Merck drug dispensed to every Medicaid patient at every contract pharmacy associated with every FQHC in the country. While uploading this data to the ESP portal may be relatively easy, collecting it would be a major undertaking for FQHC pharmacy staff.

3. **The requested data would give Merck a competitive advantage.** The requested data would provide Merck with valuable insights into which drugs are prescribed, by whom, where, and when -- insights that would certainly be useful from a competitive perspective. Given the breadth and one-size-fits-all nature of Merck's request, it seems reasonable to assume that the data will be used in this fashion. It is inappropriate to ask an FQHC to undertake onerous reporting processes to provide data that will be used for competitive purposes, particularly without documented evidence that the FQHC was involved with duplicate Medicaid discounts.

As previously stated, FQHCs remain willing to engage in "good faith efforts" to identify and rectify duplicate Medicaid discounts, and we would be happy to discuss less burdensome and more targeted ways that FQHCs could collaborate with Merck to achieve this goal. However, it is not appropriate to ask FQHCs to engage in an onerous reporting process to hunt for potential duplicate Medicaid discounts when there is no evidence or history to suggest that they are responsible for such discounts -- and when their efforts will provide a competitive advantage to the organization demanding the data.

Data on Drugs Dispensed to Medicare and Commercially Insured Patients

Your letter states that Merck wants to "ensure it isn't paying… duplicate discounts on Medicare Part D and commercial utilization". We read this statement as indicating that you do not want to pay voluntary discounts to Pharmaceutical Benefits Managers (PBMs) for drugs purchased under 340B.

We have two concerns about the request for data on Medicare and commercial insured patients. Unlike in the Medicaid program, the rebates that Merck provides to PBMs for Medicare Part D and commercial drugs are purely voluntary; they are not required under 340B or any other statute. As such, there are no 340B program integrity issues involved with these rebates, and FQHCs are under no obligation to support Merck's efforts to avoid paying them. It is inappropriate to expect FQHCs to engage in an onerous reporting process to provide Merck with data that will be used for its financial gain, independent of any 340B requirements.

Our second -- and more important concern -- is that providing this data will accelerate the difficulties that FQHCs already face in "holding onto" the discounts that Congress intended (and drug manufacturers provide) for them. In recent years, FQHCs have faced a dramatic and worrisome expansion of what we call "discriminatory contracting." This term refers to contracting practices used by third parties, such as PBMs and insurers, to effectively transfer the benefit of 340B savings from the FQHC to themselves. For example, a PBM will pay the FQHC significantly less for a drug simply because it was purchased under 340B than they would otherwise. In this way, the benefit of the 340B discount is transferred from the FQHC to the PBM.

The expansion of discriminatory contracting under 340B is a major concern for FQHCs across the country, as it is rapidly eroding their ability to retain the benefit of 340B discounts, and in turn, their ability to affordable pharmaceutical and other services to their low-income patients. Unfortunately, at present there are no legal restrictions that prevent PBMs (or other groups) from engaging in discriminatory contracting. Our concern is that if Merck uses data submitted by FQHCs to reduce rebates to PBMs, the PBMs will make up for the shortfall by reducing reimbursement to the FQHCs. As a result, Merck will still be providing 340B discounts, but FQHC will no longer be benefitting from them. In other words, complying with Merck's request for data on Medicare and commercial patients will undermine the benefit of the 340B program for FQHCs, threatening their on-going ability to offer affordable pharmaceuticals and other services for their low-income, medically-vulnerable patients.

Request to Meet to Discuss Alternative Approaches

My staff and I would welcome an opportunity to discuss alternative approaches that could meet Merck's needs without further eroding FQHCs' ability to retain 340B savings , or placing undue burdens on their staff. For example, we have several ideas around duplicate Medicaid discounts that we would be happy to share, and we would appreciate your insights on how to address discriminatory contracting. To schedule a meeting, or to request further information, please contract NACHC's Chief Strategy Officer, Steve Carey, at scarey@nachc.org, or our Senior Policy Advisor, Colleen Meiman, at cmeiman@nachc.org.

Sincerely,

Tom Van Coverden

TOM VAN COVERDEN
President & CEO