UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

MaineGeneral Medical Center, 35 Medical Center Parkway Augusta, Maine 04330 *Plaintiff*, v. Carole Johnson, in her official capacity as Administrator, Health Resources and Services Administration, 5600 Fishers Lane, Rockville, Maryland 20852 and Xavier Becerra, in his official capacity as Secretary, United States Department of Health and Human Services, 200 Independence Avenue, S.W., Washington, D.C. 20201 *Defendants*.	Civil Action No.: _____

COMPLAINT

Plaintiff MaineGeneral Medical Center by and through its attorneys, Hall, Render, Killian, Heath & Lyman, P.C., brings this Complaint against Carole Johnson, in her official capacity as Administrator, Health Resources and Services Administration, and Xavier Becerra, in his official capacity as Secretary, United States Department of Health and Human Services, and allege as follows:

PRELIMINARY STATEMENT

1. This is an action for declaratory relief and for injunctive relief enjoining a recent action by the Health Resources & Services Administration ("**HRSA**"). On June 19, HRSA unlawfully authorized a certain manufacturer that participates in the drug pricing program authorized under Section 340B of the Public Health Service Act ("**340B Program**") to audit Plaintiff's confidential business records.

2. Under the 340B Program, a limited set of authorized safety-net providers called "**covered entities**" are guaranteed an opportunity to purchase outpatient drugs at reasonable prices in order to stretch scarce federal resources available to provide care to underserved communities.

3. In effect, the 340B Program limits the extent to which drug manufacturers can use government-granted rights, including patent protections and periods of exclusivity, to divert funds from the healthcare safety net to enhance their profits.

4. Drug manufacturers voluntarily participate in the 340B Program because doing so allows the Medicare and Medicaid programs to reimburse providers when they use the manufacturers' drugs.

5. The statute authorizing the 340B Program, 42 U.S.C. § 256b ("**340B Statute**"), grants participating manufacturers a limited right to audit covered entities' records.

6. In performing an audit, the Statute requires that manufacturers "act[] in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits". 42 U.S.C. § 256b(a)(5)(C).

7. Covered entity records subject to audit are those "that directly pertain to the entity's compliance with the requirements described in subparagraphs 2 (A) or (B) [of the 340B Statute] with respect to drugs of the manufacturer." *Id.*

8. Subparagraphs 2 (A) and (B), respectively: a) prohibit a covered entity from obtaining 340B Program pricing when the manufacturer pays a Medicaid fee-for-service program rebate for the same drug (called a "**duplicate discount**"); and b) prohibit a covered entity from reselling or otherwise transferring a 340B-priced drug to anyone other than its own patient (called "**diversion**").

9. The procedures governing manufacturer audits referenced in the 340B Statute were established when, between 1994 and 1997, the Secretary followed procedures consistent with those required for informal rulemaking under the Administrative Procedure Act ("**APA**") to promulgate "**Manufacturer Audit Guidelines**." *See* 5 U.S.C. § 553.

10. In 1994, the Secretary published a "Notice" that contained "proposed manufacturer audit guidelines" and invited members of the public to comment on them for a period of 30 days. 59 Fed. Reg. 30,021, 30,022 (Jun. 10, 1994).

11. In 1996, the Secretary published a "**Final Notice**" that included the "final program guidelines concerning manufacturer audit guidelines[.]" 61 Fed. Reg. 65,406 (Dec. 12, 1996).

12. The Final Notice has the procedural hallmarks of an APA rule, including a summary of and response to 12 public comments received by the Secretary and an effective date 30 days after the Final Notice's publication date. *Cf.* 5 U.S.C. §§ 553(c), 553(d).

13. The Manufacturer Audit Guidelines set thresholds that a manufacturer must meet before an audit is permitted.

14. First, the manufacturer must notify a covered entity in writing when it believes that the covered entity has violated provisions of the 340B Statute. 61 Fed. Reg. at 65,410.

15. Then, the Guidelines require that the manufacturer work in good faith with the covered entity for at least 30 days, seeking to resolve the issue. *Id.*

16. Finally, "[i]f the matter is not resolved and the manufacturer desires to perform an audit," it must submit an audit work plan, a clear description of why it believed a duplicate discount or diversion has occurred, and facts and evidence supporting this belief. *Id.*

17. This procedure limits the scope of audits to issues which cannot be resolved through good-faith engagement between a manufacturer and a covered entity.

18. If HRSA finds that there is reasonable cause to believe that duplicate discounts or diversion have occurred, it "will not intervene." *Id.*

19. On June 19, 2024, HRSA approved a manufacturer's request to audit Plaintiff's confidential business records.

20. The manufacturer never notified Plaintiff in writing that it believed Plaintiff violated the 340B Statute.

21. Plaintiff asked HRSA to reconsider its audit approval decision and to provide Plaintiff with copies of documents it relied on in making its decision.

22. HRSA denied these requests.

23. Plaintiff has been denied the opportunity to understand and potentially resolve the manufacturer's concerns without undergoing an intrusive audit.

24. HRSA therefore approved an audit that is outside the scope of audits permitted under the 340B Statute and the Manufacturer Audit Guidelines.

25. Plaintiff seeks a declaration that the Manufacturer Audit Guidelines are both binding and mandatory with respect to manufacturers and the Secretary.

26. Plaintiff also seeks to enjoin the Secretary from allowing the audit to proceed and to enjoin Secretary from removing Plaintiff from the 340B Program or taking any other action

against Plaintiff for any alleged failure to respond to the manufacturer's premature, burdensome, and unlawfully approved audit demands.

JURISDICTION

27. Jurisdiction in this Court is grounded upon and proper under 28 U.S.C. § 1331, in that this civil action arises under the laws of the United States; 28 U.S.C. § 1346, in that this case involves claims against the federal government; 28 U.S.C. § 1361, in that this is an action to compel officers of the United States to perform their duty; and 28 U.S.C. §§ 2201–2202, in that there exists an actual justiciable controversy as to which Plaintiff requires a declaration of its rights by this court and injunctive relief to prohibit Defendants from violating federal law.

VENUE

28. Venue is proper in this district under 28 U.S.C. § 1391(b) and (e) because this is a civil action in which Defendants are officers of the United States acting in their official capacities and one of the Defendants maintains his office and conducts business in this judicial district.

PARTIES

29. Plaintiff MaineGeneral Medical Center is a Maine non-profit corporation with its principal place of business at 35 Medical Center Parkway, Augusta, Maine. It operates a rural Sole Community Hospital of the same name with 198 in-patient beds and has participated in the 340B Program for more than 15 years.

30. Defendant Xavier Becerra is the Secretary of Health and Human Services. Defendant Becerra maintains an office at 200 Independence Avenue, S.W., Washington, D.C. 20201, and is sued in his official capacity only.

31. Defendant Carole Johnson is the Administrator of the Health Resources and Services Administration, an operating division within the Department of Health and Human Services. The Administrator maintains an office at 5600 Fishers Lane, Rockville, Maryland 20852. The administrator is sued in her official capacity only.

BACKGROUND ON THE 340B PROGRAM

The 340B Program

32. Congress created the 340B Program in 1992 to address rapidly increasing drug prices faced by safety-net hospitals and grant-funded clinics. Veterans Health Care Act of 1992, Pub. L. 102-585 (Nov. 4, 1992); H.R. Rep. No. 384, 102d Cong., 2d Sess. Pt. 2 at 10-12 (1992).

33. The 340B Program permits covered entities to purchase certain drugs at the same rate that state Medicaid programs pay. *See generally* 42 U.S.C. § 256b(a)(1) (referencing the "average manufacturer price" under Title XIX of the Social Security Act); *see also* 42 U.S.C. § 1396r-8 (establishing the Medicaid Drug Rebate Program under which manufacturers pay rebates to state Medicaid agencies).

34. The 340B Statute itself is uncomplicated, spanning only five pages of the printed United States Code. 42 U.S.C. § 256b (2022). Among other things, it defines the safety-net entities that are eligible to participate in the 340B Program (again, "**covered entities**"), *id.* § 256b(a)(4); prohibits them from engaging in "duplicate discounts" and "diversion," each as defined above, *id.* §§ 256b(a)(5)(A)-(B); and establishes penalties for violations. *Id.*, §§ 256b(a)(5)(D), 256b(d)(2)(B)(v).

35. The 340B Statute also creates a limited audit right for the Secretary and participating manufacturers. It states:

> A covered entity shall permit the Secretary and the manufacturer of a covered outpatient drug…**(acting in accordance with acting in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits)** to audit at the Secretary's or manufacturers expense the records of the covered entity that directly pertain to the entity's compliance with [the duplicate discount and diversion prohibitions] with respect to drugs of the manufacturer. 42 U.S.C. § 256b(a)(5)(C) (emphasis added).

The Manufacturer Audit Guidelines

36. Through a process consistent with the APA's requirements for informal rulemaking, HRSA published Manufacturer Audit Guidelines in 1996. 61 Fed. Reg. 65,406 (Dec. 12, 1996); 59 Fed. Reg. 30,021(Jun. 10, 1994) (issuing proposed guidelines and opening a 30-day public comment period).

37. HRSA invoked § 256b(a)(5)(C) when it published the Guidelines. 61 Fed. Reg. at 65,406.

38. The Manufacturer Audit Guidelines set thresholds that any manufacturer wishing to audit a covered entity must pass. 61 Fed. Reg. at 65,410 ("Procedures To Be Followed").

39. These thresholds are not particularly taxing, but they are important.

40. Prior to auditing a covered entity, a manufacturer must "notify the entity in writing when it believes the entity has violated provisions of section 340B." 61 Fed. Reg. at 65,410.

41. The notice triggers a mandatory 30-day period in which the parties "attempt in good faith to resolve the matter." *Id.*

42. If, and only if, the good-faith attempt fails, the manufacturer may inform HRSA that it intends to audit the entity. *Id.*

43. Under the Guidelines, "[a] manufacturer shall conduct an audit only when it has documentation which indicates that there is reasonable cause." *Id.*

44. Before conducting an audit, the manufacturer is required to provide HRSA with: (i) an audit work plan; (ii) "a clear description of why it has reasonable cause to believe that ta violation of section 340B(a)(5) (A) or (B) has occurred," which must be supported by "sufficient facts and evidence[;]" and (iii) "copies of any documents supporting its claims." *Id.*

45. HRSA reviews these materials to determine if "reasonable cause" exists. *Id.*

46. "'Reasonable cause' means that a reasonable person could believe that a covered entity may have violated a requirement of section 340B(a)(5) (A) or (B)[.]" *Id.* at 65,409.

47. If HRSA finds that the documentation provided by the manufacturer shows reasonable cause, it "will not intervene[,]" *id.* at 65,410, and the covered entity is required to participate in the audit.

48. Unless it receives written notice from a manufacturer, a covered entity has no way of knowing what facts HRSA considered when determining that "reasonable cause" exists.

