



340B Health Analysis

Hospitals Should Consider Legal and Operational Burdens Imposed by Merck's Request for Data that there is No Legal Obligation under 340B to Provide

July 20, 2020

340B Health is aware of the [letter](#) from pharmaceutical manufacturer Merck to 340B covered entities dated June 29, 2020 asking for contract pharmacy claims data for commercial and Medicaid claims. **Please know that covered entities are not legally required under the 340B statute to share this data with the manufacturer.**

Merck threatens that it will take “less collaborative, and substantially more burdensome” action to obtain this data if too few covered entities comply with the request. Manufacturers have the authority to audit covered entities, but we think the risk of audit is very low. That said, we have been informed of actions that other manufacturers are taking or considering taking, such as [no longer making 340B pricing available for drugs used by contract pharmacies](#) and potentially attempting to make 340B pricing available only as a rebate, instead of an up-front discount. HRSA has informed us that it has limited authority to enforce all the policies listed in its guidances and views its 2010 guidance on contract pharmacies to be legally unenforceable. HRSA has not opined publicly on Merck's proposal.

340B Health takes the position that a manufacturer's refusal to offer 340B prices to covered entities would violate the 340B statute and that HRSA has the authority to enforce manufacturer obligations under the statute. With the 340B Coalition, we have sent a [letter](#) to HHS asking them to halt this action. 340B Health is also exploring legal options and advocacy. In the meantime, we outline below issues for hospitals to consider as they evaluate Merck's request.

A. 340B Health Concerns

1. Data Requested and HIPAA Implications

Merck is asking all 340B covered entities to share 340B program contract pharmacy claims for Merck drugs commonly dispensed through retail, specialty, and outpatient pharmacies registered as contract pharmacies on the 340B Office of Pharmacy Affairs Information System (OPAIS). Merck requests the data be submitted through Second Sight Solutions, using its 340B ESP platform. Merck asks covered entities to register for the platform at www.340BESP.com by August 14, 2020, and continue submitting data on a bi-weekly basis. The platform is designed to use data mapping to submit the prescription number, prescribed date, fill date, national drug code, quantity, pharmacy ID, prescriber ID, wholesaler invoice number, and 340B covered entity ID for claims. Second Sight Solutions says that any additional data elements included in a data file selected for upload will automatically be removed prior to data submission.

The required claims elements include PHI (prescription number, prescribed date, and fill date, for example) but the company claims in an FAQ on the 340B ESP platform that the data will be de-identified through a HIPAA compliant process (referred to on the company's website as

“hashing”) prior to any data being uploaded to 340B ESP. According to the FAQ, this process was granted an “Expert Determination” indicating that it meets the definition of a de-identified data set under HIPAA and does not contain PHI. While HHS recognizes the “Expert Determination” method as one of two methods to achieve de-identification of PHI in accordance with HIPAA, it would be the hospital’s responsibility, as the HIPAA covered entity, to accept the expert’s analysis and the determination that the data is de-identified sufficiently to present a very small risk of re-identification. Nevertheless, we note that the Terms of Use acknowledge that PHI could be submitted inadvertently and that Second Sight Solutions, the vendor for the 340B ESP platform, assumes no responsibility for such error.

HIPAA noncompliance is a serious infraction and can result in fines and loss of public trust. 340B Health has not independently evaluated whether hospitals’ HIPAA obligations are adequately addressed under this arrangement, nor the overall HIPAA risk that this arrangement would present, especially since the arrangement does not appear to include use of a HIPAA-compliant business associate agreement to protect PHI. This risk should be evaluated carefully by hospital counsel. We understand that the company will share the expert’s report at a hospital’s request. We would be interested in hearing from hospitals on that point, as well as the overall burden of uploading the data. Hospitals can get more information on this at <https://340besp.com/faqs#section4>.

2. Recoupment of 340B Discounts from Covered Entities Without Legal Authority

Merck says it will use the contract pharmacy claims data submitted by covered entities to match against rebate claims it receives from state Medicaid agencies and commercial payers. Because the purpose of Merck’s request is to prevent Merck from paying rebates on 340B drugs, Merck will presumably contact Medicaid agencies if they identify rebates that were paid on such drugs. Though states are legally prohibited from collecting rebates on 340B drugs for Medicaid managed care, and there are no federal rules requiring repayment by covered entities to make up for State errors or negligence, Second Sight Solutions’ website states that manufacturers will attempt to recoup the 340B discount from the covered entity if the state Medicaid agency does not agree to refund the rebate to the manufacturer.

3. Recoupment of Rebates from Commercial Payers, Potentially Leading to Discriminatory Reimbursement for Covered Entities.

