UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA, ex rel J. Douglas Strauser, *et al*., Plaintiffs v. STEPHEN L. LAFRANCE HOLDINGS, INC., *et al*., Defendants	Misc. Action No. 20-5 (CKK)

MEMORANDUM OPINION
(May 14, 2020)

In this matter, Defendants Walgreen Co., Stephen L. LaFrance Holdings, Inc., and Stephen L. LaFrance Pharmacy, Inc., filed a Motion to Compel the Court for an order compelling the Centers for Medicare and Medicaid Services ("CMS") to produce documents in response to a subpoena. Following discussions between Defendants and CMS only two issues remain for the Court's adjudication. First, the Court must decide whether or not Defendants can compel disclosure of particular portions of Direct and Indirect Remuneration ("DIR") data files. Second, the Court must determine the responsibility for expenses associated with non-party CMS's search, processing, and production of the subpoenaed information.

Upon consideration of the pleadings,[1] the relevant legal authorities, and the record as a whole, the Court will GRANT IN PART and DENY IN PART Defendants' Motion to Compel.

[1] The Court's consideration has focused on the following documents:

- Defs.' Mot. to Compel Production of Docs. from CMS ("Defs.' Mot."), ECF No. 1;
- Nonparty CMS's Opp'n to Walgreens' Mot. to Compel ("CMS's Opp'n"), ECF No. 15; and
- Defs.' Reply in Support of its Mot. to Compel Production of Docs. from CMS ("Defs.' Reply"), ECF No. 17.

In an exercise of its discretion, the Court finds that holding oral argument in this action would not be of assistance in rendering a decision. *See* LCvR 7(f).

The Court concludes that Defendants cannot compel the requested DIR data because of statutory restrictions on the use of such information. The Court further finds that, as a non-party, CMS must be protected from significant expense. As such, Defendants are required to pay for 60% of the costs of the search, processing, and production of information pursuant to their subpoena. CMS shall cover the remaining costs.

I. Background

The Motion to Compel currently before the Court stems from litigation which began on May 14, 2013 in the United States District Court for the Northern District of Oklahoma. *See United States ex rel. Strauser v. Stephen L. LaFrance Holdings, Inc*., No 18-cv-673 (N.D. Okla.). A realtor filed suit against Defendants claiming violations of the False Claims Act ("FCA") based on an alleged price matching program involving, in part, the Medicare Part D program. The United States has declined to intervene in the underlying litigation.

On October 11, 2019, Defendants served CMS with a subpoena seeking documents. Ex. A, ECF No. 1-2. As is relevant to this case, Defendants sought four categories of Medicare Part D data—prescription drug event data files by beneficiary and claim transaction; monthly membership report data files by beneficiary and month; payment reconciliation summary report ("PRS") data files by plan and year; and low income cost sharing category level data by beneficiary and month. *Id*. On October 21, 2019, CMS served objections to the subpoena. Ex. C, ECF No. 1-4. Unable to resolve their disagreements, on January 28, 2020, Defendants filed the Motion to Compel which is currently before the Court. ECF No. 1.

Since initiating this lawsuit, Defendants and CMS have worked to narrow the issues requiring litigation. CMS has agreed to produce to Defendants the requested prescription drug event data, monthly membership report data, low income cost sharing data, and PRS data

without the DIR data. CMS's Opp'n, ECF No. 15, 4. As such, the two issues remaining for the Court's resolution are whether or not CMS can be compelled to produce the DIR data and who should pay for the cost of compliance with the subpoena.

II. Legal Standard

Pursuant to Federal Rule of Civil Procedure 45, a court has the power to compel the production of documents from a non-party. *See In re Sealed Case*, 141 F.3d 337, 341 (D.C. Cir. 1998). In considering whether or not to grant a motion to compel, Rule 45 "'requires that district courts quash subpoenas that call for privileged matter or would cause an undue burden.'" *In re Micron Tech., Inc. Sec. Litig*., 264 F.R.D. 7, 9 (D.D.C. 2010) (quoting *Watts v. SEC*, 482 F.3d 501, 508 (D.C. Cir. 2007)). On a motion to compel, "[t]he burden lies on the party resisting discovery to show that the documents requested are either unduly burdensome or privileged." *Id.* The court first considers whether or not the requested discovery is relevant to the underlying litigation. Generally, "[p]arties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense." Fed. R. Civ. P. 26(b)(1). If a court determines that the requested discovery is relevant, the court next considers whether or not the discovery would place an undue burden on the non-party. "The text of Rule 45 makes quite clear that parties and attorneys who issue subpoenas have an affirmative duty to prevent undue burden or expense to the persons subject to the subpoena," *Millennium TGA, Inc. v. Comcast Cable Comms*., 286 F.R.D. 8, 11 (D.D.C. 2012). The court "ha[s] the discretion to limit discovery to prevent undue expense to third parties, even if the discovery sought is within the permissible scope." *Id.*