49. In 1996, a commenter asked that covered entities be allowed to respond to a manufacturer's request for an audit. 61 Fed. Reg. at 65,408. HRSA demurred:

> The guidelines provide for a 30 day period before the manufacturer submits to the Department an audit work plan in which the manufacturer and the covered entity must attempt in good faith to resolve the matter. When the manufacturer submits its audit work plan, it has already discussed the matter with the covered entity;

> therefore, we do not believe there is a need for the covered entity to comment on a manufacturer's submission of an audit workplan. The Department, at its discretion, may contact the covered entity as part of the review process of the proposed manufacturer's audit. Likewise, we do not believe that there is a need for the covered entity to review and comment on the manufacturer's proposed workplan once it has been reviewed by the Department. 61 Fed. Reg. 65,408.

50. Thus, written notice of a diversion or duplicate discount violation is vital to the manufacturer audit process, including because it is the only way that the covered entity is able to participate in good faith to resolve the matter within the 30 day period.

51. Since HRSA reviews and approves manufacturers' audit work plans and reasonable cause documentation on an *ex parte* basis, written notice is a covered entity's only protection against frivolous or vexatious audits.

PROCEDURAL HISTORY OF THE CHALLENGED AUDITS

52. On April 22, 2024, Plaintiff received an unsigned email from Johnson & Johnson ("**J&J**") requesting a meeting to discuss the Plaintiff's 340B program.

53. As to scope, the message stated that J&J "would like to discuss and ask questions regarding your entity's 340B utilization." Email from 340B_JJHCS@its.jnj.com to J. Kent of MaineGeneral (Apr. 22, 2024) (**Exhibit 1**).

54. MaineGeneral responded to J&J's initial email within 90 minutes.

55. MaineGeneral sent a substantive response to J&J on May 2.

56. Within a week, the parties agreed to a meeting on May 15.

57. Throughout the course of these communications, J&J asked questions and provided few, if any, answers.

58. Plaintiff never received a written statement from J&J stating that it believed Plaintiff had engaged in diversion or duplicate discounts.

Deloitte & Touche Contacts Plaintiff

59. On June 20, 2024, Plaintiff received a letter from Deloitte & Touche, LLP ("**Deloitte**") explaining that HRSA had approved J&J's request to audit Plaintiff just one day earlier—June 19, a Federal holiday (**Exhibit 2**).

60. Deloitte's letter further explained that pursuant to the Manufacturer Audit Guidelines, J&J had engaged Deloitte to perform the audit.

61. Enclosed with the letter was a document request list demanding access to voluminous, confidential records held by Plaintiff relating to its patients, employees, business operations, and clinical operations (**Exhibit 3**).

62. Deloitte's letter asked Plaintiff to make itself available for a call during the week of June 24—the Monday following the date Plaintiff received Deloitte's letter.

63. Deloitte's letter also asked Plaintiff to compile all of the requested documents by July 5.

64. The requested documents include patients' HIPAA-protected health information, personally identifiable information for many of Plaintiff's employees and other providers, and contracts and other business records that would require legal review and redaction.

65. On June 28, Plaintiff, through undersigned counsel, sent a responsive letter to Deloitte contesting the validity of HRSA's audit approval (**Exhibit 4**).

66. By this letter, Plaintiff requested that Deloitte provide a copy of J&J's written notice to the Plaintiff, J&J's audit work plan, and a "reasonable cause" letter to HRSA referenced in Deloitte's June 20 communication.

67. Plaintiff also asserted that, if the proposed audit were to move forward, Deloitte or J&J would need to provide reasonably tailored information related to the audit process.

68. On July 8, counsel for J&J offered to provide the information Plaintiff requested if Plaintiff would agree to keep the information confidential (**Exhibit 5**).

HRSA's Final Agency Action

69. On June 26, a HRSA official contacted Plaintiff and confirmed that it approved J&J's requested audit (**Exhibit 6**). The communication specifies:

> After careful review, HRSA determined that J&J met the thresholds identified in HRSA's Manufacturer Audit Guidelines and Dispute Resolution Process, 61 Fed. Reg. 65,406 (Dec. 12,1996) and Clarification of Manufacturer Audits of 340B Covered Entities, 340B Drug Pricing Program Notice 2011-3 (Nov. 21, 2011) in order to pursue an audit, as defined in section 340B(a)(5)(A) of the Public Health Service Act. *Id.*

70. On June 28, undersigned counsel contacted HRSA on behalf of Plaintiff and requested that HRSA reconsider its decision to approve J&J's proposed audit (**Exhibit 7**).

71. Plaintiff asserted that J&J had failed to notify it in writing that it believed Plaintiff had violated the 340B Statute.

72. Plaintiff requested that HRSA provide it with J&J's "reasonable cause" letter, audit work plan, and supporting documents.

73. On July 10, HRSA sent a letter denying Plaintiff's request to reconsider the audit approval and denying its request for documentation (**Exhibit 8**).

74. As to the lack of written notice, HRSA stated that it had considered the "good faith timelines" applicable to Plaintiff when making its initial—and now final—decision to approve J&J's requested audits.

75. HRSA also denied Plaintiff's request to produce documents, offering two alternatives: request them from J&J or submit a Freedom of Information Act request.

HRSA's Audit Approvals are Unlawful

76. HRSA's decision to approve J&J's proposed audit of Plaintiff is unlawful.

77. The 340B Statute permits a manufacturer to audit a covered entity only "in accordance with procedures established by the Secretary relating to the scope, duration, and number of audits[.]" 42 U.S.C. § 256b(a)(5)(C).

78. HRSA specifically invoked subparagraph (C) when it published the final Manufacturer Audit Guidelines in 1996. 61 Fed. Reg. at 65,406.

79. The Manufacturer Audit Guidelines are the "procedures" mandated by Congress.

80. The Guidelines provide that the manufacturer "shall" notify the covered entity in writing, and that the manufacturer and covered entity "shall have at least 30 days" to attempt to resolve the dispute in good faith. 61 Fed. Reg. at 65,410.

81. This procedure limits the scope of manufacturers' audits to issues that cannot be resolved through good-faith engagement between manufacturers and covered entities

82. The Manufacturer Audit Guidelines are legally binding upon manufacturers and covered entities.

83. HRSA has a duty to enforce the Manufacturer Audit Guidelines.

84. Thus, the written notice and good-faith attempt procedure is mandatory.

85. HRSA's decision to approve J&J's audit request despite its failure to adhere to the notice and good-faith attempt procedure is a final agency action subject to judicial review.

86. As demonstrated by HRSA's July 10 letter, HRSA's approval decision is final.

87. Unless the Court intervenes, Plaintiff must comply with the manufacturer's audit demands. *See* 61 Fed. Reg. at 65,409.

88. HRSA's decision will cause Plaintiff immediate and irreparable harm.

89. Deloitte's auditors set an aggressive audit timeline, demanding voluminous sensitive documents in the minimum time allowed by the Manufacturer Audit Guidelines. *Id.* at 65,410 ("The covered entity will have at least 15 days to prepare for the audit.").

90. When Plaintiff asked HRSA for more time to respond, it was directed to ask J&J for an extension.

91. Setting aside any consequences it may face if the audit reveals noncompliance, Plaintiff would expend substantial resources simply collecting the requested materials, armed only with suspicions about what J&J may believe it will find.

92. The harm to Plaintiff will also be irreparable, including likely damage to Plaintiff's reputation among the public and other 340B Program stakeholders and inevitable damage to its legal standing in any challenge to J&J's audit findings.

93. J&J has strong business interests in limiting the 340B Program. J&J's 2023 annual investor report coyly stated that limiting covered entities' access to 340B drugs "had discount implications which positively impacted sales to consumers in 2023." Johnson & Johnson, Form 10-K for 2023, p. 38. J&J has also identified 340B utilization as a risk to its bottom line. *Id.*, p. 10.

94. On its website, J&J has accused covered entities of using "arbitrage, opportunism, and opacity" to "reap significant financial windfalls" from the Program. Johnson & Johnson Innovative Medicine, *The 340B Program* () (last accessed July 18, 2024).

95. In 2023, J&J took the unusual step of filing an *amicus curiae* brief with a federal district court, injecting itself into APA proceedings between a covered entity and HRSA.

96. In its brief, J&J alleged that "[t]oo many covered entities, like [the plaintiff in the case], abuse the program, pursuing profits by systematically engaging in diversion." *Genesis Healthcare Inc. v. Becerra*, D.S.C. Case No. 4:19-cv-01531-RBH, *Brief of the Janssen Pharmaceutical Companies as Amici Curiae in Support of Defendants' Motion for Summary Judgment*, at 8 (Dkt. No. 121) (hereinafter "**J&J's Amicus Brief**").

97. Indeed, J&J's Amicus Brief amounted to 34 pages of vitriol in which it accused the plaintiff in that case and other covered entities of "abuse" at least eight times. J&J stated that it believed covered entities engage in "widespread abuse and exploitation of the 340B program" enabled by "HRSA's failings…and lax enforcement generally[.]" *Id.* at 8-9.

98. Although the court wisely decided to rely only on facts and arguments in the administrative record, *see* Text-Only Order of August 23, 2023 in the same case, it still allowed J&J's Amicus Brief to be filed in its entirety, without redaction. It is available on PACER for $3.00.

99. Ultimately, and notwithstanding J&J's involvement, the court ruled in the covered entity's favor, overturning HRSA's unlawfully rigid interpretation of the 340B Statute.

100. Given J&J's failure to follow the good-faith engagement procedure, its stated interest in diminishing 340B utilization, and its history of publicly accusing covered entities of 340B

Program abuse, Plaintiff reasonably believes that J&J will misuse the audit process to further its own pecuniary interests and publicly damage Plaintiff's reputation.

101. Even if J&J never vilifies Plaintiff in public, drug manufacturers talk to one another about covered entities' involvement in 340B Program, giving J&J ample opportunity to disparage Plaintiff to other manufacturers.

102. Like at least 35 of its competitors, J&J uses a platform called "340B ESP" to administer its 340B contract pharmacy restriction policies. Johnson & Johnson, *Notice to 340B and Non-340B End Consumers Regarding Updates to 340B Delivery Limitations*, at 4 (Feb. 15, 2023) (https://340besp.com/JJHCS%20Notice%20to%20End%20Customers%20Regarding%20Updates%20to%20340B%20Delivery%20Limitations.pdf) (last accessed July 18, 2024).

103. In May 2023, the consultancy behind 340B ESP hosted a 340B Industry Roundtable where attendees would "have the opportunity to network and collaborate with other leading industry stakeholders on a variety of 340B-related themes" and engage in "[s]olutions-oriented discussions proctored by an antitrust attorney." Berkeley Research Group, *Agenda for 2023 340B Industry Roundtable,* (available via Berkeley Research Group website at https://media.thinkbrg.com/wp-content/uploads/2023/04/10152706/340B-Workshop-Program_2023.pdf) (last accessed July 18, 2024).

104. The agenda for this event included "case studies of several health systems using publicly available information" focusing on "expanded interpretation of the patient definition," among other things. This session led immediately to a 60-minute cocktail reception and a 90-minute dinner.

105. Given J&J's history of disparaging covered entities in public fora and documented opportunities to do so in private, Plaintiff is reasonably concerned that J&J will use any audit

results to irreparably injure its reputation in public or in communications with other 340B Program stakeholders.

106. In addition, HRSA's unlawful audit approval decision will irreparably damage Plaintiff's legal standing if it avails itself of the process for challenging any findings from the manufacturer's audit.

