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Your Rights and Obligations in Response to Merck and Sanofi Demands for 340B Contract Pharmacy Claims Data

Clients and Friends of the Firm:

We have received numerous inquiries regarding two letters sent by drug manufacturers – Merck Sharp & Dohme Corp. ("Merck") and Sanofi – asking 340B program covered entities to provide 340B contract pharmacy claims data through a third party called Second Sight Solutions ("Second Sight"). The letter from Merck was sent to seemingly all 340B covered entities using contract pharmacies, "asking" them to share contract pharmacy claims data with Merck through the Second Sight platform. The letter from Sanofi "require[s]" covered entities to submit the claims data.

The manufacturers have no right to the data requested, and 340B program covered entities have no obligation to share the data with the drug manufacturers or Second Sight. The manufacturers will use the data to serve their own best interests, likely to the detriment of covered entities. Each covered entity should determine whether its program and patients would benefit most from voluntarily complying with the requests, waiting to see how the issues develop, or declining to participate.

Both Merck and Sanofi claim that they need data to verify rebate claims in managed Medicaid and for their privately negotiated Medicare Part D and commercial plan rebates. Drug manufacturers have the right to audit, at their own expense and following procedures established by HRSA, covered entities to determine whether the covered entity is complying with the diversion prohibition and the prohibition against causing fee-for-service Medicaid duplicate discounts. HRSA states that manufacturers can only conduct such audits when they have a good faith reason to believe that the covered entity is violating one of those provisions.[1] Manufacturers have no right to audit contract pharmacy claims relating to managed Medicaid, Medicare, or private insurance rebates.[2]

We believe that the manufacturers would use the requested data in a way that would jeopardize 340B program savings for covered entities. Merck and

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[1] Manufacturer Audit Guidelines and Dispute Resolution Process, 61 Fed. Reg. 65,406 (Dec. 12, 1996). Though HRSA generally does not have the authority to create rules through Federal Register notices, the 340B statute gives HRSA the authority to establish manufacturer audit procedures. *See* 42 U.S.C. § 256b(a)(5)(C).

[2] State Medicaid agencies are obligated to identify and remove 340B utilization from managed Medication drug utilization data. *See* Social Security Act §§ 1903(m)(2)(A)(xiii), 1927(j)(1); 42 C.F.R. § 438.3(s)(3). Federal law does

Sanofi explain that they want to compare 340B utilization data to rebate requests that they receive from payers – managed Medicaid, Medicare and private insurers – and their pharmacy benefit managers ("PBMs") so that they can reject rebate claims from the payers/PBMs on 340B drugs.

Covered entities do not bear that responsibility. States and managed care organizations ("MCOs") have a statutory obligation to prevent rebates on 340B drugs in managed Medicaid. Medicare Part D and PBM rebates are privately negotiated tools used by drug manufacturers to secure desired goals – like formulary placement – and are not the responsibility of covered entities. When payers lose their rebates they respond by either a) preventing the use of 340B drugs; or b) reducing reimbursement rates to replace the lost rebates. That trend is already apparent in the marketplace and would predictably be accelerated if the payer rebates are threatened.

Further, the manufacturers would use the data for their own profit. Claims data is valuable, even when it is "deidentified" to remove protected health information.[3] The data that is being requested is valuable to manufacturers not only to protect their own profits in the form of rebate savings, but also to analyze trends in how their drugs are being prescribed, and by whom. We also assume that the data obtained will be used to undermine the 340B program broadly, because the founders of Second Sight Solutions have ties to Berkeley Research Group, a think tank that frequently has supported drug manufacturer criticisms of the contract pharmacy model.

Sanofi, in its letter, states that it will not ship drugs purchased by covered entities that fail to enroll with Second Sight to the entities' contract pharmacies beginning on October 1. We feel strongly, as does the rest of the 340B community to our knowledge, that Sanofi is required under the 340B statute to sell outpatient drugs to covered entities at 340B pricing, regardless of where the covered entity chooses to ship the drugs. Nothing in the 340B statute gives

not place the burden on any party to protect drug manufacturers from the rebates that they negotiate with Medicare Part D plans and private payers. Those rebates have been described as "kickbacks." *See Executive Order on Lowering Price for Patients by Eliminating Kickbacks to Middlemen* (July 24, 2020), at https://www.whitehouse.gov/presidential-actions/executive-order-lowering-prices-patients-eliminating-kickbacks-middlemen/.

[3] Any covered entity that does submit the requested data should investigate whether Second Sight Solutions' deidentification processes are effective and sufficiently protect the covered entity.

manufacturers the discretion to pick and choose where to ship drugs. If Sanofi follows through on its threat, its actions likely will be challenged.

Nevertheless, some covered entities might determine that the acute risk of losing access to Sanofi (and potentially Merck) products through their contract pharmacies could outweigh the broader risks of providing the requested information to Second Sight Solutions. In addition to the risks described above and the benefits of maintaining uninterrupted access to Merck and Sanofi products, consider the cost and burden of providing the requested data directly or through your 340B administrator. Each covered entity needs to determine for itself whether its patients and program would be best served by voluntarily providing the information, waiting to see how the issues develop in the coming months, or deciding not to participate.

If you have any questions or would like any further information regarding this alert, please feel free to contact Jason Reddish (jreddish@ftlf.com) or Michael Glomb (mglomb@ftlf.com) at 202-466-8960. This is a general statement and should not be construed as legal advice or an attorney-client communication.