MERCK

June 29, 2020

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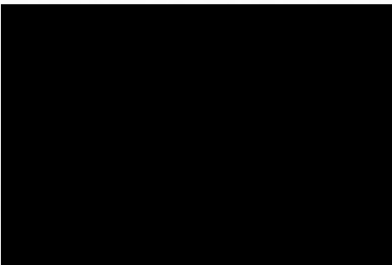
I am writing to inform you of a new 340B Drug Discount Program ("340B Program") integrity initiative that Merck is implementing in order to monitor operations and help ensure compliance with the 340B Program requirements. Merck strongly supports the mission of the 340B Program and is committed to maintaining and strengthening its foundations. One of those foundations is the statutory prohibition on payment of Medicaid rebates to states for prescription drugs purchased under the 340B Program. However, manufacturers continue to pay Medicaid rebates to states on prescriptions filled with 340B Program purchased drugs despite this being statutorily prohibited. To help address this problem, Merck seeks to work collaboratively with 340B covered entities through this initiative.

What are we asking you to do? We are asking all 340B covered entities to share 340B Program contract pharmacy claims data for Merck products. Merck will use this data to match against rebate claims it receives to ensure it isn't paying duplicate Medicaid discounts and duplicate discounts on Medicare Part D and commercial utilization through our contracts with commercial payers.

Why is this important to you as a 340B Program covered entity? The initiative is important to you because the 340B Program is critical in the mission of providing much-needed services in underserved populations. By working together, we can improve 340B Program integrity and preserve the mission of the 340B Program and assist the patients it supports. 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.
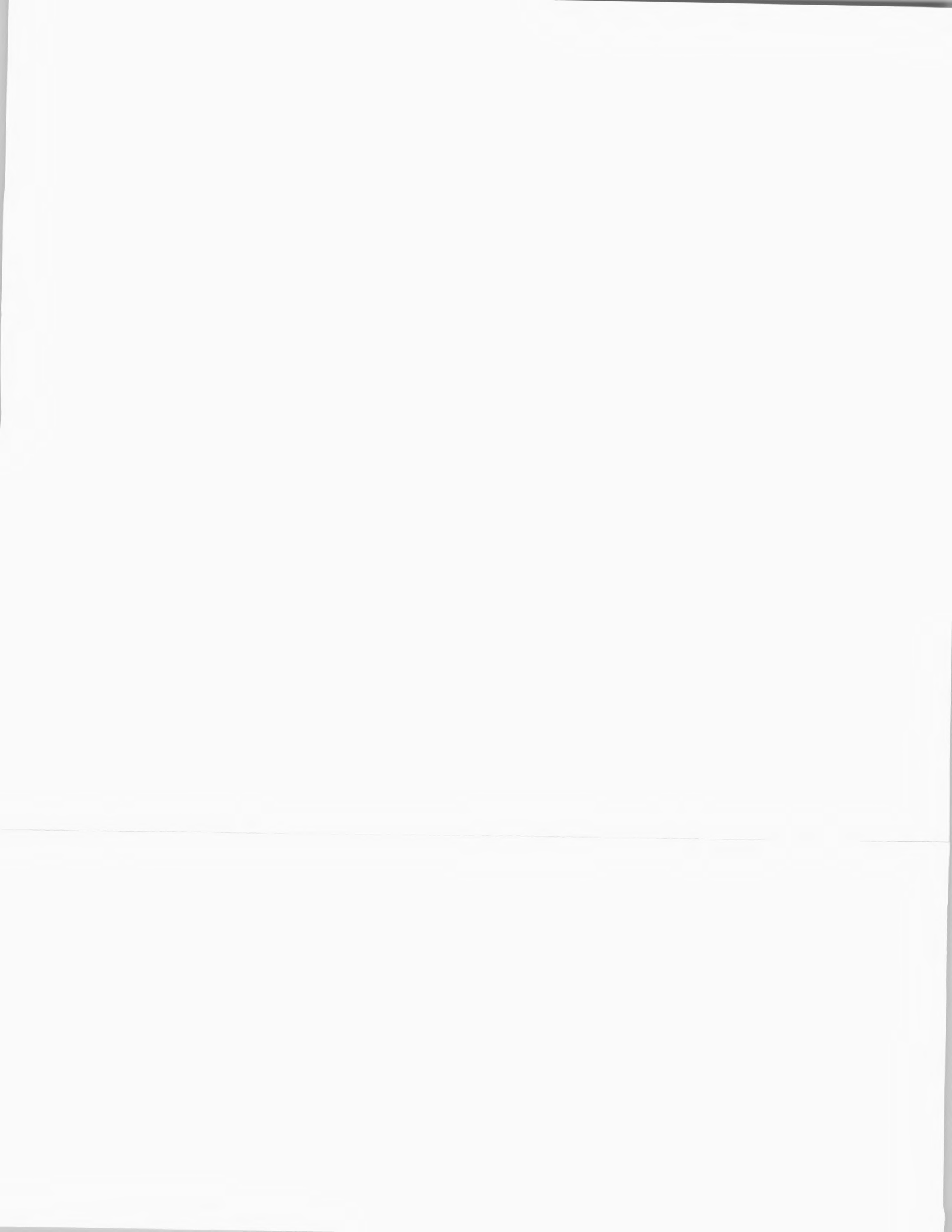
What should you do next? This initiative is enabled through Merck's vendor Second Sight Solutions and their 340B ESP™ platform. This platform is made available to 340B covered entities at no cost and Merck asks all 340B covered entities to register at www.340BESP.com by **August 14, 2020**. 340B ESP™ enables 340B covered entities to 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. Included with this letter is a more detailed description of 340B ESP™ along with next steps for registering and utilizing the platform.

Merck has maintained a strong commitment to the 340B Program since its inception. We have worked collaboratively with 340B Program covered entities to improve program integrity and will continue this commitment to the 340B Program through 340B ESP™.

Best regards,

Philip A. Rinnander

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

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 have 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 information 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 Program 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 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.