107. As part of its audit request, J&J submitted a "reasonable cause letter."

108. HRSA evaluated this letter and, apparently, agreed that the documentation J&J provided, which documentation Plaintiff has never seen, shows "reasonable cause to believe that a violation…occurred[.]" 61 Fed. Reg. at 65,410.

109. If the audit proceeds, Plaintiff is obligated to repay the manufacturer for noncompliant 340B drug use, if any. If Plaintiff disagrees with Deloitte's findings by, for example, disagreeing with Deloitte's determination that a so-called "expanded interpretation of the patient definition" constitutes diversion, J&J's recourse is to file a petition with the HHS 340B Administrative Dispute Resolution Board seeking to compel Plaintiff's repayment. 42 C.F.R. § 10.21.

110. J&J's petition would be heard by a panel selected by HRSA's Office of Pharmacy Affairs Director.

111. HRSA's Office of Pharmacy Affairs director is also the official who twice informed Plaintiff that J&J had established reasonable cause to conduct an audit based on HRSA's *ex parte* review of materials supplied by J&J.

112. Since HRSA declined to reconsider its initial decision, Plaintiff now faces the prospect of an ADR Panel where every possible member is supervised by an official who previously decided that J&J's claim has merit.

113. To avoid this apparently inevitable conflict, Plaintiff requested that HRSA's decision be reconsidered by an official who was not involved in making the initial determination: "If you approved these audits in your role as OPA Director, we respectfully request that the reconsideration be performed by an independent official who was not involved in the initial decision."

114. Plaintiff cannot file suit against J&J over its failure to follow the Manufacturer Audit Guidelines. Under Supreme Court precedent, covered entities lack standing to sue manufacturers for noncompliance with 340B Program requirements, such as the Manufacturer Audit Guidelines. *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 120 (2011).

115. Plaintiff's only protection runs through HRSA and this Court.

COUNT 1

(Administrative Procedure Act, 5 U.S.C. §§ 700, *et seq.*)

116. MaineGeneral Medical Center repeats and realleges paragraphs 1 through 115 hereof, as if fully set forth herein.

117. The APA prohibits HRSA from carrying out the agency's statutory and regulatory duties in a manner that is unlawful, arbitrary, capricious, an abuse of discretion, contrary to law, or without observance of procedure required by law. See 5 U.S.C. § 706(2). HRSA's decision to authorize J&J's audit request, even though the manufacturer failed to provide the required written notice to Plaintiff, was arbitrary, capricious, and unlawful.

118. HRSA's decision represents a final agency action for which Plaintiff has no other remedy at law.

119. Plaintiff would be immediately and irreparably harmed if HRSA's decision were allowed to stand.

120. The intent of Congress and the public interest will be served by an Order vacating HRSA's audit approval decision with respect to Plaintiff, declaring that the Manufacturer Audit Guidelines are binding and mandatory upon HRSA and manufacturers, and prohibiting HRSA from approving any proposed audit in the absence written notice and good-faith attempts to resolve the issue, as described in the Manufacturer Audit Guidelines.

WHEREFORE, MaineGeneral Medical Center prays for the following relief:

A. A declaration pursuant to 28 U.S.C. § 2201 that the Manufacturer Audit Guidelines are binding and mandatory upon both the agency and manufacturers.

B. An order vacating HRSA's decision to approve J&J's audit request with respect to Plaintiff on the grounds that the decision was arbitrary, capricious, contrary to law, and an abuse of discretion.

C. Preliminary and permanent injunctive relief barring the Defendants and any entities acting in concert with them from initiating and/or pursuing any enforcement actions against Plaintiff in connection with J&J's proposed audits.

D. An order awarding Plaintiff costs, expenses, and attorneys' fees incurred in these proceedings pursuant to 28 U.S.C. § 2412; and

E. Such other and further relief that the Court deems just and proper.

Dated: July 24th, 2024

Respectfully submitted,

By: /s James Junger

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Attorneys for Plaintiff MaineGeneral Medical Center

Junger, James

From: Kent, Jennifer
Sent: Wednesday, May 8, 2024 2:28 PM
To: '340B_JJHCS'
Cc: Paluzzi, Lauren [JJCUS]; Nelson, Ken [HCSUS]; Gimpel-Blanchard, Andrea
Subject: RE: Meeting Request: J&J and MaineGeneral (DSH200039) 340B Program Discussion

Wednesday May 15th between 2:00-3:30PM EST?

From: 340B_JJHCS <340B_JJHCS@its.jnj.com>
Sent: Wednesday, May 8, 2024 1:36 PM
To: Kent, Jennifer <jennifer.kent@mainegeneral.org>
Cc: Paluzzi, Lauren [JJCUS] <lpaluzzi@ITS.JNJ.com>; Nelson, Ken [HCSUS] <KNelson8@its.jnj.com>; Gimpel-Blanchard, Andrea <Andrea.Gimpel-Blanchard@MaineGeneral.org>
Subject: <EXTERNAL> RE: Meeting Request: J&J and MaineGeneral (DSH200039) 340B Program Discussion

Thank you for your reply. We appreciate all you are doing to get our meeting scheduled. When you have some options, please send to our team so we can find a slot that will work with our availability as well.

Thank you,

340B J&J Health Care Systems Team

From: Kent, Jennifer <jennifer.kent@mainegeneral.org>
Sent: Wednesday, May 8, 2024 12:50 PM
To: 340B_JJHCS <340B_JJHCS@its.jnj.com>
Cc: Paluzzi, Lauren [JJCUS] <lpaluzzi@ITS.JNJ.com>; Nelson, Ken [HCSUS] <KNelson8@its.jnj.com>; Iwanski, Yvonne [JANUS] <YIwanski@its.jnj.com>; Gimpel-Blanchard, Andrea <Andrea.Gimpel-Blanchard@MaineGeneral.org>
Subject: [EXTERNAL] RE: Meeting Request: J&J and MaineGeneral (DSH200039) 340B Program Discussion

Yes, I've been trying to organize something with all the different schedules. I'll send an invite soon.

From: 340B_JJHCS <340B_JJHCS@its.jnj.com>
Sent: Wednesday, May 8, 2024 10:35 AM
To: Kent, Jennifer <jennifer.kent@mainegeneral.org>
Cc: Paluzzi, Lauren [JJCUS] <lpaluzzi@ITS.JNJ.com>; Nelson, Ken [HCSUS] <KNelson8@its.jnj.com>; Iwanski, Yvonne [JANUS] <YIwanski@its.jnj.com>; Gimpel-Blanchard, Andrea <Andrea.Gimpel-Blanchard@MaineGeneral.org>
Subject: <EXTERNAL> RE: Meeting Request: J&J and MaineGeneral (DSH200039) 340B Program Discussion

Good morning,

Thanks for your initial responses, we are reaching out again as a follow up to schedule a good faith discussion about concerns we have in your 340B utilization. Please let us know when you can schedule over the next 2 weeks.

Look forward to your partnership.

Thank you,

340B J&J Health Care Systems Team

From: 340B_JJHCS <340B_JJHCS@its.jnj.com>
Sent: Thursday, May 2, 2024 8:09 PM
To: Kent, Jennifer <jennifer.kent@mainegeneral.org>
Cc: Paluzzi, Lauren [JJCUS] <lpaluzzi@ITS.JNJ.com>; Nelson, Ken [HCSUS] <KNelson8@its.jnj.com>; Iwanski, Yvonne [JANUS] <YIwanski@its.jnj.com>; Gimpel-Blanchard, Andrea <Andrea.Gimpel-Blanchard@MaineGeneral.org>
Subject: RE: Meeting Request: J&J and MaineGeneral (DSH200039) 340B Program Discussion

Good evening,

We appreciate your response and your commitment to working with us. Please provide us with your availability and we can schedule a meeting.

Thank you for your engagement and we look forward to discussing this further with you.

Thank you,

340B J&J Health Care Systems Team

From: Kent, Jennifer <jennifer.kent@mainegeneral.org>
Sent: Thursday, May 2, 2024 2:22 PM
To: 340B_JJHCS <340B_JJHCS@its.jnj.com>
Cc: Paluzzi, Lauren [JJCUS] <lpaluzzi@ITS.JNJ.com>; Nelson, Ken [HCSUS] <KNelson8@its.jnj.com>; Iwanski, Yvonne [JANUS] <YIwanski@its.jnj.com>; Gimpel-Blanchard, Andrea <Andrea.Gimpel-Blanchard@MaineGeneral.org>
Subject: [EXTERNAL] RE: Meeting Request: J&J and MaineGeneral (DSH200039) 340B Program Discussion

Good afternoon, I apologize for taking so long to get back to you, I have been indisposed.

MaineGeneral is committed to working with Johnson & Johnson, in good faith, regarding questions you may have. As a non-profit rural health system with both an acute care hospital and cancer center, participation in the 340B program is very important to MaineGeneral.

MaineGeneral does NOT have an inhouse (a retail pharmacy owned by the covered entity) pharmacy at this time.

MaineGeneral has one designated contract pharmacy, and those claims are uploaded in 340B ESP as required for that pharmacy.

MaineGeneral's goal is to provide excellent healthcare to the residents of Maine, so there has been program expansion and/or growth in several clinical areas which has driven increased utilization outside of the designated contract pharmacy.

Thank you so much.

Jennifer Kent
340B Program Supervisor
MaineGeneral Medical Center
207-248-5160
Jennifer.kent@mainegeneral.org

From: 340B_JJHCS <340B_JJHCS@its.jnj.com>
Sent: Monday, April 22, 2024 2:36 PM
To: Kent, Jennifer <jennifer.kent@mainegeneral.org>
Cc: Paluzzi, Lauren [JJCUS] <lpaluzzi@ITS.JNJ.com>; Nelson, Ken [HCSUS] <KNelson8@its.jnj.com>; Iwanski, Yvonne [JANUS] <YIwanski@its.jnj.com>
Subject: <EXTERNAL> RE: Meeting Request: J&J and MaineGeneral (DSH200039) 340B Program Discussion

Good afternoon,

Thank you for your response and question. In general, we are looking to better understand the reasons for the growth in your 340B program utilization. We will be asking questions about any changes in your organization's structure or policies to see if that is the basis for the growth we are seeing, or whether there are other reasons why utilization is trending as it has been.

We do appreciate your engagement and look forward to speaking with you.

Thank you,

340B J&J Health Care Systems Team

From: Kent, Jennifer <jennifer.kent@mainegeneral.org>
Sent: Monday, April 22, 2024 1:00 PM
To: 340B_JJHCS <340B_JJHCS@its.jnj.com>
Cc: Paluzzi, Lauren [JJCUS] <lpaluzzi@ITS.JNJ.com>; Nelson, Ken [HCSUS] <KNelson8@its.jnj.com>; Iwanski, Yvonne [JANUS] <YIwanski@its.jnj.com>
Subject: [EXTERNAL] RE: Meeting Request: J&J and MaineGeneral (DSH200039) 340B Program Discussion

I've already given information to 340B ESP. Happy to reach out to our leadership regarding scheduling a call but they would like a more detail as to what the concerns are?