As explained on the Second Sight Solutions’ website, your contract pharmacy claims data will also be used to allow Merck to recoup voluntary rebates it paid to commercial payers on 340B drugs. It is common practice for drug manufacturers to pay rebates to PBMs, and some manufacturers would like to refrain from doing so for drugs already discounted under 340B. Your data could be used to help payers identify 340B claims and would be likely to spur additional discriminatory reimbursement practices by PBMs towards pharmacies dispensing 340B drugs.

4. Use of Your Data for Public Reports Critical of 340B?

340B Health is also concerned that claims data and other information submitted through the 340B ESP platform could be used by the Berkeley Research Group (BRG), the entity behind Second Sight Solutions, for research and analytics. BRG has published a number of negative reports on

340B in the past that have been funded by PhRMA. 340B Health strongly disagrees with the data analysis and conclusions put forth in these reports.

- 2014 [report](#) on contract pharmacy (suggesting that 340B DSH hospitals seek out contract pharmacies in affluent areas to obtain more revenue)
- 2018 [report](#) on Medicare Part B drug utilization at 340B hospitals (suggesting that there is a financial incentive for 340B hospitals to use more drugs or more expensive drugs on Medicare Part B beneficiaries)
- 2018 [report](#) measuring the size of the 340B program (finding that the 340B program has grown significantly and suggesting the program is inadequately overseen by HRSA)
- 2014 [report](#) on 340B covered entity acquisitions of physician-based oncology practices (suggesting that 340B hospitals misuse the 340B program and harm their patients in the process)

5. Legal Obligations Imposed Through “Terms of Use.”

In accessing 340B ESP, covered entities acknowledge that they have read and understand the platform’s [Terms of Use](#). The Terms of Use, which are attached to this memorandum, would impose a number of binding legal requirements that covered entities should carefully evaluate. The Terms of Use contain additional information on how contract pharmacy claims data submitted by 340B covered entities will be used, including for purposes unrelated to duplicate discount prevention. We call your attention to the following provisions:

- Covered entity claims data may be combined with commercial and Medicaid rebate data that commercial payers and State Medicaid agencies provide to participating pharmaceutical manufacturers in order to identify duplicate reimbursements. Duplicate reimbursements, together with any other platform data, may be reported to manufacturers, commercial payers, state Medicaid agencies or other parties.
- Covered entities agree to the disclosure and sub-licensing of covered entity claims data and any other data derived from the interpretation, analysis, and combination of the data with other platform data. Such information may be disclosed or sub-licensed to manufacturers, commercial payors, state Medicaid agencies, or other parties.
- Covered entity claims data may be used for benchmarking, research and analytics, and to monitor, improve, and refine the functionality of the platform and the services offered.
- Covered entity user information may be used in the aggregate for benchmarking, research and analytics.

6. Merck Has No Authority Under the 340B Statute to Request Information Relating to Commercial Claims, Medicare Part D Claims, or Medicaid Managed Care Claims

Merck’s request for contract pharmacy data on commercial claims is outside the scope of the 340B statute under any analysis, suggesting that Merck’s plan is not based solely on ensuring covered entity compliance with 340B rules. Federal law does not protect manufacturers from providing 340B discounts on Medicare Part D claims, nor does it require covered entities to help prevent a manufacturer from paying both a 340B discount and a commercial rebate that manufacturers voluntarily provide to PBMs on the same drug. Accordingly, Merck’s request that covered entities share contract pharmacy claims data to ensure it is not paying “duplicate discounts” on Medicare Part D and commercial claims is unrelated to compliance obligations 340B covered entities have under the 340B program.

The 340B statute gives manufacturers authority to inquire about Medicaid Fee-for-Service (FFS) duplicate discounts. However, Merck's request goes well beyond assessing FFS duplicate discounts. According to Merck, by providing 340B program claims data originating from contract pharmacies, covered entities will enable Merck to identify and resolve "duplicate Medicaid and commercial rebates." Federal law protects manufacturers from having to pay a 340B discount and a Medicaid rebate on the same drug (i.e., a Medicaid duplicate discount). The 340B statute clearly places an obligation to prevent duplicate discounts for Medicaid FFS claims on covered entities and permits HRSA and manufacturers to audit covered entities for duplicate discounts for Medicaid FFS claims.

The 340B statute does not address the prevention of duplicate discounts for claims billed to Medicaid managed care organizations (MCOs). However, the Medicaid statute prevents Medicaid managed care duplicate discounts, and Medicaid regulations require states and MCOs to create mechanisms to prevent Medicaid managed care duplicate discounts. Many states have their own policies requiring covered entities to identify 340B MCO claims to prevent duplicate discounts. HRSA does not have a policy addressing the prevention of Medicaid managed care duplicate discounts and does not evaluate whether such duplicate discounts have occurred during covered entity audits.