III. Subpoena of the DIR Data

DIR data relates to price concessions, "including discounts, charge backs or rebates, cash discounts, free goods contingent on a purchase agreement, up-front payments, coupons, goods in

kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers[] from any source (including manufacturers, pharmacies, enrollees, or any other person) that would serve to decrease the costs incurred under the Part D plan." 42 C.F.R. § 423.308. As such, the DIR data includes information on rebates and other forms of price concessions that were negotiated under the Medicare Plan D program. Such data contains propriety trade information and confidential pricing information.

Defendants contend that the DIR data is relevant to their lawsuit because it "would allow for the recalculation of [certain payments] in order to determine if an alleged improper downstream payment was offset by reductions in these other payments, such that the government suffered no financial losses." Defs.' Reply, ECF No. 17, 6. CMS does not dispute that the requested DIR data is relevant to the underlying litigation. As such, for purposes of this Memorandum Opinion, the Court assumes that the subpoenaed DIR data is relevant to the underlying litigation.

Defendants stress that they have requested the production of a very limited subset of the DIR Data for the years 2007-2014. Defendants contend that, even if DIR data is generally sensitive, the limited subset of data that they request is unlikely to contain highly proprietary or confidential information. Defendants further propose that the Court could enter an additional protective order stating that the DIR data would be used only by Defendants' attorneys and their experts for purposes of this lawsuit and would be protected from public disclosure.

However, even though the data is relevant and could be subject to an additional protective order, CMS argues that disclosure cannot be compelled because the information is statutorily protected. Pursuant to Section 1860D-15(f)(1) of the Social Security Act, plan sponsors must submit "such information as the Secretary determines is necessary to carry out this

section." 42 U.S.C. § 1395w-115(f)(1). Such information includes that which is necessary to determine the Medicare reimbursement payments that a Medicare Part D plan sponsor may receive. To determine these reimbursement payments, plan sponsors must report all costs incurred, including DIR received from any source which decreases the costs incurred by plan sponsors for Medicare Part D drugs. CMS has explained that the requirement to provide DIR data stems from section 1860D-15(f)(1). *See* Jennifer R. Shapiro, Revised Final Medicare Part D DIR Reporting Requirements for 2018, 4 (April 30, 2019) https://www.cms.gov/Research-Statistics-Data-andSystems/Computer-Data-and-Systems/HPMS/HPMS-Memos-Archive-Weekly-Items/SysHPMSMemo-2019-Week5-Apr-29-30) (explaining that § 1860D-15(f)(1) requires Part D sponsors "to report drug costs and DIR associated with the Medicare prescription drug benefit to CMS").

Because plan sponsors are required by section 1860D-15(f)(1) to report DIR data, such information is protected by the restrictions of section 1860D-15(f)(2). According to that section, information disclosed pursuant to section 1860D-15(f)(1) may be used only "(A) by officers, employees, and contractors of the Department of Health and Human Services for the purposes of, and to the extent necessary in—(i) carrying out this section; and (ii) conducting oversight, evaluation, and enforcement under this subchapter; and (B) by the Attorney General and the Comptroller General of the United States for the purposes of, and to the extent necessary in, carrying out health oversight activities." 42 U.S.C. § 1395w-115(f)(2). Combining sections 1860D-15(f)(1) and 1860D-15(f)(2), DIR data may be used only by the Department of Health and Human Services for certain purposes relating to health oversight activities or by the Attorney General and the Comptroller General for health oversight activities. *See* Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B

for CY 2017; Medicare Advantage Pricing Data Release; Medicare Advantage and Part D Medical Low Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model, 81 Fed. Reg. 46162, 46400 (July 15, 2016) (explaining that "these protections would generally prohibit public release of such data" including DIR data).

Maintaining the privacy of DIR data serves an important purpose for CMS. DIR reduces the costs of providing prescription drug coverage. Providing information on DIR and other rebates could make it more difficult to obtain price concessions. A reduction in the level of rebates and other DIR would increase costs for plan sponsors and thus increase costs for the Medicare Part D program generally. *See* Congressional Budget Office, Cost Estimate, 15 (July 22, 2003) (available at https://www.cbo.gov/publication/14667) ("PBMs operating as part of the Medicare prescription drug plan would find it more difficult to obtain significant price concessions and rebates from drug manufacturers, who would be concerned that the terms of these favorable deals could be determined by competitors and other purchasers.").