Jennifer Kent
340B Program Supervisor
MaineGeneral Medical Center
Alfond Center for Health
207-248-5160

From: 340B_JJHCS <340B_JJHCS@its.jnj.com>
Sent: Monday, April 22, 2024 11:35 AM
To: Kent, Jennifer <jennifer.kent@mainegeneral.org>
Cc: Patrie, Denise <Denise.Patrie@mainegeneral.org>; Paluzzi, Lauren [JJCUS] <lpaluzzi@ITS.JNJ.com>; Nelson, Ken [HCSUS] <KNelson8@its.jnj.com>; Iwanski, Yvonne [JANUS] <YIwanski@its.jnj.com>
Subject: <EXTERNAL> Meeting Request: J&J and MaineGeneral (DSH200039) 340B Program Discussion

Good morning,

We are reaching out to request time to discuss your Covered Entity's 340B program. Specifically, we would like to discuss and ask questions regarding your entity's 340B utilization.

We look forward to a productive discussion. Please provide the appropriate contacts of your entity to include in this meeting and provide availability options in the coming week, and we can schedule a quick call.

Appreciate the partnership and look forward to speaking.

Thank you,

340B J&J Health Care Systems Team

Johnson&Johnson

Deloitte.

Deloitte & Touche LLP
350 South Grand Avenue
Suite 200
Los Angeles, CA 90071-3462
USA

Tel: (213) 553-1642
Fax: (213) 673-6082
www.deloitte.com

June 20, 2024

Jennifer A Kent, 340B Coordinator, and Primary Contact [1]
MaineGeneral Medical Center
35 Medical Center Parkway
Augusta, ME 04330
340B ID: DSH200039
LETTER SENT VIA EMAIL: jennifer.kent@mainegeneral.org

Re: 340B Performance Audit of MaineGeneral Medical Center on behalf of Johnson & Johnson

Dear Jennifer:

On June 19, 2024, the Health Resources and Services Administration ("HRSA") Office of Pharmacy Affairs ("OPA") approved Johnson & Johnson Health Care Systems Inc.'s ("J&J's") request to audit Maine General Medical Center ("MGMC"), based on the reasonable cause letter and audit work plan submitted to HRSA. J&J has engaged Deloitte and Touche LLP ("Deloitte & Touche") as an independent audit organization to conduct the audit ("340B Performance Audit").

Objective & Scope

The objective of the audit is to determine the MGMC's compliance with Section 340B(a)(5)(A) and (B) of the Public Health Service Act ("PHSA"), from March 01, 2023 – March 31, 2024 for the following J&J Products:

- STELARA 45 MG/0.5 ML ULTRASAFE PFS (57894-0060-03)
- STELARA 45 MG/VIAL 24 CT (57894-0060-02)
- STELARA 90 MG/1.0 ML ULTRASAFE PFS (57894-0061-03)
- STELARA IV 1X130MG VIAL USA (57894-0054-27)
- TREMFYA 1X100MG ONE PR. USA (57894-0640-11)
- TREMFYA 1X100MG USAFEPL USA (57894-0640-01)

The objectives of the approved 340B Performance Audit Work Plan are to:

- Gain an understanding of the MGMC's policies, procedures, operations and internal controls to mitigate the risk of product diversion.
- Obtain and assess various procurement, inventory, distribution, dispensing, replenishment, and billing records to determine whether the MGMC was and remains in compliance with section 340B(a)(5)(B) of the Public Health Service Act related to product diversion for the in-scope audit period.
- Gain an understanding of the MGMC's operations and procedures to mitigate the risk of manufacturer duplicate discounts and impact of entity's decision to carve out or carve in Medicaid prescriptions and the related impact on inventory monitoring.

[1] As noted on the Office of Pharmacy Affairs Information System ("OPAIS")

- Obtain and assess records for 340B and Medicaid activity, including purchasing, inventory, and dispense data to determine if the MGMC was in compliance with section 340B(a)(5)(A) of the Public Health Service Act related to non-provision of duplicate discounts for the in-scope audit period.
- Communicate results in a formal report.

Data and Documentation Request List ("DRL")

In order to facilitate the 340B Performance Audit we have prepared – and attached – an initial DRL, which lists the documentation necessary in order to execute our audit procedures. Please note that additional information may be requested based on our initial review of DRL items, following sample selection, and throughout the audit.

Any and all requested DRL items that are available and able to be provided before the start of our field work will expedite the 340B Performance Audit and may potentially decrease the number of days required from MGMC. Please provide the requested DRL items by July 5, 2024.

Fieldwork

Our fieldwork will be completed virtually and include interviews of MGMC's 340B stakeholders and walkthroughs of applicable 340B processes. We are targeting the fieldwork to begin the week of July 8, 2024 and are committed to limiting interruptions to MGMC's operations to the extent possible. Additionally, we have controls in place to ensure privacy requirements are upheld throughout the 340B Performance Audit.

Upon completing the 340B Performance Audit, Deloitte & Touche will prepare a draft audit report communicating the results to J&J. J&J will be responsible for submitting the draft audit report to MGMC, and MGMC will have an opportunity to provide a response to the report within 30 days of receipt. Upon receipt of the response from MGMC, Deloitte & Touche reserves the right to incorporate this response into the draft report, making any final updates, as needed. J&J will submit copies of the 340B Performance Audit report to HRSA and the Office of Inspector General.

Immediate Next Steps

We would like to schedule a call with you for the week of June 24, 2024 to identify the appropriate MGMC point of contact for the 340B Performance Audit, confirm your understanding of our DRL, answer any questions or concerns that you might have, and discuss timeline and logistics. Please contact me at mimada@deloitte.com at your earliest convenience to confirm receipt of audit notification and to schedule this call.

We look forward to working with you on the 340B Performance Audit and thank you in advance for your time and participation.

Sincerely,

Marcy Imada
Managing Director, Deloitte & Touche LLP

Initial Documentation and Data Request List ("DRL")

This is the initial documentation and data request list for the 340B Performance Audit. As fieldwork progresses and samples are selected, there may be supplemental documents and data requested. We ask that you provide all documents and data via Deloitte Connect, a secure and efficient platform, for managing our DRL. Following is a link to our user demo video: Deloitte Connect User Video

Please email Abel Haile at abhaile@deloitte.com with a list of contacts from your organization for whom access needs to be provided to Deloitte Connect. Once we receive this information, we will add each user to the Deloitte Connect page and an automated email will be sent, to each user, with instructions to create a username and password credentials. After completing the necessary steps, each user will be able to access Deloitte Connect and start using it for document/data provision. **Please provide the requested DRL items by July 5, 2024.**

Request Category	Request Area	Request Description
340B Program Overview	Policies and Procedures **Note:** Provide all versions of the policy that were effective within the audit period	Documentation related to existing 340B policies and procedures, including: • Definition of "eligible site", process of determining what sites are eligible and list of 340B drug dispensing locations • Definition of "eligible patient" • Definition of "eligible provider" and medical staff relationships • Mechanism to prevent diversion and duplicate discounts at CE, off-site facilities, and retail / contract pharmacy dispenses • Medicaid billing requirements & carve-in / out status (by state) • Process for ensuring that the 340B OPAIS record is up to date/accurate for the parent, applicable off-site outpatient facilities and contract pharmacies • Process for procuring, distributing, and billing 340B drugs (including purchases made outside 340B software, borrow and loan processes, as applicable) • Processes to manage 340B physical and / or virtual inventory (including applicable 340B software maintenance activities) • Processes designed to prevent non-compliance with 340B Program requirements and guidelines, specifically as it relates to diversion and duplicate discount compliance (including monitoring activities utilized to detect non-compliance of diversion and duplicate discount) • Processes to prevent the resale or transfer of drugs to a person that is not a patient of the CE (*i.e.*, diversion) and contract pharmacy processes to confirm the following: o Patient eligibility (including status change) o Site eligibility location o Referral / responsibility of care remained with CE o Medical / patient health record

Request Category	Request Area	Request Description
		○ Provider eligibility (relationship) ○ Service in the scope of grant (if applicable/non-hospital) ○ Documenting and accounting for wastage of a drug not administered • When and how CE would self-disclose and CE's definition of noncompliance material breach • CE's process for conducting oversight of its contract pharmacy(ies), including Internal audits and independent audits
340B Personnel	340B Personnel Names and Contact Information	Personnel involved in 340B activities, to participate in audit interviews and process walkthroughs including, but not limited to, the following (as applicable): • Roles identified in 340B Enrollment (i.e., Authorizing Official, Primary Contact, Grant Manager, etc.) • 340B Point of Contact (e.g., Pharmacy Director) • Systems Owners (e.g., split-billing software) • Individuals involved in patient intake/handling/processing, purchasing, dispensing, or billing of applicable drugs • Individuals with relevant clinical and admissions responsibilities, for example: • Hospital Admissions Personnel
340B Oversight	Independent Audits and Corrective Action Plans ("CAP"), as applicable	If independent audit(s) are performed – to evaluate for 340B diversion and compliance with the prohibition of duplicate discounts – provide: • documentation of the methodology applied • any corrective action related to the NDC-11s and time period subject to this manufacturer audit.
340B Oversight	Communications with State Medicaid Agencies	Communications with state Medicaid Agencies related to Medicaid billing, including potential duplicate discounts CAPs
340B Oversight	Internal Monitoring Activities and CAPs, as applicable	If internal monitoring activities are performed - to evaluate for 340B diversion and compliance with the prohibition of duplicate discounts - provide: • documentation of the methodology applied • any corrective action related to the NDC-11s and time period subject to this manufacturer audit.
340B Agreements	TPA Agreement	Current contract in place with 340B TPA (*i.e.*, software vendor used for 340B operations) **Note:** Proprietary business-related information within the contract not related to the prevention of diversion and/or duplicate discounts may be redacted by CE.
340B Agreements	Pharmacy Service Agreements ("PSA")	A listing of contract pharmacies utilized, and the current contracts individually identifying in-scope contract pharmacy (this is for purposes of confirming compliance with diversion and duplicate discounting through contract pharmacy relationships).

