Ryan White Clinics for 340B Access

August 12, 2020

VIA EMAIL TO: Phil_Rinnander@merck.com

Phil Rinnander
Executive Director, Finance
Customer Contract Management
Merck Sharp Dohme Corp.
P.O. Box 1000
New Wales, PA 19454-2505

Dear Mr. Rinnander,

I am writing on behalf of Ryan White Clinics for 340B Access (RWC-340B) in response to your letter dated June 29, 2020 to many of our members regarding participation in the 340B ESP™ program. RWC-340B supports Merck's goal of identifying 340B claims to avoid duplicate discounts on Medicaid claims and therefore wants to cooperate with Merck in that effort. RWC-340B has concerns, however, about the scope of the 340B ESP™ program, the program's "Terms of Use" and whether its members will be able to comply with Merck's data request in accordance with federal and state privacy laws.

RWC-340B is a national organization of HIV/AIDS health care providers that receive funding under the Ryan White CARE Act, either through a primary grant or subgrant, and participate as covered entities in the federal 340B program.[1] Ryan White clinics (RWCs) are at the front lines of caring for low-income and vulnerable patients suffering from HIV/AIDS. RWCs are highly dependent on the 340B program to support its mission of providing care to underserved populations. Without access to the discounted pricing available through the 340B program, RWCs would be forced to provide fewer services and/or serve fewer patients. RWC-340B members are therefore committed to doing their part to protect the integrity of the program. Among other things, RWC-340B members have established safeguards within their clinics to protect against duplicate discounts and routinely perform self-audits to ensure those safeguards are working.

RWC-340B has carefully reviewed Merck's 340B ESP™ program and consulted legal counsel about the potential risks of participating in the program. We have concluded that the program raises several legal issues that need to be carefully addressed and resolved before our members can safely enroll. RWC-340B is ready to discuss these issues with Merck with the hope that the parties can reach agreement on how best to resolve them. Set forth below is a brief summary of RWC-340B's concerns.

[1] Many RWC-340B members also participate in the 340B program as sexually transmitted disease clinics, federally qualified health centers (FQHCs) and FQHC look-alikes.

Request for Non-Medicaid Claims Data

Merck's request for data on claims submitted to Medicare Part D and private insurers falls outside the scope of the 340B program. The 340B statute protects a manufacturer from paying duplicate discounts on Medicaid fee-for-service claims. The Medicaid drug rebate statute protects a manufacturer from paying duplicate discounts on claims submitted to a Medicaid managed care organization (MCO). Neither statute protects a manufacturer from paying a rebate to a Medicare Part D or private insurance plan for a 340B drug provided to those categories of plans. To the extent Merck is protected from paying a rebate, or paying a fuller rebate, to Medicare Part D or private insurance plans for 340B drug claims, those protections are purely contractual in nature and do not involve 340B covered entities. RWC-340B recognizes that covered entities are responsible for preventing duplicate discounts on Medicaid fee-for-service claims. With respect to Medicaid MCO claims, RWC-340B members are willing to work with Merck, the state Medicaid agency, and the Medicaid MCO plans to avoid duplicate discounts.[2] We do not, however, believe that our members have any obligation to help Merck or any other manufacturer protect itself from duplicate discounts involving Medicare Part D or commercial plans.

We note that a manufacturer is permitted to audit the records of a 340B covered entity that "directly pertain to the entity's compliance with the requirements" of the duplicate discount and diversion prohibitions.[3] Manufacturers do not have the right to audit covered entities with respect to duplicate discounts that are related to Medicare Part D or private insurance claims. RWC-340B members cooperate with good faith inquiries from manufacturers related to the prohibition on duplicate discounts and diversion because they are committed to supporting the integrity of the 340B program. We also recognize a manufacturer's right to conduct a more formal audit under the statutory provision above. But again, Merck's request for claims data far exceeds the bounds of a good faith inquiry because the Medicare Part D and private insurance claims could not be the precursor to a more formal audit.