7. Noncompliance with Merck's Request Unlikely to Result in Audits

340B manufacturers have the authority under the statute to audit covered entities in the area of preventing duplicate Medicaid discounts and diversion, according to procedures established by the Secretary.¹ HRSA published guidance around how manufacturers should conduct audits in 1996.² Under that guidance, a manufacturer may not conduct an audit until it has demonstrated that it has "reasonable cause" and outlined such cause in an audit work plan, which it must submit to HRSA for approval. HRSA defines reasonable cause to mean that a reasonable person could believe that a covered entity may have violated the 340B statute's prohibitions against diversion and duplicate discounts. HRSA has indicated that a hospital's failure to respond to a manufacturer's 340B compliance inquiry that precedes a formal audit may give the manufacturer reasonable cause to audit the entity.

Merck, however, has not indicated an intent to audit covered entities, would not even have the authority to audit commercial claims, and could not feasibly audit the thousands of covered entities that received its letter. Moreover, there is nothing in the 340B statute permitting Merck to request information on, or otherwise take any action related to, commercial claims. Therefore, even though HRSA suggests that it has limited ability to enforce its guidances, audits do not seem to be a significant threat here. As explained above, however, it is possible that Merck could be considering other action apparently being contemplated by manufacturers, such as [no longer making 340B pricing available for drugs used by contract pharmacies](#) and potentially attempting to make 340B pricing available only as a rebate, instead of an up-front discount. HRSA has informed us that it has limited authority to enforce all the policies listed in its guidances and views its 2010 guidance on contract pharmacies to be legally unenforceable.

¹ 42 U.S.C. § 256b(a)(5)(C).

² HRSA's 1996 [Manufacturer Audit Guidelines](#), Page 65406; HRSA's [Policy Release](#) on Clarification of Manufacturer Audits of 340B Covered Entities (stating that OPA will approve or deny a manufacturer's request submitted work plan within 15 days of receipt).

HRSA has not opined so far on its ability to enforce its 1996 guidance around procedures manufacturers should follow when conducting audits.

8. Potential Burden of Data Submission

Finally, 340B Health is also concerned about the potential burden of Merck's request on covered entities. Merck describes the 340B ESP platform as "simple" and estimates that it will take covered entities five minutes to submit contract pharmacy claims on a biweekly basis once entities have set up accounts on the 340B ESP platform. 340B Health would like to hear from hospitals about the burden associated with submitting the data.

B. Recommended Next Steps

As 340B Health explores its legal options on this issue, hospitals should keep in mind that they have no legal obligation to share this data under the 340B statute. We recommend that hospitals carefully consider the legal and operational burden imposed by this proposal and the potential ways that their data could be used.

340B Health would like to hear from hospitals about the burden of Merck's request, their legal concerns around HIPAA compliance, and any other concerns related to Merck's request. This information will be helpful for our advocacy. Finally, please share with us any additional communications your hospital or health system receives from any manufacturer that may threaten 340B contract pharmacy. We will continue to analyze these documents and will share additional comments with you soon.

If you have any questions about the Merck notice or the steps we are taking in response, please contact our Senior Vice President of Legal and Policy, Chris Crosswhite (chris.crosswhite@340bhealth.org or 202-552-5851) or 340B Health Legal Counsel, Amanda Nagrotsky (amanda.nagrotsky@340bhealth.org or 202-552-5866).

Attachment to Analysis
340B ESP Terms of Use

Welcome to 340B ESP™, provided by Second Sight Solutions LLC and its affiliates (“Second Sight,” “Company,” “we,” “us,” “our”). These legally binding Terms of Use, as may be amended by us from time to time (“Terms”), apply to the website portal hosted at www.340besp.com and associated web pages (our “Websites”) and the 340B ESP™ offering made available therein (together with any updates provided by Second Sight and any corresponding documentation, associated media, printed materials, and online or electronic documentation) (collectively, the “Platform”).

340B ESP™ enables a 340B covered entity to submit certain de-identified 340B pharmacy claims data to Second Sight. Second Sight then enables analysis of this data for pharmaceutical manufacturers in order to identify duplicate Medicaid and commercial rebates. For additional information about the Platform, please see our Frequency Asked Questions (“FAQs”), available online at www.340besp.com/faqs.

Please read and review these Terms carefully before accessing or using the Platform. In order to use the Platform, you must register for an account using an e-mail address associated with a 340B covered entity by whom you are employed or acting as an agent (“Covered Entity”) and on whose behalf you will be submitting de-identified 340B pharmacy claims data (“Covered Entity Claims Data”), or you must register using an invitation received from an Administrator Account (defined below) associated with the Covered Entity. Our 340B ESP™ Privacy Policy, available online at www.340besp.com/privacy or such other location as we may make available (“Privacy Policy”), and incorporated herein by reference, explains how we collect and use the Covered Entity Claims Data and User Information (defined below).