Request Category	Request Area	Request Description
		Note: Proprietary business-related information within the contract not related to the prevention of diversion and/or duplicate discounts may be redacted by CE.
340B Data Universe*	Data universe	For the audit in-scope time period and NDC-11s, a listing of applicable drug orders or prescriptions (include all account types: Wholesale Acquisition Cost ("WAC"), Group Purchasing Order ("GPO") and 340B) for both hospital-based and contract pharmacy transactions in Excel format. The following data elements should be included: • Unique identifying number – this is likely the prescription (Rx) number, but can be any number you assign that will allow tracking through your system to retrieve all information associated with the order • The drug / product name / NDC • The acquisition price • The type of account the drug was purchased through and the associated 340B ID number • The quantity issued • The patient ID number (*e.g.*, Medical Record Number ("MRN")) • The payer (All payers including Medicaid) • The date of the order and date it was dispensed or administered • The ordering provider • The location / site drug was administered / ordered / prescribed • Whether the drug was dispensed / or used, reversed, or returned to stock • Any modifiers indicating use of 340B drugs, as applicable
340B Data Universe	Description of universe	A narrative describing the methodology by which the data was gathered, and any limitations or exclusions (*e.g.*, whether reversed transactions, or any other elements, were excluded or other drug orders or dispenses, were direct purchases included or other purchasing mechanisms).
340B Data Universe	NPI and MPN	Copy of the CE's Medicaid provider enrollment verification letters, including NPI, Medicaid ID number(s) or Provider Number for all entities, including out-of-state billing numbers
340B Data Universe	Prescriber file	A listing of all providers, employed and contracted with the CE, that include start dates and termination dates.
340B Data Universe	EHR departmental crosswalk	Full listing of Electronic Health Record ("EHR") department classifications including Department ID and Description.
340B Software Documents	Patient eligibility configuration settings	A report/screenshot of existing patient eligibility settings for hospital-based and retail/contract pharmacy transactions.
340B Software Documents	Split-billing software accumulator report	List of the most current accumulations of 340B and GPO drugs for each in-scope NDC-11 by accumulation repository.
340B Software Documents	CDM-NDC Crosswalk	Listing of each in-scope NDC-11 assigned to a specific Charge Data Master ("CDM") and applicable Billing Units Per Package ("BUPP"), as applicable

Request Category	Request Area	Request Description
340B Software Documents	Split-billing software adjustments	List of adjustments made in split-billing software that would impact in-scope drugs (*e.g.*, manual adjustments, updates to crosswalks and BUPPs, etc.)
Drug Purchasing Documents	Drug purchasing accounts	For the in-scope period a listing of all accounts used to purchase drugs for the parent and off-site outpatient facilities, which includes locations dispensing or distributing 340B drugs and a description of the applicable pricing (340B, GPO, WAC). This applies to wholesaler, direct purchases (made outside of the wholesaler), and any materials management accounts that are used to support 340B drug procurement.
Drug Purchasing Documents	Drug purchase history	For the in-scope period a listing of applicable wholesaler drug purchase orders, including price paid. This is for all account types including 340B, GPO and WAC.
Drug Purchasing Documents	Drugs purchased outside of wholesaler	For the in-scope period a report of applicable drugs purchased outside of wholesaler, including price paid. This is for all account types including 340B, GPO and WAC.
Drug Purchasing Documents	Perpetual Inventory	Report detailing the number of packages currently in stock by dispensing location / department for each in-scope NDC-11 used during the audit in-scope period.
Drug Purchasing Documents	Dispensing locations	A listing of all clinics and locations where health care services are provided to individuals for which the CE deems itself responsible for the health care services provided for purposes of meeting 340B eligibility. Include indication of inventory model utilized at each location (*e.g.*, virtual inventory model vs physical inventory model)
340B Samples **Note:** This would be part of a supplemental documentation and data request to be issued upon sample selection	Screenshots of Patient Medical Records	For selected hospital-based and contract pharmacy transactions samples provide screenshots from the EHR of the following: • applicable drug dispense / administration supporting documentation, including (1) administered NDC-11 and quantity, (2) dispensing / administering provider, department, and time stamp • inpatient admission order, as applicable • outpatient prescriptions, including (1) ordering provider and department (2) written date (3) drug name, quantity, and applicable refills

*Covered Entity is requested to provide documentation and data to auditors limiting the amount of protected health information ("PHI") and personally identifiable information ("PII") to that which is specifically requested (*e.g.*, prescription number, patient ID number). J&J respects Covered Entity's responsibility to protect patient confidentiality and proprietary information. Therefore, confidential patient information and / or proprietary information which auditors may access in the performance of an audit will not be disclosed to J&J.

HALL RENDER
KILLIAN HEATH & LYMAN

Hall, Render, Killian, Heath & Lyman, P.C.
330 East Kilbourn Avenue, Suite 1250
Milwaukee, WI 53202
https://www.hallrender.com

T. James Junger
(414) 721-0922
jjunger@hallrender.com

June 28, 2024

Via E-mail to mimada@deloitte.com

Marcy Imada
Managing Director
Deloitte & Touche LLP

RE: 340B Performance Audit of MaineGeneral Medical Center on Behalf of Johnson & Johnson

Dear Ms. Imada:

MaineGeneral Health ("**MaineGeneral**") has engaged Hall Render to represent it in connection with Johnson & Johnson's proposed audit of MaineGeneral Medical Center.

MaineGeneral was surprised to have received your request. As you know, the controlling Manufacturer Audit Standards require a manufacturer to "notify the covered entity in writing when it believes the covered entity has violated the provisions of section 340B."[1] We are not aware of any such notification. As a result, MaineGeneral declines your request to set up a call for the week of June 24 and does not anticipate providing the materials you requested by July 5. We are aware that HRSA OPA's Director Britton confirmed in an e-mail dated June 26, 2024 that the agency believes J&J met the thresholds identified in Agency guidance to pursue an audit. However, since we have submitted a formal request for reconsideration of the audit approval with the Agency, we have advised MaineGeneral to await a determination from the Agency on that request prior to proceeding with the audit.

MaineGeneral is a rural provider with limited resources available. As such, it must efficiently deploy its resources by prioritizing responses to inquiries such as these based on confirmation of facts and compliance with applicable law. If the audit is finally determined to have been appropriately approved, MaineGeneral will of course willingly and collaboratively move forward with the process. You will note that we have copied Director Britton on this correspondence in the interest of transparency.

While MaineGeneral supports a manufacturer's right to audit covered entity records directly related to compliance with the duplicate discount and diversion prohibitions, manufacturers must comply with HRSA OPA's procedures "relating to the number, duration, and scope of audits[.]"[2]

[1] 61 Fed. Reg. 65,406, 65,410 (Dec. 12, 1996).
[2] 42 U.S.C. § 256b(a)(5)(C).

Those procedures direct covered entities and manufacturers to take at least 30 days "to attempt in good faith to resolve the matter."[3] To our knowledge, this period has not yet started.

Document Requests

To help confirm whether your request complies with applicable 340B Program standards, please send the materials listed below. If you are not the appropriate person to provide any of these materials, please provide us with correct contact information as soon as possible.

1. A statement from Johnson & Johnson authorizing Deloitte to conduct an audit of MaineGeneral on its behalf.

2. A complete and accurate copy of the June 19, 2024 communication from HRSA OPA approving the proposed audit.

3. A complete and accurate copy of the audit work plan that Johnson & Johnson submitted to HRSA OPA.

4. A complete and accurate copy of the reasonable cause letter that Johnson & Johnson submitted to HRSA OPA.

5. Complete and accurate copies of all other communications between Johnson & Johnson or Deloitte and HRSA OPA related to this issue.

6. Complete and accurate copies of all communications between Johnson & Johnson and MaineGeneral related to this issue, including, but not limited to, any communications in which Johnson & Johnson notified MaineGeneral that it believes MaineGeneral violated the provisions of section 340B.

If you decline to provide any of these materials, please identify the provision of the applicable *Government Auditing Standards* that supports your decision.

Information Requests

If the proposed audit moves forward, MaineGeneral will require the following information prior to completing any document request:

1. Confirm whether the audit would be conducted pursuant to *Government Auditing Standards* 2018 Revision Technical Update April 2021 or *Government Auditing Standards* 2024 revision.

2. Confirm whether, consistent with the *Government Auditing Standards*, Deloitte would incorporate performance audit standards from any other authority, as permitted under §

[3] 61 Fed. Reg. at 65,410.

2.14 of the *Government Auditing Standards*, 2024 revision and § 2.15 of the *Government Auditing Standards* 2018 Revision Technical Update April 2021.

3. Confirm that either Deloitte or Johnson & Johnson will reimburse MaineGeneral for the reasonable costs it incurs in responding to the audit.

4. Identify the individual who will sign the performance audit report for Deloitte.

Please copy me on all future communications regarding the proposed audit. We appreciate the opportunity to work with your firm.

Cordially,

Hall, Render, Killian, Heath & Lyman, P.C.

T. James Junger

CC:

Dir. Chantelle Britton

Marci Alexander, Esq.

Jennifer A. Kent

Todd A. Nova, Esq.

Junger, James

From: Handwerker, Jeffrey L. <Jeffrey.Handwerker@arnoldporter.com>
Sent: Monday, July 8, 2024 7:09 PM
To: Junger, James
Cc: Nova, Todd A.; Ramer, Paula
Subject: J&J Audit: Confidentiality Request

Jeffrey Handwerker
Partner | Bio

Arnold & Porter
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Washington, DC 20001-3743
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From: Britton, Chantelle (HRSA) <CBritton@hrsa.gov>
Sent: Wednesday, June 26, 2024 10:18 AM
To: Kent, Jennifer <jennifer.kent@mainegeneral.org>; Brann, Terry <Terry.Brann@MaineGeneral.org>
Cc: Imada, Marcy A <mimada@deloitte.com>; Crain, Clarissa <ccrain@deloitte.com>; Haile, Abel <abhaile@deloitte.com>; HRSA HSB 340B Pricing <340BPricing@hrsa.gov>; Herzog, Michelle (HRSA) <MHerzog@hrsa.gov>
Subject: <EXTERNAL> RE: Response requested: 340B Audit of MaineGeneral Medical Center on behalf of Johnson & Johnson

Thank you for your message.

Johnson & Johnson (J&J) brought their concerns to HRSA's attention through their request to review the work plan to audit MaineGeneral Medical Center. After careful review, HRSA determined that J&J met the thresholds identified in HRSA's Manufacturer Audit Guidelines and Dispute Resolution Process, 61 Fed. Reg. 65,406 (Dec. 12,1996) and Clarification of Manufacturer Audits of 340B Covered Entities, 340B Drug Pricing Program Notice 2011-3 (Nov. 21, 2011) in order to pursue an audit, as defined in section 340B(a)(5)(A) of the Public Health Service Act.

HRSA encourages MaineGeneral Medical Center to cooperate with the auditors working on behalf of J&J, in order to demonstrate MaineGeneral Medical Center's compliance with the 340B Program.

Please let me know if you have any other questions.

Thank you,
Chantelle

From: Haile, Abel <abhaile@deloitte.com>
Sent: Tuesday, June 25, 2024 6:48 PM
To: Britton, Chantelle (HRSA) <CBritton@hrsa.gov>
Cc: jennifer.kent@mainegeneral.org; Imada, Marcy A <mimada@deloitte.com>; Crain, Clarissa <ccrain@deloitte.com>
Subject: [EXTERNAL] Response requested: 340B Audit of MaineGeneral Medical Center on behalf of Johnson & Johnson

Dear Director Britton,

On behalf of Johnson & Johnson Health Systems Inc. and regarding HRSA's 6/19/24 approval of the audit of MaineGeneral Medical Center, we are requesting that HRSA provide written approval of the audit to MaineGeneral Medical Center (DSH200039). Can you please confirm approval with all on copy. This will enable us to proceed with the audit.

Thanks,

Abel Haile
Manager
Deloitte & Touche LLP

HALL RENDER
KILLIAN HEATH & LYMAN

Hall, Render, Killian, Heath & Lyman, P.C.
330 East Kilbourn Avenue, Suite 1250
Milwaukee, WI 53202
https://www.hallrender.com

Todd A. Nova
(414) 721-0464
tnova@hallrender.com

June 28, 2024

VIA E-MAIL: Chantelle.Britton@hrsa.hhs.gov

Chantelle Britton
Director
HRSA Office of Pharmacy Affairs

RE: Reconsideration Request and Document Requests re HRSA's Approval of Johnson & Johnson's Proposed Audits of Multiple Covered Entities

Dear Director Britton:

We are writing on behalf of the three 340B Covered Entities identified in the enclosed letters. Late last week, Deloitte & Touche, LLP ("**Deloitte**") notified each of these entities that HRSA OPA approved Johnson & Johnson Health Care Systems' ("**J&J**") request to audit them. Each Deloitte letter is dated June 20th, and each states that HRSA OPA approved J&J's audit request on June 19th. Deloitte's letters and information requests are also enclosed for your review.