RWC-340B also has concerns that the data will be used by private payers as fodder to support reimbursement practices that discriminate against covered entities and their contract pharmacies. Private payers are increasingly offering payment rates to covered entities and their pharmacies that are far less than the rates paid for drugs that are purchased outside the 340B program. Some private payers have even suggested reducing reimbursement rates for all retail drugs purchased by covered entities regardless of whether the drugs were purchased through the 340B program or not. The benefit of the 340B program is intended for the safety net providers that meet the eligibility requirements set forth in the 340B statute, not private payers. RWC-340B is extremely wary of any effort or program that could be used to support discriminatory reimbursement practices by payers. We appreciate the importance of privately-negotiated manufacturer rebate arrangements with Part D and private plans because these arrangements are used to generate preferred placement on the plans' formularies. But formulary placement is strictly a business issue between the manufacturer and payer. It is not an issue that is necessarily within the interests of covered entities and their patients, let alone an issue requiring covered entities' support and involvement.

[2] The burden of protecting manufacturers from Medicaid MCO duplicate discounts falls on the state Medicaid agency, not the covered entity. So, although covered entities have a role to play, ultimate responsibility for avoiding MCO duplicate discounts lies with the state.

[3] 42 U.S.C. § 256b(a)(5)(C). The requested claims data does not implicate the prohibition against diversion.

Potential Exposure Under HIPAA and Other Federal and State Privacy Laws

The Health Insurance Portability and Accountability Act (HIPAA) privacy rule governs the use and disclosure of protected health information (PHI) held by health plans, health care clearinghouses, and any health care provider that transmits health information in an electronic form.[4] RWCs are governed by HIPAA and, as a result, are responsible for maintaining the privacy and security of their patients' PHI and could incur significant liability if a breach were to occur. We are therefore concerned about the kind of data being requested for the 340B ESP™ platform and the potential implications that may arise should PHI be inadvertently used, disclosed, or accessed.

Based on our preliminary review of the 340B ESP™ Terms of Use[5] and Expert Determination report[6], it is our understanding that data entered by RWC-340B will be de-identified through a HIPAA-compliant hashing process and will have an additional layer of security called a "salt" that will be applied prior to any data being uploaded to 340B ESP™.[7] RWC-340B appreciates that Second Sight, the owner of the 340B ESP™ software program, has already considered some of the potential HIPAA implications of the ESP™ data request and has taken steps to ensure that data submitted by the covered entity to the 340B ESP™ platform will be de-identified in a HIPAA-compliant manner. We also recognize that once the data is de-identified, it is no longer subject to HIPAA.[8] However, RWC-340B is concerned that its members will be held completely accountable for a HIPAA breach if the hashing process fails, or if the 340B ESP™ platform is somehow compromised, resulting in PHI being improperly used, disclosed, or accessed.

HIPAA data breaches expose health care providers to serious financial, legal, and reputational harm. Hence, it is extremely important that RWC-340B members fully understand the risk of submitting PHI (including de-identified PHI) and alleviate any of the potential liability in the case of a breach. Currently, the Terms of Use for the 340B ESP™ program do not provide participants with any protections for potential technological failures or negligent actions of either Second Sight or Merck. Adding such protections to the Terms of Use would provide RWC-340B members with greater comfort when responding to the 340B ESP™ data request and submitting our patients' PHI.

Furthermore, participation in the 340B ESP™ program could expose RWC-340B members to liabilities under other federal and/or state privacy laws should there be any inadvertent or improper disclosure of PHI. HIPAA provides baseline requirements governing the disclosure of health information. Other federal and state privacy laws require health care providers to obtain additional consent before disclosing a patient's health information. They may also impose another layer of notification and remediation requirements should health information be improperly exposed.[9] RWC-340B members

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[4] 45 C.F.R. § 164.104.

[5] 340B ESP™ Terms of Use, last updated June 2020, available at https://340besp.com/terms-of-use#section1.

[6] B. Malin, *Expert's Assessment of Second Sight 340B ESP™ De-identification Procedure*, July 9, 2020.