These Terms are a legally binding agreement between Second Sight, the Covered Entity and its affiliates, your employer or principal if you are employed or acting as an agent for a legal entity other than the Covered Entity and such entity’s affiliates, and you (“Agreement”). The terms “you” and “your” shall refer to the Covered Entity and its affiliates, your employer if a legal entity other than the Covered Entity, and you.

BY USING THIS WEBSITE YOU (A) ACKNOWLEDGE THAT YOU HAVE READ AND UNDERSTAND THESE TERMS AND OUR PRIVACY POLICY; AND (B) REPRESENT THAT YOU HAVE THE AUTHORITY TO ENTER INTO THE AGREEMENT. IF YOU DO NOT AGREE TO THESE TERMS OR DO NOT HAVE SUCH AUTHORITY, DO NOT USE THE PLATFORM. PLEASE NOTE SECTION 6.2 CONTAINS INFORMATION ABOUT A DISCLAIMER; 6.3 CONTAINS INFORMATION ABOUT LIABILITY LIMITS, SECTION 10 INCLUDES CHOICE OF LAW; AND SECTION 11.6 CONTAINS INFORMATION ABOUT HOW THESE TERMS CAN BE AMENDED.

1. Data Collected By the Platform

1. Covered Entity Claims Data. The Platform enables you to upload, on behalf of the Covered Entity, Covered Entity Claims Data that is fully de-identified as defined under the Health Insurance Portability and Accountability Act of 1996, as amended, and its implementing regulations (“HIPAA”). When you load 340B pharmacy claims data for prescriptions processed by the Covered Entity into your internet browser, the Platform software running locally within your internet browser (“Platform Browser Software”) first processes the data locally within your internet browser to enable the extraction of the data fields

listed below. We exclude and do not collect any other data elements that are included in your claims data file.

- “NDC” shall mean National Drug Code, a unique identifier of a drug dispensed to a patient according to a prescription;
 - “Quantity Dispensed” shall mean number of units dispensed to the patient;
 - “Pharmacy Nabp” or “Pharmacy ID” shall mean the National Association of Boards of Pharmacy number of the pharmacy that filled the prescription;
 - “Service Provider ID” shall mean the NPI of the pharmacy that filled the prescription;
 - “Prescriber ID” shall mean the National Provider Identifier (“NPI”) of the physician that wrote the prescription;
 - “Wholesaler Invoice Number” shall mean the identifier of a replenishment order made by the Covered Entity;
 - “Prescription Number” or “Rx Number” shall mean an identifier applied to a prescription by a pharmacy;
 - “Prescribed Date” shall mean date on which the prescription was written by the physician;
 - “Date of Service” or “Fill Date” shall mean date on which the prescription was filled at the pharmacy; and
 - “Contracted Entity ID” shall mean the Health Resources and Services Administration (“HRSA”) assigned identifier of the 340B covered entity that designated the prescription as 340B and has a contract pharmacy arrangement with the dispensing pharmacy. | The Platform Browser Software applies one-way encryption to each of the Prescription Number, Prescribed Date and Fill Date. The Platform Browser Software then uploads the resultant de-identified data set as the Covered Entity Claims Data to Second Sight’s servers for further processing. For additional information, please see the FAQs.
2. De-Identification Method. The Covered Entity Claims Data is fully de-identified in accordance with the HIPAA expert determination method pursuant to 45 C.F.R. §164.514(b)(1) and does not contain any “Protected Health Information” or “PHI” as defined under HIPAA. Additional information on this HIPAA expert determination may be requested by contacting us at support@340besp.com.

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3. Re-Identification. Second Sight shall not attempt to re-identify or de-anonymize any of the Covered Entity Claims Data, including, without limitation, attempting to correlate any such data with any number, identifier, characteristic or other information that could be used, alone or in combination with other information, to identify any individual patient.
 4. Data Accuracy. You represent and warrant that the 340B pharmacy claims data that you load into Platform Browser Software and the Covered Entity Claims Data that you submit through the Portal will be complete and accurate, and follow the format and instructions provided within the Portal, as noted in Sections 3.1.1, 4.2.4 and 4.4. If any data is provided in an incorrect format (e.g., a misidentification of a field) the de-identification process may not work as intended. If you inadvertently submit any PHI to the Platform, Second Sight shall upon discovery of such error delete the PHI from the Platform and notify you accordingly. Second Sight assumes no responsibility or liability for any errors in the data received from you, nor shall Second Sight be responsible under any circumstances for any such errors in the data, regardless of the cause thereof.
 5. You agree to grant us rights to use the Covered Entity Claims Data and User Information discussed in further detail below in Sections 3.1 and 3.2.
2. Rights We Grant to You.
1. Subject to and conditioned upon your compliance with these Terms, Second Sight hereby grants a revocable, non-sublicensable, non-transferable, non-assignable, non-exclusive, limited right and license, to access and use the Platform for the Term of this Agreement (“Platform License”). This Platform License transfers to you neither title nor any proprietary or intellectual property rights to the Platform, related documentation, or any copyrights, patents, or trademarks, embodied therein or used in connection therewith, except for the rights expressly granted herein. Second Sight may terminate this Platform License at any time for any reason. All rights not expressly granted hereunder are reserved by Second Sight.
 2. Except as otherwise provided below, you agree that you will not yourself, or through any parent, subsidiary, affiliate, agent or other third party: (i) sell, lease, license or sublicense the Platform or any documentation, information, data or anything else accessible through the Platform; (ii) decompile, disassemble, or reverse engineer the Platform, in whole or in part; (iii) write or develop any derivative work based upon the Platform or any documentation, information, data, confidential information, or anything else accessible through the Platform; (iv) use the Platform in violation of any federal, state, or local law, regulation or rule (“Applicable Laws”); (v) use the Platform for purposes of competitive analysis of the Platform, the development of competing software products or services or any other purpose that is to the commercial disadvantage of Second Sight; (vi) provide, disclose, divulge or make available to, or permit access or use of the Platform, by any third party; (vii) retrieve, index, scrape, harvest, data mine or otherwise systematically gather or store content of the Platform; or (viii) remove any copyright, trademark or other proprietary notice or legend contained on (or printed from) the Platform.