We assume that Deloitte is correct in stating that HRSA OPA approved J&J's audit request, and that in doing so, it relied on a "reasonable cause letter and audit work plan" for each of these Covered Entities. Having reviewed the communications between J&J and each Covered Entity, we believe that HRSA's approval was improvidently granted, and we request that HRSA reconsider this decision.

In particular, we believe HRSA OPA erred by approving, or failing to deny, an audit request and work plan when J&J failed to provide any Covered Entity with a notification "in writing" stating its belief that the Covered Entity has violated sections of the 340B statute subject to manufacturer audit. We believe this is contrary to HRSA OPA's Congressionally-authorized manufacturer audit guidelines, is arbitrary and capricious, and an abuse of discretion. Per HRSA OPA's 1996 Manufacturer Audit Guidelines ("**Audit Guidelines**"), "audits should be performed only when there is reasonable cause for their performance."[1] Therefore, before an audit is initiated, a manufacturer "shall notify the covered entity in writing when it believes the covered entity has violated the provisions of section 340B."[2] This written notification triggers a period of "at least 30 days…[for the manufacturer and covered entity] to attempt in good faith to resolve the matter."[3]

[1] 61 Fed. Reg. 65,407 (Dec. 12, 1996)
[2] *Id.* at 65,406, 65,410.
[3] *Id.*

The good-faith engagement period is not a mere formality, but a crucial procedural safeguard and the sole basis for HRSA OPA's decision not to allow covered entities to respond to manufacturers' (procedurally proper) audit requests and workplans:

> *Comment:* A covered entity should be given an opportunity to respond to a manufacturer's request for an audit before the Department determines whether an audit may be performed and should be permitted to review a comment on the manufacturer's proposed audit workplan before it is approved by the Department.
>
> *Response:* The guidelines provide for a 30 day period before the manufacturer submits to the department an audit work plan in which the manufacturer and the covered entity must attempt in good faith to resolve the matter. When the manufacturer submits its audit work plan, it has already discussed the matter with the covered entity; therefore, we do not believe there is a need for the covered entity to comment on a manufacturer's submission of an audit workplan. The Department, at its discretion, may contact the covered entity as part of the review process of the proposed manufacturer's audit. Likewise, we do not believe that there is a need for the covered entity to review and comment on the manufacturer's proposed workplan once it has been reviewed by the Department.[4]

Thus, in addition to giving a covered entity and a manufacturer an opportunity to resolve any issues without an audit, should the parties fail to reach a resolution, the good-faith engagement period helps to ensure that audits are performed "with the least possible disruption to the covered entity" by allowing a covered entity and a manufacturer to work together to "voluntarily develop[] mutually beneficial audit procedures."[5]

Our understanding is that each of these Covered Entities responded to an apparently general request from J&J to discuss 340B Program compliance. We understand that during their meetings and correspondence with the Covered Entities, J&J asked questions, but provided no notice to any Covered Entity that it believed the Covered Entity violated either the prohibition on diversion or duplicate discounts. As a result, none of the Covered Entities is aware of specific allegations of noncompliance from J&J, nor have they been given any opportunity to resolve those allegations through good-faith engagement.

We are aware that J&J may be pursuing at least three other substantially similar audits. Given the nearly identical communications and document requests that Deloitte sent to each Covered Entity, it seems unlikely that J&J separately established "reasonable cause" as to the duplicate discount prohibition or the diversion prohibition with respect to each Covered Entity.

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[4] *Id.* at 65,408.
[5] *Id.* at 65,406, 65,408.

HRSA OPA has a duty to apply its Congressionally-authorized and statutorily mandated Audit Guidelines. If a manufacturer fails to demonstrate that it provided the required notice in writing and engaged in good faith for at least 30 days, HRSA OPA cannot, consistent with the Audit Guidelines, permit the audit to go forward. Approving J&J's audit requests violated the plain language of the 340B Statute and the Audit Guidelines and was arbitrary and capricious. Among other concerns, we note that J&J's audit requests require information not required in a formal HRSA OPA request. For that and other reasons we believe the audit requests are improper and out of scope. Furthermore, HRSA OPA abused its discretion by failing to "contact the covered entity as part of the review process of the proposed manufacturer's audit."[6]

Pending your response to this reconsideration request, we intend to advise our clients to refrain from providing responses to the audit information requests from J&J and their agent. Of course, if confirmed, they will comply fully with appropriate audit requests in a timely manner.

Reconsideration Request

On behalf of each Covered Entity, we interpret HRSA OPA's decision to permit J&J to perform a manufacturer audit to be an agency action that will cause each Covered Entity immediate harm. We therefore request that you reconsider, and ultimately reverse, this decision to determine whether the official who approved the audits:

1. Determined that J&J provided each Covered Entity with the written notification and 30-day "good-faith engagement" opportunity provided in the 1996 Manufacturer Guidelines;

2. Determined that J&J met the "reasonable cause" standard established in the 1996 Manufacturer Guidelines with respect to each Covered Entity;

3. Made that determination separately for suspected violations of the diversion and duplicate discount prohibitions for each Covered Entity; and

4. Relied on adequate evidence in making the foregoing determinations.

If you approved these audits in your role as OPA Director, we respectfully request that the reconsideration be performed by an independent official who was not involved in the initial decision.

Document Requests

We requested the below materials from Deloitte for each of the Covered Entities, and by this letter, we are requesting them from HRSA OPA, too.

1. For each Covered Entity, please provide a complete and accurate copy of any communication from HRSA OPA approving the proposed audit.

[6] *Id.*

2. For each Covered Entity, please provide a complete and accurate copy of any audit work plan that Johnson & Johnson submitted to HRSA OPA. This includes any work plans submitted directly by Johnson & Johnson or by Deloitte or another agent.

3. For each Covered Entity, please provide a complete and accurate copy of any reasonable cause letter that Johnson & Johnson submitted to HRSA OPA. This includes any reasonable cause letters submitted directly by Johnson & Johnson or by Deloitte or another agent.

4. For each Covered Entity, please provide complete and accurate copies of all other communications between Johnson & Johnson or Deloitte and HRSA OPA related to this issue.

5. For each Covered Entity, and to the extent they are in HRSA OPA's possession, please provide complete and accurate copies of all communications between Johnson & Johnson and each Covered Entity related to this issue, including but not limited to any communications in which Johnson & Johnson notified the Covered Entity that it believed that the Covered Entity violated the provisions of section 340B.

We believe that each Covered Entity is entitled to these documents as a matter of course. J&J failed to provide them with the required written notification and good-faith engagement period, which was HRSA OPA's sole basis justifying the *ex parte* process provided in the Audit Guidelines. However, if you interpret this as a request pursuant to the Freedom of Information Act, we request expedited processing. We also assert that by their nature, the materials cannot include information exempt from disclosure under FOIA Exemption 4, which covers only trade secrets and confidential commercial information. As HHS has stated before, a manufacturer's legal position such as its interpretation of what the 340B Statute requires or prohibits "is neither."[7] To the extent that J&J submitted information purportedly related to any Covered Entity's 340B purchase history, it is likely that the original source of that information is the Covered Entity itself, and J&J would have no reasonable basis on which to claim such information is confidential. We will pay any charges associated with producing these records.

We would appreciate any opportunity to discuss this matter or provide you with further information.

[7] Letter from HHS General Counsel Robert P. Charrow to Eli Lilly Senior Vice President and General Counsel Anat Hakim, p. 2 (Sept. 21, 2020), available at https://tinyurl.com/5dd265dm.

Sincerely,

Hall, Render, Killian, Heath & Lyman, P.C.

Todd A. Nova

cc: James Junger, Esq.
Brandon Helms, Esq.
Heather Mogden, Esq.

Enclosures

Deloitte.

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June 20, 2024

Jennifer A Kent, 340B Coordinator, and Primary Contact[1]
MaineGeneral Medical Center
35 Medical Center Parkway
Augusta, ME 04330
340B ID: DSH200039
LETTER SENT VIA EMAIL: jennifer.kent@mainegeneral.org

Re: 340B Performance Audit of MaineGeneral Medical Center on behalf of Johnson & Johnson

Dear Jennifer:

On June 19, 2024, the Health Resources and Services Administration ("HRSA") Office of Pharmacy Affairs ("OPA") approved Johnson & Johnson Health Care Systems Inc.'s ("J&J's") request to audit Maine General Medical Center ("MGMC"), based on the reasonable cause letter and audit work plan submitted to HRSA. J&J has engaged Deloitte and Touche LLP ("Deloitte & Touche") as an independent audit organization to conduct the audit ("340B Performance Audit").

Objective & Scope

The objective of the audit is to determine the MGMC's compliance with Section 340B(a)(5)(A) and (B) of the Public Health Service Act ("PHSA"), from March 01, 2023 – March 31, 2024 for the following J&J Products:

- STELARA 45 MG/0.5 ML ULTRASAFE PFS (57894-0060-03)
- STELARA 45 MG/VIAL 24 CT (57894-0060-02)
- STELARA 90 MG/1.0 ML ULTRASAFE PFS (57894-0061-03)
- STELARA IV 1X130MG VIAL USA (57894-0054-27)
- TREMFYA 1X100MG ONE PR. USA (57894-0640-11)
- TREMFYA 1X100MG USAFEPL USA (57894-0640-01)

The objectives of the approved 340B Performance Audit Work Plan are to:

- Gain an understanding of the MGMC's policies, procedures, operations and internal controls to mitigate the risk of product diversion.
- Obtain and assess various procurement, inventory, distribution, dispensing, replenishment, and billing records to determine whether the MGMC was and remains in compliance with section 340B(a)(5)(B) of the Public Health Service Act related to product diversion for the in-scope audit period.
- Gain an understanding of the MGMC's operations and procedures to mitigate the risk of manufacturer duplicate discounts and impact of entity's decision to carve out or carve in Medicaid prescriptions and the related impact on inventory monitoring.

[1] As noted on the Office of Pharmacy Affairs Information System ("OPAIS")

- Obtain and assess records for 340B and Medicaid activity, including purchasing, inventory, and dispense data to determine if the MGMC was in compliance with section 340B(a)(5)(A) of the Public Health Service Act related to non-provision of duplicate discounts for the in-scope audit period.
- Communicate results in a formal report.

Data and Documentation Request List ("DRL")

In order to facilitate the 340B Performance Audit we have prepared – and attached – an initial DRL, which lists the documentation necessary in order to execute our audit procedures. Please note that additional information may be requested based on our initial review of DRL items, following sample selection, and throughout the audit.

Any and all requested DRL items that are available and able to be provided before the start of our field work will expedite the 340B Performance Audit and may potentially decrease the number of days required from MGMC. Please provide the requested DRL items by July 5, 2024.