[7] *See also* 340B ESP™ Frequently Asked Questions, Data Security and Technical Specifications, available at https://340besp.com/faqs#section3.

[8] 45 C.F.R. § 164.502(d).

[9] E.g., 42 C.F.R. Part 2 imposes restrictions on the use and disclosure of certain substance use disorder patient health records. The Minnesota Medical Records Privacy Act requires health care providers obtain patient permission before disclosing health information, even for treatment purposes. (*see* Minn. Stat. 144.293). New York's data security protections laws impose additional risk mitigation requirements on health care providers in regard to inadvertent disclosures. (*see* N.Y. Gen. Bus. Law§ 899-aa). Health care providers in New York are also required to notify state officials should a breach of private information occur. (*Id*.).

therefore need to consider not only the HIPAA implications of Merck's data request, but also the more stringent privacy laws with which health care providers must sometimes comply when handling their patients' PHI.

It is our understanding that Merck will not enter into a business associate agreement with covered entities that elect to participate in the 340B ESP™ program. Because covered entities that register for 340B ESP™ are doing so voluntarily, RWC-340B requests that Merck and Second Sight indemnify RWC-340B members for any breach of PHI that is caused by the negligent actions of Merck or Second Sight. We would also expect Merck to pay its proportionate share of the costs associated with any notification to affected individuals and any fines and/or administrative penalties imposed for such breach or for delayed reporting. RWC-340B believes that this is an eminently reasonable request in light of Merck's expectation that RWC-340B members rely on the Second Sight de-identification process to protect them from a HIPAA breach or other federal or state privacy law violations.

Terms of Use Put Covered Entities at a Severe Disadvantage

RWC-340B is concerned that the 340B ESP™ Terms of Use put covered entities at a severe disadvantage and expose covered entities to undue risk. An over-riding concern is with the one-sided indemnification provision. We noted above our concerns under HIPAA related to the indemnification provision. As you know, however, the indemnification provision covers a broad range of potential liabilities and protects Second Sight and its directors, officers, managers, employees, agents, representatives, successors and assigns. It also requires the covered entity to "assume control of the defense and settlement" of any claims against Second Sight, and pay all costs associated with that defense, including attorneys' fees.[10] The Terms of Use do not include any indemnification from Second Sight to a covered entity. As such, RWC-340B finds it unfair to its members that voluntarily register for 340B ESP™ to agree to an indemnification provision that is not mutual.

As another example, the Terms of Use state that the covered entity represents and warrants that the 340B contract pharmacy claims uploaded to the 340B ESP™ website are "complete and accurate, and follow the format and instructions provided within the Portal."[11] Furthermore, the covered entity must agree that "Second Sight assumes no responsibility or liability for any errors in the data received from [the covered entity], nor shall Second Sight be responsible under any circumstance

for any such errors in the data, regardless of the cause thereof."[12] RWC-340B members cannot be expected to agree that Second Sight is not responsible for any errors in the data regardless of whether Second Sight caused the errors. This is especially problematic given the fact that covered entities are given such a short window of time to submit claims data to the portal.

RWC-340B is also concerned that the Terms of Use allow Second Sight to use contract pharmacy claims data in a way that goes beyond the scope of identifying or resolving duplicate discounts. The Terms of Use allow Second Sight to use participating covered entities' data for "benchmarking, research and analytics".[13] According to the frequently asked questions that accompanied your June 29th letter, "[d]ata uploaded by 340B Program covered entities will be used to identify and resolve duplicate

[10] 340B ESP™ Terms of Use § 7, *supra* note 4.
[11] *Id*. § 1.4.
[12] *Id*.
[13] *Id*. § 3.4.

Medicaid and commercial rebates." Merck's letter does not explain or put RWC-340B members on notice that their data will be used for benchmarking, research, or analytics. The Terms of Use also allow Second Sight to disclose and sub-license claims data and "any other data derived from the interpretation, analysis, and combination of the foregoing data with other data" with participating manufacturers, commercial payors, state Medicaid agencies, or other designated parties.[14] These terms are overly broad and vague, and asking a covered entity to agree to this license for use of its claims data is simply unrealistic and troubling. As stated above, RWC-340B is concerned, at a minimum, that such usage may support efforts by private payers to impose discriminatory pricing terms on covered entities.