3. You acknowledge that Second Sight provides services to entities whose businesses may be competitive with yours. Nothing in this Platform License shall restrict Second Sight's ability to license the access and use of the Platform or provide any other services to any third parties, regardless of any potential conflict between such third parties and you.

3. Rights You Grant to Us.

1. Data License. You represent and warrant that you have any and all necessary right, title, license and authority (including any and all necessary permissions from third-party owners and rights holders) to provide the Covered Entity Claims Data to the Platform. You grant Second Sight a worldwide, sublicensable, non-exclusive, royalty-free, perpetual, irrevocable license to collect, process, disclose, create derivative works of and otherwise use the Covered Entity Claims Data ("Data License") for the purposes set forth herein, and represent and warrant that you are authorized to grant such Data License on behalf of the Covered Entity. This Data License continues after termination of the Agreement.
2. You assume responsibility for ensuring that data is entered correctly into the Platform Browser Software to ensure correct submission of Covered Entity Claims Data. You agree to follow all instructions provided within the Platform to provide 340B pharmacy claims data on behalf of the Covered Entity in the specified format to facilitate de-identification thereof and submission of Covered Entity Claims Data.
3. You agree that Second Sight may collect and use Covered Entity Claims Data to facilitate the development of the Platform and provision of software updates, software support, and other services for you and the Covered Entity.
4. You agree that Second Sight may use the Covered Entity Claims Data provided by you for benchmarking, research and analytics, and to monitor, improve, and refine the functionality of the Platform and the services offered therefrom. When used for such purposes, all such data is de-identified and aggregated without any PHI or personally identifiable information.
5. You agree that Second Sight may use the Platform Browser Software to collect Covered Entity Claims Data for pharmaceutical manufacturers identified within the Platform ("Participating Pharmaceutical Manufacturers"), and that Second Sight may reach out to third party administrators for 340B pharmacy claims data associated with the Covered Entity, based on your indication within the Platform to do so.
6. You agree that Second Sight may enable Covered Entity Claims Data to be combined with commercial and Medicaid rebate data remitted to Participating Pharmaceutical Manufacturers by commercial payers and state Medicaid agencies ("Rebate Data") in order to identify duplicate reimbursements. You agree that Second Sight may enable reporting of the duplicate reimbursements, together with any other Platform Data (as defined below), to Participating Pharmaceutical Manufacturers, commercial payors, state Medicaid agencies or other parties designated by the foregoing entities.

