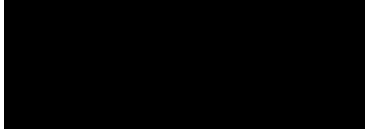




July 13, 2020



Dear [REDACTED]

I am following up on my letter dated June 29, 2020 regarding Merck's use of 340B ESP™, a new 340B compliance platform. As I stated in the previous letter, this platform will enable Merck and [REDACTED] to work collaboratively to strengthen the integrity of the 340B Program by helping to eliminate duplicate discounts that originate from 340B Program contract pharmacy utilization. Merck is making 340B ESP™ available to all 340B Program covered entities at no cost and we are asking all 340B covered entities to visit www.340BESP.com and register their account by **August 14, 2020**.

Instances of duplicate Medicaid rebates remain a serious issue in the 340B Program. Between 2017 and 2019, 29% of audits identified instances of duplicate Medicaid rebates.¹ This rate of non-compliance is not sustainable and 340B Program covered entities and manufacturers must do more to address this problem. This is why Merck is using the 340B ESP™ platform available through Second Sight Solutions. Through this platform, 340B Program covered entities can load into the platform their 340B Program claims data for Merck products, so that the platform may run a comparison of the 340B Program claims against rebate claims submitted to Merck by state Medicaid agencies and commercial payers. Absent significant cooperation from covered entities, Merck may take further action to address 340B Program integrity, which may include seeking 340B Program claims information in a manner that may be less collaborative, and substantially more burdensome for covered entities.

To date, [REDACTED] **has not registered on 340B ESP™** and we ask that you take the time to do so now. By working together to address the ongoing problem of duplicate discounts, we can ensure that the 340B Program will continue to support [REDACTED] in our shared mission of improving the health of your patients.

Best regards,

A handwritten signature in cursive script that reads "Philip A. Rinnander".

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

¹HRSA Audit Findings: 2017 – 2019; www.hrsa.gov

NEXT STEPS AND FREQUENTLY ASKED QUESTIONS

To get started with 340B ESP™, follow these three simple steps:

1. Go to www.340BESP.com to register your account. Upon initial registration you will be prompted with an onboarding tutorial that will walk you through the account set up process step by step. This process takes ~15 minutes.
2. Once your account is activated, you will be able to securely upload data to 340B ESP™. You will receive periodic notifications of pending data submissions and new contract pharmacy set up activities.
3. Login to 340B ESP and submit your 340B Program contract pharmacy claims data on a bi-weekly basis. Once your account is set up, the claims upload process takes ~ 5 minutes.

In addition to the frequently asked questions below, you can visit www.340BESP.com/FAQs to learn more about 340B ESP™. For further help with the registration, account setup, and data submission process please call 888-398-5520. If you had additional questions about this letter, please contact Merck directly at our Merck National Service Center by calling 1-800-672-6372.

Q: How will the 340B Program claims data that we provide through 340B ESP™ be used?

A: Data uploaded by 340B Program covered entities will be used to identify and resolve duplicate Medicaid and commercial rebates.

Q: How does 340B ESP™ protect the privacy of my patients?

A: Data uploaded to 340B ESP™ will automatically be de-identified by the platform software in accordance with the de-identification standards prescribed in the privacy regulations implementing HIPAA. This means no protected health information (PHI) will be used in the data-matching process and none will be shared with Merck or its vendors. And data security controls are embedded throughout the platform.

Q: Is use of 340B ESP™ voluntary or is Merck requiring that 340B Program covered entities utilize this platform?

A: Merck is making this service available to 340B Program covered entities at no cost with the goal of working collaboratively to address the ongoing problem of duplicate discounts. Use of 340B ESP™ is voluntary, however, absent significant cooperation from covered entities Merck may take further action to address 340B Program integrity, which may include seeking 340B Program claims in a manner that will be substantially more burdensome for covered entities. Merck is asking all 340B covered entities to register at www.340BESP.com and begin providing 340B Program claims data by **August 14, 2020**.

Q: Is Merck requesting data for all Merck products?

A: No. Merck is only requesting data for Merck drugs commonly dispensed through retail, specialty and outpatient pharmacies registered on the HRSA database as a contract pharmacy. Physician-administered drugs are not part of this program. 340B ESP™ automatically limits the data in your upload file to the applicable NDCs.

Q: Is Merck requesting data for pharmacies that are registered with HRSA as a covered entity?

A: No. Merck is only requesting data for 340B Program claims that originate from contract pharmacies. Covered entities do not need to provide 340B Program claims data for prescriptions filled in their own outpatient pharmacies.

Q: What benefit do we, as a 340B covered entity, realize by using 340B ESP™?

A: By providing 340B Program claims data originating from contract pharmacies, you will enable Merck to identify duplicate discounts provided through Medicaid rebates. Covered entities will then be informed via an email that will identify which pharmacies are dispensing 340B purchased drugs to Medicaid patients, in order to further strengthen compliance with federal statutory law.

Q: Does HRSA and/or Apexus support this initiative?

A: HRSA encourages 340B covered entities to work with pharmaceutical manufacturers in good faith to resolve issues of non-compliance in the 340B program. Although neither HRSA nor Apexus has commented on this specific initiative, Merck believes 340B ESP™ provides a simple platform for Merck and 340B covered entities to engage collaboratively and in good faith to address duplicate discounts.

Q: How often will I need to upload 340B Program contract pharmacy claims data to 340B ESP™?

A: Merck is requesting data uploads every two weeks. The actual upload process takes ~5 minutes and should not significantly burden any 340B Program covered entity operations. Email reminders are automatically generated from 340B ESP™ and covered entities can monitor claims submission status when logged in to the platform.

Q: What technology requirements exist to successfully upload data to 340B ESP™?

A: 340B ESP™ is compatible with most internet browsers including Windows Explorer, Google Chrome, Safari, FireFox, and others. Users will need an internet connection and access to a supported browser to successfully upload data.