Fieldwork

Our fieldwork will be completed virtually and include interviews of MGMC's 340B stakeholders and walkthroughs of applicable 340B processes. We are targeting the fieldwork to begin the week of July 8, 2024 and are committed to limiting interruptions to MGMC's operations to the extent possible. Additionally, we have controls in place to ensure privacy requirements are upheld throughout the 340B Performance Audit.

Upon completing the 340B Performance Audit, Deloitte & Touche will prepare a draft audit report communicating the results to J&J. J&J will be responsible for submitting the draft audit report to MGMC, and MGMC will have an opportunity to provide a response to the report within 30 days of receipt. Upon receipt of the response from MGMC, Deloitte & Touche reserves the right to incorporate this response into the draft report, making any final updates, as needed. J&J will submit copies of the 340B Performance Audit report to HRSA and the Office of Inspector General.

Immediate Next Steps

We would like to schedule a call with you for the week of June 24, 2024 to identify the appropriate MGMC point of contact for the 340B Performance Audit, confirm your understanding of our DRL, answer any questions or concerns that you might have, and discuss timeline and logistics. Please contact me at mimada@deloitte.com at your earliest convenience to confirm receipt of audit notification and to schedule this call.

We look forward to working with you on the 340B Performance Audit and thank you in advance for your time and participation.

Sincerely,

Marcy Imada

Marcy Imada
Managing Director, Deloitte & Touche LLP

Initial Documentation and Data Request List ("DRL")

This is the initial documentation and data request list for the 340B Performance Audit. As fieldwork progresses and samples are selected, there may be supplemental documents and data requested. We ask that you provide all documents and data via Deloitte Connect, a secure and efficient platform, for managing our DRL. Following is a link to our user demo video: Deloitte Connect User Video

Please email Abel Haile at abhaile@deloitte.com with a list of contacts from your organization for whom access needs to be provided to Deloitte Connect. Once we receive this information, we will add each user to the Deloitte Connect page and an automated email will be sent, to each user, with instructions to create a username and password credentials. After completing the necessary steps, each user will be able to access Deloitte Connect and start using it for document/data provision. **Please provide the requested DRL items by July 5, 2024.**

Request Category	Request Area	Request Description

340B Program Overview	Policies and Procedures
	
	Note: Provide all versions of the policy that were effective within the audit period
		Documentation related to existing 340B policies and procedures, including:
		• Definition of "eligible site", process of determining what sites are eligible and list of 340B drug dispensing locations
		• Definition of "eligible patient"
		• Definition of "eligible provider" and medical staff relationships
		• Mechanism to prevent diversion and duplicate discounts at CE, off-site facilities, and retail / contract pharmacy dispenses
		• Medicaid billing requirements & carve-in / out status (by state)
		• Process for ensuring that the 340B OPAIS record is up to date/accurate for the parent, applicable off-site outpatient facilities and contract pharmacies
		• Process for procuring, distributing, and billing 340B drugs (including purchases made outside 340B software, borrow and loan processes, as applicable)
		• Processes to manage 340B physical and / or virtual inventory (including applicable 340B software maintenance activities)
		• Processes designed to prevent non-compliance with 340B Program requirements and guidelines, specifically as it relates to diversion and duplicate discount compliance (including monitoring activities utilized to detect non-compliance of diversion and duplicate discount)
		• Processes to prevent the resale or transfer of drugs to a person that is not a patient of the CE (*i.e.*, diversion) and contract pharmacy processes to confirm the following:
		  ○ Patient eligibility (including status change)
		  ○ Site eligibility location
		  ○ Referral / responsibility of care remained with CE
		  ○ Medical / patient health record

Request Category	Request Area	Request Description
		○ Provider eligibility (relationship) ○ Service in the scope of grant (if applicable/non-hospital) ○ Documenting and accounting for wastage of a drug not administered • When and how CE would self-disclose and CE's definition of noncompliance material breach • CE's process for conducting oversight of its contract pharmacy(ies), including Internal audits and independent audits
340B Personnel	340B Personnel Names and Contact Information	Personnel involved in 340B activities, to participate in audit interviews and process walkthroughs including, but not limited to, the following (as applicable): • Roles identified in 340B Enrollment (i.e., Authorizing Official, Primary Contact, Grant Manager, etc.) • 340B Point of Contact (e.g., Pharmacy Director) • Systems Owners (e.g., split-billing software) • Individuals involved in patient intake/handling/processing, purchasing, dispensing, or billing of applicable drugs • Individuals with relevant clinical and admissions responsibilities, for example: • Hospital Admissions Personnel
340B Oversight	Independent Audits and Corrective Action Plans ("CAP"), as applicable	If independent audit(s) are performed – to evaluate for 340B diversion and compliance with the prohibition of duplicate discounts – provide: • documentation of the methodology applied • any corrective action related to the NDC-11s and time period subject to this manufacturer audit.
340B Oversight	Communications with State Medicaid Agencies	Communications with state Medicaid Agencies related to Medicaid billing, including potential duplicate discounts CAPs
340B Oversight	Internal Monitoring Activities and CAPs, as applicable	If internal monitoring activities are performed - to evaluate for 340B diversion and compliance with the prohibition of duplicate discounts - provide: • documentation of the methodology applied • any corrective action related to the NDC-11s and time period subject to this manufacturer audit.
340B Agreements	TPA Agreement	Current contract in place with 340B TPA (*i.e.*, software vendor used for 340B operations) **Note:** Proprietary business-related information within the contract not related to the prevention of diversion and/or duplicate discounts may be redacted by CE.
340B Agreements	Pharmacy Service Agreements ("PSA")	A listing of contract pharmacies utilized, and the current contracts individually identifying in-scope contract pharmacy (this is for purposes of confirming compliance with diversion and duplicate discounting through contract pharmacy relationships).

Request Category	Request Area	Request Description
		Note: Proprietary business-related information within the contract not related to the prevention of diversion and/or duplicate discounts may be redacted by CE.
340B Data Universe*	Data universe	For the audit in-scope time period and NDC-11s, a listing of applicable drug orders or prescriptions (include all account types: Wholesale Acquisition Cost ("WAC"), Group Purchasing Order ("GPO") and 340B) for both hospital-based and contract pharmacy transactions in Excel format. The following data elements should be included: • Unique identifying number – this is likely the prescription (Rx) number, but can be any number you assign that will allow tracking through your system to retrieve all information associated with the order • The drug / product name / NDC • The acquisition price • The type of account the drug was purchased through and the associated 340B ID number • The quantity issued • The patient ID number (*e.g.*, Medical Record Number ("MRN")) • The payer (All payers including Medicaid) • The date of the order and date it was dispensed or administered • The ordering provider • The location / site drug was administered / ordered / prescribed • Whether the drug was dispensed / or used, reversed, or returned to stock • Any modifiers indicating use of 340B drugs, as applicable
340B Data Universe	Description of universe	A narrative describing the methodology by which the data was gathered, and any limitations or exclusions (*e.g.*, whether reversed transactions, or any other elements, were excluded or other drug orders or dispenses, were direct purchases included or other purchasing mechanisms).
340B Data Universe	NPI and MPN	Copy of the CE's Medicaid provider enrollment verification letters, including NPI, Medicaid ID number(s) or Provider Number for all entities, including out-of-state billing numbers
340B Data Universe	Prescriber file	A listing of all providers, employed and contracted with the CE, that include start dates and termination dates.
340B Data Universe	EHR departmental crosswalk	Full listing of Electronic Health Record ("EHR") department classifications including Department ID and Description.
340B Software Documents	Patient eligibility configuration settings	A report/screenshot of existing patient eligibility settings for hospital-based and retail/contract pharmacy transactions.
340B Software Documents	Split-billing software accumulator report	List of the most current accumulations of 340B and GPO drugs for each in-scope NDC-11 by accumulation repository.
340B Software Documents	CDM-NDC Crosswalk	Listing of each in-scope NDC-11 assigned to a specific Charge Data Master ("CDM") and applicable Billing Units Per Package ("BUPP"), as applicable

Request Category	Request Area	Request Description
340B Software Documents	Split-billing software adjustments	List of adjustments made in split-billing software that would impact in-scope drugs (*e.g.*, manual adjustments, updates to crosswalks and BUPPs, etc.)
Drug Purchasing Documents	Drug purchasing accounts	For the in-scope period a listing of all accounts used to purchase drugs for the parent and off-site outpatient facilities, which includes locations dispensing or distributing 340B drugs and a description of the applicable pricing (340B, GPO, WAC). This applies to wholesaler, direct purchases (made outside of the wholesaler), and any materials management accounts that are used to support 340B drug procurement.
Drug Purchasing Documents	Drug purchase history	For the in-scope period a listing of applicable wholesaler drug purchase orders, including price paid. This is for all account types including 340B, GPO and WAC.
Drug Purchasing Documents	Drugs purchased outside of wholesaler	For the in-scope period a report of applicable drugs purchased outside of wholesaler, including price paid. This is for all account types including 340B, GPO and WAC.
Drug Purchasing Documents	Perpetual Inventory	Report detailing the number of packages currently in stock by dispensing location / department for each in-scope NDC-11 used during the audit in-scope period.
Drug Purchasing Documents	Dispensing locations	A listing of all clinics and locations where health care services are provided to individuals for which the CE deems itself responsible for the health care services provided for purposes of meeting 340B eligibility. Include indication of inventory model utilized at each location (*e.g.*, virtual inventory model vs physical inventory model)
340B Samples **Note:** This would be part of a supplemental documentation and data request to be issued upon sample selection	Screenshots of Patient Medical Records	For selected hospital-based and contract pharmacy transactions samples provide screenshots from the EHR of the following: • applicable drug dispense / administration supporting documentation, including (1) administered NDC-11 and quantity, (2) dispensing / administering provider, department, and time stamp • inpatient admission order, as applicable • outpatient prescriptions, including (1) ordering provider and department (2) written date (3) drug name, quantity, and applicable refills

*Covered Entity is requested to provide documentation and data to auditors limiting the amount of protected health information ("PHI") and personally identifiable information ("PII") to that which is specifically requested (*e.g.*, prescription number, patient ID number). J&J respects Covered Entity's responsibility to protect patient confidentiality and proprietary information. Therefore, confidential patient information and / or proprietary information which auditors may access in the performance of an audit will not be disclosed to J&J.

Deloitte.

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June 20, 2024

Joe E Ness, SVP and Chief Operating Officer, and Authorizing Official [1]
Jennifer Zanon, Director Pharmacy Services; Regulatory Compliance, and Primary Contact[1]
Oregon Health Science Center University Hospital
3181 SW Sam Jackson Park Rd
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340B ID: DSH380009
LETTER SENT VIA EMAIL: jness610@icloud.com and zanon@ohsu.edu

Re: 340B Performance Audit of Oregon Health Science Center University Hospital on behalf of Johnson & Johnson

Dear Joe and Jennifer:

On June 19, 2024, the Health Resources and Services Administration ("HRSA") Office of Pharmacy Affairs ("OPA") approved Johnson & Johnson Health Care Systems Inc.'s ("J&J's") request to audit Oregon Health Science Center University Hospital ("OHSCUH"), based on the reasonable cause letter and audit work plan submitted to HRSA. J&J has engaged Deloitte and Touche LLP ("Deloitte & Touche") as an independent audit organization to conduct the audit ("340B Performance Audit").