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7. You agree that Second Sight may disclose and sub-license the Covered Entity Claims Data and any other data derived from the interpretation, analysis, and combination of the foregoing data with other data (the "Platform Data") with the Participating Pharmaceutical Manufacturers, commercial payors, state Medicaid agencies or other parties designated by the foregoing entities under the same Terms as applicable to us.
 8. User Information License. Through your use of the Platform, you may provide information that allows us to identify you, directly or indirectly including but not limited to identifiers (e.g., name, address, e-mail address, and telephone numbers) ("User Information"). You grant Second Sight a worldwide, sublicensable, non-exclusive, royalty-free, perpetual, irrevocable license to collect, process, disclose, create derivative works of and otherwise use User Information ("User Information License") for the purposes set forth herein, and represent and warrant that you are authorized to grant such User Information License on behalf of the Covered Entity. This User Information License continues after termination of the Agreement.
 9. You agree that Second Sight may collect and use User Information to facilitate the development of the Platform and provision of software updates, software support, and other services for you and the Covered Entity.
 10. You agree that the User Information may be used in the aggregate, anonymous, and de-identified by Second Sight for benchmarking, research and analytics, and to monitor, improve, and refine the functionality of the Platform and the services offered therefrom. When used for such purposes, all such data is de-identified and aggregated without any protected health information or personally identifiable information.
4. Use of the Platform. Your access and use of the Platform shall be solely for your use on behalf of the Covered Entity and you will be assigned, upon registration, a User ID and password to access and use the Platform ("Account").
 1. User Accounts. In order to register for an Account, you must either (a) use an email address having a domain name associated with the Covered Entity to register for an Account that can invite other users to register on behalf the Covered Entity ("Administrator Account"), or (b) register using an invitation from the Administrator Account of the Covered Entity. As part of the registration process you must provide your first name, last name, work e-mail address, cell phone number, and the Covered Entity on whose behalf you are accessing the Platform. Your registration may be subject to our verification and further requests for information and may be denied for any reason or no reason.
 1. You consent to Second Sight contacting you via your work e-mail or cell phone number (by call or text) in order to authenticate your identity, provide notifications regarding the Platform, and improve the services.
 2. You consent to Second Sight sharing your e-mail address with participating pharmaceutical manufacturers. You consent to said participating pharmaceutical manufacturers contacting you via e-mail regarding the use of our Platform.

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3. If you register using a work e-mail having a domain name associated with the Covered Entity, you represent and warrant that you are an employee or agent of the Covered Entity. If you register via an invitation by the Administrator Account using a work e-mail having a domain name different than the Covered Entity, you represent and warrant that you are an employee or agent of the Covered Entity, or an employee or agent of a legal entity that has been contracted and authorized by the Covered Entity to provide Covered Entity Claims Data to the Platform on its behalf.
2. Conditions of Use. You agree to comply with these Terms as well as all Applicable Laws related to or in connection with the Platform, its use, and data provided to or displayed by the Platform.
 0. You (i) shall not provide access to your User ID or password to any third party; (ii) shall promptly notify Second Sight of any unauthorized use of your User ID or password; and (iii) shall ensure that you exit from your Platform account at the end of each session.
 1. You shall comply with the restrictions set forth in Section 2.2 above.
 2. You agree, without limiting Second Sight's other rights and remedies, that you are responsible and liable for your access to, and use of, the Platform, including any negligent acts or omissions or your breach of any of these Terms.
 3. You agree to timely submit Covered Entity Claims Data through the Platform in the intervals specified therein, and to correct any errors in submission within the time period identified below in Section 4.4 Monitoring.
 4. If you are the registrant or account holder of an Administrator Account, you represent, warrant and agree that you shall invite only individuals to the Platform that are employed by or authorized to act as an agent of the Covered Entity associated with the Administrator Account for the purposes of this Agreement.
3. Account Access and Termination. Second Sight reserves the right to deny access to any user, or terminate the use of any User ID and password, at any time in the event Second Sight determines in its sole discretion that unauthorized or otherwise inappropriate use of the Platform by a user has occurred or may occur, including but not limited to conduct in breach of these Terms or in violation of Applicable Laws.
4. Monitoring. You acknowledge and grant us the right to (i) monitor your use of the Platform, (ii) monitor compliance with this Agreement, (iii) investigate any complaint or reported violation of our policies; (iv) report any activity that we suspect may violate any law or regulation to regulators, law enforcement officials or other persons or entities that we deem appropriate; or (v) issue warnings, suspend or terminate use of the Platform, deny access to all or part of the Platform or Websites or take any other action that we deem appropriate. If any such monitoring reveals that you are not using the Websites or the Platform in compliance with this Agreement, then you will

remedy any such non-compliance within five (5) business days of receiving notice from us.