In this case, Defendants, including Walgreens who is an actual competitor as it has invested in at least one pharmacy benefit manager, are requesting DIR data. Pursuant to statute, DIR data may be used only by the Department of Health and Human Services for certain purposes relating to health oversight activities or by the Attorney General and the Comptroller General for health oversight activities. 42 U.S.C. § 1395w-115(f). Defendants are not part of the Department of Health and Human Services nor are they associated with the Attorney General or the Comptroller General. As such, by statutory mandate, the DIR data may not be used by Defendants.

Despite the unambiguous statutory language, Defendants argue that CMS is not prohibited from disclosing the DIR data for Defendants' use. First, Defendants contend that the statute "does not prohibit CMS from producing the DIR Data in this specific case because the statute is silent as to whether the government may produce the DIR Data pursuant to a validly served subpoena." Defs.' Reply, ECF No. 17, 11-12. While Defendants are correct that the statute makes no mention of a subpoena, silence does not indicate acquiescence. Here, the statute is explicit that the DIR data may be used only by select groups, of which Defendants are not members. Because the statute enumerates the only circumstances in which the data may be used, the statute is not required to also enumerate all instances in which the data may not be used.

Defendants also argue that, while authorities indicate that DIR data is not generally available for public release, such data may be available in this case. Defendants explain that they do not intend to publicly release the DIR data and would instead use the data as inputs for calculations. The calculations would be aggregated so that the DIR data would not be decipherable for a specific plan. Additionally, Defendants propose to execute an additional protective order over the data. Again, Defendants' argument is stymied by the explicit language of the statute. The statute does not broadly prohibit public release of DIR data. Instead, the statute limits the groups who may use the data and the purposes for which the data may be used. Because Defendants are not members of the specified groups, they may not use the data. Defendants' guarantees not to release the data publicly and to execute an additional protective order are not relevant given the statutory bar on the use of the DIR data.

Next, Defendants argue that the statute does not preclude disclosure because the underlying litigation is a "health oversight activity." Defendants contend that "if the government would be able to use the DIR Data in an FCA case in which it intervened, it should likewise be

required to produce the DIR Data in an FCA case in which it has not intervened and instead has assigned its prosecutorial rights to the realtor." *Id.* at 14. Defendants may be correct that if the government had elected to intervene in this case, the government could use the DIR Data in conducting a "health oversight activity." However, this hypothetical will not come to pass as the government has already elected not to intervene in this case. It is possible that the government elected not to intervene in this case because DIR data would be required, and the government decided that such information was too sensitive. Regardless of the government's reasons for not intervening, the fact remains that the statute restricts the use of DIR data to certain governmental entities. And, Defendants are not governmental entities. While the underlying litigation is a FCA action in which the "United States is a real party in interest, … [that] does not make it the equivalent of a party to the suit." *U.S. ex rel. Pogue v. Diabetes Treatment Centers of Am.*, 474 F. Supp. 2d 75, 78 n.2 (D.D.C. 2007).

In reviewing the submitted briefing, the Court acknowledges Defendants' need for the DIR data. Defendants require the data to calculate any potential damages suffered by the government in the underlying FCA litigation. Without the DIR data, Defendants may be required to rely on estimates of damages. However, Defendants' need for the DIR does not overcome the statutory restriction on the data's use. Section 1860D-15(f)(2) provides that only certain governmental entities may use the DIR data in specified circumstances. Defendants' need for the data and Defendants' subpoena does not overcome this statutory restriction on disclosing the DIR data.

Accordingly, the Court DENIES Defendants' Motion to Compel disclosure of the DIR data.

IV. Costs of Production

Even though the Court will not compel production of the DIR data, CMS has agreed to comply with the subpoena and to produce to Defendants the prescription drug event data, the monthly membership report data, the low income cost sharing data, and the PRS data without the DIR data. While CMS has agreed to produce this information, CMS and Defendants disagree on who should bear the cost of the production.

Pursuant to Federal Rule of Civil Procedure 45, a court order compelling the production of documents "must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance." Fed. R. Civ. P. 45(d)(2)(B)(ii). Here, the government elected not to intervene in this case, and Defendants do not dispute that CMS is not a party to the underlying litigation. CMS estimates a total cost of between $150,000 and $170,000 for the requested document production. Dec. of Cathy Carter, ECF No. 15-1; Dec. of Dinah Horton, ECF No. 15-2. As such, the question is whether or not complying with the subpoena at a cost of $150,000 to $170,000 would subject CMS to "significant expense."