The Terms of Use also provide Second Sight with the ability to amend the posted terms "at any time in its sole discretion", and that it is the covered entity's responsibility to be aware of and comply with such changes by "checking and reading these Terms from time to time".[15] Given that the Terms of Use are currently drafted in an overly broad manner that already places covered entities at a disadvantage, we believe that it would be reasonable for Second Sight or Merck to give explicit notice to RWC-340B members, and all other participating covered entities, regarding any material changes to the Terms of Use.

Potential Breach of Contract Pharmacy Agreements

RWC-340B is concerned that providing the requested 340B claims data could lead to a breach of our members' agreements with various parties, including contract pharmacies, third party administrators, prescription benefit managers, and others. While we have not reviewed our members' agreements in preparation of this letter, we are aware that certain provisions within those contracts could be obstacles to their participation in the 340B ESP™ program. For example, 340B contracts often include confidentiality provisions that could potentially be breached if a covered entity provides claims data to the 340B ESP™ program. And these contracts almost always include provisions that require the parties to comply with federal and state law. As stated above, RWC-340B has concerns about the risks associated with the 340B ESP™ program under HIPAA and state privacy laws. Those concerns are compounded by the fact that any non-compliance would result in a breach of our members' 340B agreements. RWC-340B members would have to review each of their contractual arrangements related to their contract pharmacies to determine if participating in the 340B ESP™ program would comply with those arrangements. It is possible, even likely, that a review of those contracts will uncover other issues that would have to be addressed before RWC-340B members could safely enroll in 340B ESP™. [16]

Undue Administrative Burden

Finally, RWC-340B is concerned that the process of gathering, compiling, and submitting the requested contract pharmacy claims data to the 340B ESP™ platform will impose an undue administrative burden on RWC-340B members. Merck's letter states that covered entities must submit contract pharmacy claims data to the 340B ESP™ platform on a bi-weekly basis, and that the claims upload process will take approximately five minutes. However, the letter does not provide any additional information regarding the type of data that covered entities will be required to submit or

[14] 340B ESP™ Terms of Use § 3.7, *supra* note 4.
[15] *Id*. § 11.6.
[16] In addition, because the submission of claims data could be viewed as providing something of value to Merck, the parties will need to make sure the 340B ESP program does not create undue risk under federal and state anti-kickback laws.

what the claims upload process entails. RWC-340B has serious doubts whether the five minute estimate is accurate.

RWC-340B members likely have several contract pharmacy arrangements that are registered on the Office of Pharmacy Affairs Information System (OPAIS). Each member will be required to make arrangements for each of these pharmacies to send the requested claims data in a timely manner to ensure that they meet the bi-weekly deadline. We assume that, in certain instances, the pharmacy may be required to reorganize, reformat or otherwise manipulate the data to ensure that it contains the specific data points that Merck seeks. Therefore, while the data *upload* process may take approximately five minutes to complete, RWC-340B is concerned that the additional time to collect and prepare this data will be much greater, to say nothing of the added administrative burden.

This additional time and administrative burden is particularly concerning because RWC-340B members are being asked to begin participation in the 340B ESP™ in the midst of the COVID-19 public health emergency (PHE), which has already stretched the finances and human resources of RWC-340B members. The COVID-19 PHE has had dissimilar effects on various sectors of the health care industry, with hospitals and clinics suffering the brunt of the economic harm. RWC-340B asks that Merck consider the timing of its request and the hardship that it places on 340B safety net providers.

As we stated at the outset of this letter, RWC-340B is committed to continuing a dialogue with Merck to avoid duplicate discounts on Medicaid 340B claims. However, for all of the reasons described above, RWC-340B is concerned about the risks its members would incur by registering for the 340B ESP™ program based on the program's current structure.

Sincerely,

Shannon Stephenson
President