5. Ownership of the Platform and Feedback. As between Second Sight and you, Second Sight Solutions LLC retains sole and exclusive ownership of all right, title and interest in and to the Platform (including any improvements, copies, translations, modifications, adaptations or derivative works of the Platform) and to all copyrights, trade secrets, patents, trademarks, and other intellectual property rights therein and relating thereto. In addition, in the event you acquire any right, title or interest in the Platform, you hereby assign any such right title or interest to Second Sight Solutions LLC.. If you provide any feedback on the Platform, then we may use that feedback without obligation to you and you hereby assign all right, title and interest in such feedback to Second Sight Solutions LLC.
6. Warranty and Limitation of Liability.
 1. Mutual Representation and Warranty. Each party represents and warrants to the other party that: (i) it is duly organized, validly existing, and in good standing under its jurisdiction of organization and has the right to enter into this Agreement; (ii) the execution, delivery, and performance of this Agreement and the consummation of the transactions contemplated hereby are within the corporate powers of such party and have been duly authorized by all necessary corporate action on the part of such party, and constitute a valid and binding agreement of such party; and (iii) it has the full power, authority, and right to perform its obligations and grant the rights it grants hereunder.
 2. Disclaimer of Warranties. YOU AGREE THAT THE PLATFORM AND ANY SERVICES PROVIDED UNDER THESE TERMS BY SECOND SITE TO YOU SHALL BE ON AN "AS IS" BASIS. TO THE MAXIMUM EXTENT ALLOWED BY LAW, NEITHER SECOND SIGHT NOR ITS AFFILIATES MAKES ANY REPRESENTATION, WARRANTY, CONDITION, UNDERTAKING, OR TERM, WHETHER WRITTEN OR ORAL, EXPRESS OR IMPLIED, WITH RESPECT TO THE SUBJECT MATTER OF THIS LICENSE, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR IMPLIED WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE OR WARRANTY OF NON-INFRINGEMENT, AND ALL SUCH WARRANTIES ARE EXPRESSLY DISCLAIMED BY SECOND SIGHT. SECOND SIGHT DOES NOT WARRANT THAT DRIVE WILL BE UNINTERRUPTED, ERROR FREE OR WITHOUT DELAY, NOR DOES SECON SIGHT MAKE ANY WARRANTY AS TO ANY RESULTS THAT MAY BE OBTAINED BY USE OF DRIVE.
 3. Limitation of Liability. YOU UNDERSTAND AND AGREE THAT SECOND SIGHT SHALL NOT BE LIABLE FOR ANY DAMAGES, ECONOMIC OR OTHER LOSS OR DAMAGE, WHETHER DIRECT, INDIRECT, CONSEQUENTIAL, INCIDENTAL, SPECIAL OR PUNITIVE, AND EVEN IF SECOND SIGHT OR ITS AFFILIATES HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. THE PARTIES ACKNOWLEDGE THAT THE LIMITATIONS SET FORTH IN THIS PROVISION ARE INTEGRAL TO THE AMOUNT OF CONSIDERATION LEVIED IN CONNECTION WITH THE LICENSE AND ANY SERVICES RENDERED HEREUNDER AND THAT,

WERE SECOND SIGHT TO ASSUME ANY FURTHER LIABILITY OTHER THAN AS SET FORTH HEREIN, SUCH CONSIDERATION WOULD OF NECESSITY BE SET SUBSTANTIALLY HIGHER.

7. Indemnification. You agree to defend, indemnify and hold harmless (including reasonable expenses, costs and attorneys' fees) Second Sight and its directors, officers, managers, employees, agents, representatives, successors and assigns from any claims by third-parties, second-parties, government authorities, or actions arising from injury or damage to persons or tangible property resulting directly or indirectly from (i) your access or use or unauthorized access or use of the Platform, (ii) your breach of these Terms, (iii) any third party's access or use of the Platform permitted by you, or (iv) your sharing of Covered Entity Claims Data in breach of any agreements between you and a third party. You will assume control of the defense and settlement of any claim subject to indemnification by you; provided, however, that Second Sight may, at any time, elect to take control of the defense and settlement of any such claim without modifying or releasing your obligations hereunder. In any event, you will not settle any such claim without Second Sight's prior written consent.
8. Delivery of Services.
 1. You shall be solely responsible for any and all equipment, facilities, and/or connections necessary to enable delivery of services through the Platform to you. Second Sight is not responsible for supplying, monitoring, managing, securing, or maintaining any internet or network or for related performance, security, or availability issues.
 2. You will take appropriate steps, both before accessing and using the Platform and at all times thereafter, to copy and protect your own data and programs that may be lost, harmed or destroyed and to protect your equipment from any damage. You will be responsible for reconstruction, replacement, repair or recreation of lost programs, data or equipment in the event of any hardware, software, or services failure as a result of accessing or using the Platform. Second Sight will not, under any circumstances, be responsible for any such losses or damages.
 3. The Platform is subject to modification (including addition, alteration, or deletion) by Second Sight in its sole discretion.
9. Term and Termination.
 1. Unless otherwise defined in the Agreement, the term of the Agreement and the Platform License granted hereunder shall commence upon your agreement to these Terms and will continue for recurring 30 day periods, unless the parties enter into a subsequent written agreement that modifies this term (the "Term") or Second Sight terminates your access.
 2. Unless otherwise set forth in the Agreement, you understand that Second Sight may at any time and from time to time modify or discontinue access to the Platform (or any part), with or without notice, temporarily or permanently without liability to you or to any third party. Termination of the Platform License shall immediately and automatically terminate your right to access

and use the Platform. Upon termination, you will promptly cease using the Platform and Second Sight may immediately terminate your access to the Platform and Second Sight shall have no obligation to return to you any data stored on Second Sight's systems.

3. The sections of these Terms that by their nature survive expiration or termination shall survive any expiration or termination of the License. Notwithstanding, and without limiting the generality of, the foregoing sentence, the provisions in Sections 3, 4, 5, 6, 8, 9, 10, and 11 will survive termination of the Agreement and the Platform License.