The United States Court of Appeals for the District of Columbia Circuit has explained that Rule 45 requires the court to protect a non-party from significant expense. *Linder v. Calero-Portocarrero*, 251 F.3d 178, 182 (D.C. Cir. 2001). "Under the revised Rule 45, the questions before the district court are whether the subpoena imposes expenses on the non-party, and whether those expenses are 'significant.' If they are, the court must protect the non-party by requiring the party seeking discovery to bear at least enough of the expense to render the remainder 'non-significant.'" *Id.* In *Linder*, the D.C. Circuit had "no trouble concluding that" $199,537.08 in expenses for compliance were significant. *Id.* Similarly, here, the Court finds that between $150,000 and $170,000 in compliance costs are significant. *See G&E Real Estate, Inc.,*

v. Avison Young-Washington, D.C., LLC, 317 F.R.D. 313, 320-21 (D.D.C. 2016) (finding $3,148.44 in compliance costs significant).

Concluding that compliance with the subpoena would subject third-party CMS to significant expenses is not the end of the inquiry. Rule 45's protection of a non-party from significant expense "does not mean that the requesting party necessarily must bear the *entire* cost of compliance." *In re Exxon Valdez*, 142 F.R.D. 380, 383 (D.D.C. 1992). In determining how to allocate expenses, a court considers (1) whether the non-party has an interest in the outcome of the litigation; (2) whether the non-party can more readily bear the costs of production than the requesting party; and (3) whether the litigation is of public importance. *Linder v. Calero-Portocarrero*, 180 F.R.D. 168, 177 (D.D.C. 1998).

First, the Court acknowledges that CMS has an interest in the outcome of the litigation. The underlying litigation is a FCA action in which the realtor alleges that Defendants received reimbursements under the Medicare Part D program to which they were not entitled. CMS has an interest in ensuring that Medicare Part D participants are not overcompensated. Additionally, the government will receive a large portion of the damages if the realtor is successful. However, CMS's interest in the outcome of litigation is lessened by the fact that the government had the opportunity to intervene in this lawsuit and elected not to intervene. It is not reasonable to force CMS to bear a significant expense in the underlying litigation when the government declined to pursue the FCA claims.

Second, the Court considers whether CMS can more readily bear the cost of production. The Court acknowledges that CMS likely has greater access to funds than do Defendants. However, Defendants are large corporations, not individuals. And, CMS's funds come from

United States taxpayers. Taxpayers should not be forced to shoulder the costs of litigation for private parties.

Finally, the Court considers whether the litigation is a matter of public importance. Whether or not Defendants made false statements to receive excess compensation from the Medicare Part D program is a matter of public importance. However, the degree of public importance is lessened by the government's decision not to intervene in the underlying litigation.

Considering these factors, as well as Rule 45's mandate that the Court not subject non-parties to significant expense, the Court concludes that the costs of the search and production of documents responsive to Defendants' subpoena shall be divided as follows. Defendants are required to pay for 60% of the costs of the search, processing, and production of information pursuant to their subpoena. *See Linder v. Calero-Portocarrero*, 183 F.R.D. 314, 322 (D.D.C. 1998) (ordering requesting party to pay for half the cost of compliance of subpoena for non-party government agencies); *Prescient Acquisition Group, Inc. v. MJ Publishing Trust*, No. 05-cv-6298, 2006 WL 2996645, at *3 (S.D.N.Y. Oct. 13, 2006) (dividing fees in half where "[t]he facts do not lend themselves to an obvious methodology to determine what is reasonable for the plaintiff to bear"); *In Re: Epipen Marketing, Sales Practices and Antitrust Litigation*, No. 17-md-2785, 2018 WL 3062416, at *4 (D. Kan. June 20, 2018) (making requesting party pay for 50% of costs for subpoena production by non-party); *Dow Chemical v. Reinhard*, No. M8-85, 2008 WL 1968302, at * 2 (S.D.N.Y. April 29, 2008) (splitting costs of compliance with subpoena evenly between requesting party and non-party where there was no proposal for cost splitting and no evidence of bad faith). The Court finds that dividing the costs of subpoena compliance between CMS and Defendants in this manner accounts for CMS's pecuniary interest in the underlying litigation as well as the public interest in accurate Medicare Part D reimbursement. This splitting

of costs also acknowledges that the government declined to intervene in the underlying litigation and gives Defendants an incentive to ensure that all subpoena requests are relevant and necessary.

V. Conclusion

In conclusion, the GRANTS IN PART and DENIES IN PART Defendants' Motion to Compel. Defendants cannot compel the requested DIR data because of a statutory restriction on the use of such information. Additionally, in order to protect non-party CMS from significant expense, Defendants are required to pay for 60% of the costs of the search, processing, and production of information pursuant to their subpoena. CMS shall be responsible for 40% of the costs.

An appropriate Order accompanies this Memorandum Opinion.

/S/
COLLEEN KOLLAR-KOTELLY
United States District Judge