



July 27, 2020

To: SUNRx Clients and Business Partners

From: Jackie Artinger, VP Regulatory Affairs and Compliance

Re: Recent Activity by Pharmaceutical Manufacturer, Sanofi

It has come to our attention that the drug manufacturer, Sanofi, has instituted the same program as Merck & Co., using the same program sponsored by BRG. Sanofi's letter is worded a little stronger, "requiring" v "requesting," the use of the tool. Please note that all clients must make their own decisions as to how to react/respond. SUNRx's comments and observations to the Merck letter (included below for your convenience) apply to the Sanofi letter as well - and will most likely apply for any other manufacturer that decides to adopt the same program.

The vendor engaged by these manufacturers, "Second Sight Solutions," (sponsored by Berkeley Research Group, LLC or "BRG") has a tool called, "340B ESP." Per the letters, CEs are being asked to upload **ALL** captured 340B claims from their contract pharmacies. Please note that although it appears to help address the issue regarding the prohibition against duplicate discounts ("duplicate discounts" as defined as a Medicaid claim using drug product purchased at a 340B price and also receiving a Medicaid rebate), the request is **not** limited to only uploading Medicaid claims. The letter also mentions commercial rebates being identified for potential action to be taken by Manufacturers. The letter also appears to be a veiled threat of a "more burdensome process" if a CE does not comply regarding possible future requests for data.

SUNRx understands and agrees that 340B CEs are obligated to comply with the prohibition against duplicate discounts, but this is of course limited to MEDICAID claims only. 340B CEs are under no federal obligation to participate in nor assist manufacturers regarding any business terms (e.g. commercial rebates) the manufacturers may have imposed on any other payer (e.g. commercial health plans, PBMs, etc.). It is not uncommon for a manufacturer to place a clause in a commercial rebate agreement to prohibit 340B claims from being eligible for commercial rebate payments, however, it is extremely difficult for a commercial payer to know which of the claims they paid for have ended up being treated and replenished as 340B claims. We are not aware of a legal basis to request ALL claims, but instead this appears to be based on a business reason. Several states have enacted laws against discriminatory payment practices by PBMs or health plans regarding reimbursement rates paid to pharmacies registered as 340B contract pharmacies. These laws are intended to prevent discriminatory payment rates to these pharmacies (including due to the payers' own rebate situation.) The reasons behind paying commercial rebates are solely between a manufacturer and a payer and are wholly independent of the 340B program.

Please note the applicable trade associations, etc. are aware of this request and have provided advice and/or advocacy to or on behalf of its constituents. You may also want to consult with your own legal counsel for legal guidance since this program could have a detrimental effect to your program and there are other concerns, such as HIPAA, use of data, resources needed to comply, etc. We also believe there are other methods that could be developed to prevent duplicate discounts (such as requiring a national database or easily accessible publication on states' websites of Medicaid BIN numbers). If you do decide to sign-up, please contact your Account Representative at your earliest convenience. We also advise you to review the 340B ESP Terms of Use very carefully for any additional legal considerations you will want to assess.