10. Forum Selection

1. Requirement to File Within One Year. Notwithstanding any other statute of limitations, a claim or dispute under this Agreement must be filed pursuant to the provisions of Section 10 within one year of when it could first be filed, or such claim will be permanently barred.
2. Choice of Law: The laws of Illinois, U.S.A., excluding Illinois's conflict of laws rules, will apply to any disputes arising out of or relating to these Terms.

11. General Provisions.

1. Severability. If any provision of these Terms is held by a court of competent jurisdiction to be contrary to law, the remaining provisions of these Terms will remain in full force and effect. Without limiting the generality of the preceding sentence, if any remedy set forth in these Terms is determined to have failed of its essential purpose, then all other provisions of these Terms, including the limitation of liability and exclusion of damages shall remain in full force and effect.
2. Third Party Beneficiaries and No Agency. Except for Participating Pharmaceutical Manufacturers that are identified upon logging in to the Platform, these Terms are for the sole benefit of the parties hereto and their respective successors and permitted assigns and nothing herein, express or implied, is intended to or shall confer on any other person any legal or equitable right, benefit or remedy of any nature whatsoever under or by reason of these Terms. These Terms do not create or imply any partnership, agency, or joint venture between the parties hereto.
3. Headings. Section headings used herein are provided for convenience of reference only and shall not constitute a part of these Terms.
4. Confidentiality. You may be given access to certain non-public proprietary information related to the Platform and Second Sight (the "Confidential Information"). You shall use this Confidential Information only as necessary in exercising the rights granted to you by these Terms. You shall not disclose any Confidential Information to any third party without our prior written consent and you agree that you will protect this Confidential Information from unauthorized use, access, or disclosure in the same manner that you would use to protect your own confidential and proprietary information of a similar nature and in any event with no less than a reasonable degree of care.

Attachment to Analysis
340B ESP Terms of Use

5. **Assignment.** You may not assign, transfer or delegate any of the rights or obligations hereunder without the prior written consent of Second Sight. Notwithstanding the foregoing, this Agreement and the Data License and User Information License granted to Second Sight may be assigned by Second Sight to an affiliate, a successor entity or any entity created or acquired as a result of a corporate reorganization, merger, acquisition or the purchaser of substantially all of the 340B ESP™ business line assets. You specifically authorize our use of subcontractors and our right to delegate any of the rights or obligations hereunder.
6. **Amendments.** Second Sight may revise these Terms at any time in its sole discretion by posting such revised terms on this website, or otherwise notifying you. Such revised terms shall be effective to you upon posting or other notice, unless otherwise explicitly stated by Second Sight. It is your responsibility to be aware of any such revised terms by checking and reading these Terms from time to time and your notices. If you do not agree with any of these Terms as they may be amended from time to time, you should request to deactivate your User ID and promptly cease using the Platform.
7. **Force Majeure.** We will not be deemed to be in breach of these Terms or liable for any breach of these Terms or our Privacy Policy due to any event or occurrence beyond our reasonable control, including without limitation, acts of God, terrorism, war, invasion, failures of any public networks, electrical shortages, earthquakes or floods, civil disorder, strikes, fire, pandemics or epidemics (whether or not already active at the time you accept these Terms), act of government (including but not limited to “shelter in place,” “travel ban,” “quarantine” or “shutdown” orders, whether or not already active at the time you accept these Terms) or other disaster.
8. **No Waiver.** The failure of Second Sight to insist upon strict enforcement of any provision of these Terms shall not be construed as a waiver of any provision or right.
9. **Entire Agreement.** These Terms, including any documents incorporated into these Terms by reference, constitute the entire agreement between you and Second Sight regarding the subject matter of these Terms and supersede all prior agreements and understandings, whether written or oral, or whether established by custom, practice, policy or precedent, with respect to the subject matter of the Terms.
10. **United States Only.** The Platform is intended for use by individuals located in the United States, and is not intended for use by anyone located outside of the United States. You should not use the Platform if you are not located in the United States. Second Sight makes no claims that the Platform is accessible or appropriate outside of the United States.
11. **Age Restrictions.** The Platform is not directed to individuals under the age of 18. You must be at least 18 years of age to access and/or use the Platform. By using the Platform, you acknowledge and agree that you are at least 18 years of age.
12. **Notices.** Please contact us at:

telephone: 1.888.398.5520 (toll free)

Attachment to Analysis
340B ESP Terms of Use

e-mail: support@340Besp.com

Attn: Legal Department
Second Sight Solutions, LLC
70 W. Madison, Suite 5000 | Chicago, IL 60602

All notices to you in connection with these Terms may be delivered via email at the email address provided by you, and you agree that these email communications satisfy any legal requirements.