Objective & Scope

The objective of the audit is to determine the OHSCUH's compliance with Section 340B(a)(5)(A) and (B) of the Public Health Service Act ("PHSA"), from March 01, 2023 – March 31, 2024 for the following J&J Products:

- STELARA 45 MG/0.5 ML ULTRASAFE PFS (57894-0060-03)
- STELARA 45 MG/VIAL 24 CT (57894-0060-02)
- STELARA 90 MG/1.0 ML ULTRASAFE PFS (57894-0061-03)
- STELARA IV 1X130MG VIAL USA (57894-0054-27)
- TREMFYA 1X100MG ONE PR. USA (57894-0640-11)
- TREMFYA 1X100MG USAFEPL USA (57894-0640-01)

The objectives of the approved 340B Performance Audit Work Plan are to:

- Gain an understanding of the OHSCUH's policies, procedures, operations and internal controls to mitigate the risk of product diversion.
- Obtain and assess various procurement, inventory, distribution, dispensing, replenishment, and billing records to determine whether the OHSCUH was and remains in compliance with section 340B(a)(5)(B) of the Public Health Service Act related to product diversion for the in-scope audit period.

[1] As noted on the Office of Pharmacy Affairs Information System ("OPAIS")

- Gain an understanding of the OHSCUH's operations and procedures to mitigate the risk of manufacturer duplicate discounts and impact of entity's decision to carve out or carve in Medicaid prescriptions and the related impact on inventory monitoring.
- Obtain and assess records for 340B and Medicaid activity, including purchasing, inventory, and dispense data to determine if the OHSCUH was in compliance with section 340B(a)(5)(A) of the Public Health Service Act related to non-provision of duplicate discounts for the in-scope audit period.
- Communicate results in a formal report.

Data and Documentation Request List ("DRL")

In order to facilitate the 340B Performance Audit we have prepared – and attached – an initial DRL, which lists the documentation necessary in order to execute our audit procedures. Please note that additional information may be requested based on our initial review of DRL items, following sample selection, and throughout the audit.

Any and all requested DRL items that are available and able to be provided before the start of our field work will expedite the 340B Performance Audit and may potentially decrease the number of days required from OHSCUH. Please provide the requested DRL items by July 5, 2024.

Fieldwork

Our fieldwork will be completed virtually and include interviews of OHSCUH's 340B stakeholders and walkthroughs of applicable 340B processes. We are targeting the fieldwork to begin the week of July 8, 2024 and are committed to limiting interruptions to OHSCUH's operations to the extent possible. Additionally, we have controls in place to ensure privacy requirements are upheld throughout the 340B Performance Audit.

Upon completing the 340B Performance Audit, Deloitte & Touche will prepare a draft audit report communicating the results to J&J. J&J will be responsible for submitting the draft audit report to OHSCUH, and OHSCUH will have an opportunity to provide a response to the report within 30 days of receipt. Upon receipt of the response from OHSCUH, Deloitte & Touche reserves the right to incorporate this response into the draft report, making any final updates, as needed. J&J will submit copies of the 340B Performance Audit report to HRSA and the Office of Inspector General.

Immediate Next Steps

We would like to schedule a call with you for the week of June 24, 2024 to identify the appropriate OHSCUH primary contact for the 340B Performance Audit, confirm your understanding of our DRL, answer any questions or concerns that you might have, and discuss timeline and logistics. Please contact me at mimada@deloitte.com at your earliest convenience to confirm receipt of audit notification and to schedule this call.

We look forward to working with you on the 340B Performance Audit and thank you in advance for your time and participation.

Sincerely,

Marcy Imada

Marcy Imada
Managing Director, Deloitte & Touche LLP

Initial Documentation and Data Request List ("DRL")

This is the initial documentation and data request list for the 340B Performance Audit. As fieldwork progresses and samples are selected, there may be supplemental documents and data requested. We ask that you provide all documents and data via Deloitte Connect, a secure and efficient platform, for managing our DRL. Following is a link to our user demo video: Deloitte Connect User Video

Please email Abel Haile at abhaile@deloitte.com with a list of contacts from your organization for whom access needs to be provided to Deloitte Connect. Once we receive this information, we will add each user to the Deloitte Connect page and an automated email will be sent, to each user, with instructions to create a username and password credentials. After completing the necessary steps, each user will be able to access Deloitte Connect and start using it for document/data provision. **Please provide the requested DRL items by July 5, 2024.**

Request Category	Request Area	Request Description

340B Program Overview	Policies and Procedures
	
	Note: Provide all versions of the policy that were effective within the audit period
		Documentation related to existing 340B policies and procedures, including:
		• Definition of "eligible site", process of determining what sites are eligible and list of 340B drug dispensing locations
		• Definition of "eligible patient"
		• Definition of "eligible provider" and medical staff relationships
		• Mechanism to prevent diversion and duplicate discounts at CE, off-site facilities, and retail / contract pharmacy dispenses
		• Medicaid billing requirements & carve-in / out status (by state)
		• Process for ensuring that the 340B OPAIS record is up to date/accurate for the parent, applicable off-site outpatient facilities and contract pharmacies
		• Process for procuring, distributing, and billing 340B drugs (including purchases made outside 340B software, borrow and loan processes, as applicable)
		• Processes to manage 340B physical and / or virtual inventory (including applicable 340B software maintenance activities)
		• Processes designed to prevent non-compliance with 340B Program requirements and guidelines, specifically as it relates to diversion and duplicate discount compliance (including monitoring activities utilized to detect non-compliance of diversion and duplicate discount)
		• Processes to prevent the resale or transfer of drugs to a person that is not a patient of the CE (*i.e.*, diversion) and contract pharmacy processes to confirm the following:
		  ○ Patient eligibility (including status change)
		  ○ Site eligibility location
		  ○ Referral / responsibility of care remained with CE
		  ○ Medical / patient health record

Request Category	Request Area	Request Description
		○ Provider eligibility (relationship) ○ Service in the scope of grant (if applicable/non-hospital) ○ Documenting and accounting for wastage of a drug not administered • When and how CE would self-disclose and CE's definition of noncompliance material breach • CE's process for conducting oversight of its contract pharmacy(ies), including Internal audits and independent audits
340B Personnel	340B Personnel Names and Contact Information	Personnel involved in 340B activities, to participate in audit interviews and process walkthroughs including, but not limited to, the following (as applicable): • Roles identified in 340B Enrollment (i.e., Authorizing Official, Primary Contact, Grant Manager, etc.) • 340B Point of Contact (e.g., Pharmacy Director) • Systems Owners (e.g., split-billing software) • Individuals involved in patient intake/handling/processing, purchasing, dispensing, or billing of applicable drugs • Individuals with relevant clinical and admissions responsibilities, for example: • Hospital Admissions Personnel
340B Oversight	Independent Audits and Corrective Action Plans ("CAP"), as applicable	If independent audit(s) are performed – to evaluate for 340B diversion and compliance with the prohibition of duplicate discounts – provide: • documentation of the methodology applied • any corrective action related to the NDC-11s and time period subject to this manufacturer audit.
340B Oversight	Communications with State Medicaid Agencies	Communications with state Medicaid Agencies related to Medicaid billing, including potential duplicate discounts CAPs
340B Oversight	Internal Monitoring Activities and CAPs, as applicable	If internal monitoring activities are performed - to evaluate for 340B diversion and compliance with the prohibition of duplicate discounts - provide: • documentation of the methodology applied • any corrective action related to the NDC-11s and time period subject to this manufacturer audit.
340B Agreements	TPA Agreement	Current contract in place with 340B TPA (*i.e.*, software vendor used for 340B operations) **Note:** Proprietary business-related information within the contract not related to the prevention of diversion and/or duplicate discounts may be redacted by CE.
340B Agreements	Pharmacy Service Agreements ("PSA")	A listing of contract pharmacies utilized, and the current contracts individually identifying in-scope contract pharmacy (this is for purposes of confirming compliance with diversion and duplicate discounting through contract pharmacy relationships).

Request Category	Request Area	Request Description
		Note: Proprietary business-related information within the contract not related to the prevention of diversion and/or duplicate discounts may be redacted by CE.
340B Data Universe*	Data universe	For the audit in-scope time period and NDC-11s, a listing of applicable drug orders or prescriptions (include all account types: Wholesale Acquisition Cost ("WAC"), Group Purchasing Order ("GPO") and 340B) for both hospital-based and contract pharmacy transactions in Excel format. The following data elements should be included: • Unique identifying number – this is likely the prescription (Rx) number, but can be any number you assign that will allow tracking through your system to retrieve all information associated with the order • The drug / product name / NDC • The acquisition price • The type of account the drug was purchased through and the associated 340B ID number • The quantity issued • The patient ID number (*e.g.*, Medical Record Number ("MRN")) • The payer (All payers including Medicaid) • The date of the order and date it was dispensed or administered • The ordering provider • The location / site drug was administered / ordered / prescribed • Whether the drug was dispensed / or used, reversed, or returned to stock • Any modifiers indicating use of 340B drugs, as applicable
340B Data Universe	Description of universe	A narrative describing the methodology by which the data was gathered, and any limitations or exclusions (*e.g.*, whether reversed transactions, or any other elements, were excluded or other drug orders or dispenses, were direct purchases included or other purchasing mechanisms).
340B Data Universe	NPI and MPN	Copy of the CE's Medicaid provider enrollment verification letters, including NPI, Medicaid ID number(s) or Provider Number for all entities, including out-of-state billing numbers
340B Data Universe	Prescriber file	A listing of all providers, employed and contracted with the CE, that include start dates and termination dates.
340B Data Universe	EHR departmental crosswalk	Full listing of Electronic Health Record ("EHR") department classifications including Department ID and Description.
340B Software Documents	Patient eligibility configuration settings	A report/screenshot of existing patient eligibility settings for hospital-based and retail/contract pharmacy transactions.
340B Software Documents	Split-billing software accumulator report	List of the most current accumulations of 340B and GPO drugs for each in-scope NDC-11 by accumulation repository.
340B Software Documents	CDM-NDC Crosswalk	Listing of each in-scope NDC-11 assigned to a specific Charge Data Master ("CDM") and applicable Billing Units Per Package ("BUPP"), as applicable

Request Category	Request Area	Request Description
340B Software Documents	Split-billing software adjustments	List of adjustments made in split-billing software that would impact in-scope drugs (*e.g.*, manual adjustments, updates to crosswalks and BUPPs, etc.)
Drug Purchasing Documents	Drug purchasing accounts	For the in-scope period a listing of all accounts used to purchase drugs for the parent and off-site outpatient facilities, which includes locations dispensing or distributing 340B drugs and a description of the applicable pricing (340B, GPO, WAC). This applies to wholesaler, direct purchases (made outside of the wholesaler), and any materials management accounts that are used to support 340B drug procurement.
Drug Purchasing Documents	Drug purchase history	For the in-scope period a listing of applicable wholesaler drug purchase orders, including price paid. This is for all account types including 340B, GPO and WAC.
Drug Purchasing Documents	Drugs purchased outside of wholesaler	For the in-scope period a report of applicable drugs purchased outside of wholesaler, including price paid. This is for all account types including 340B, GPO and WAC.
Drug Purchasing Documents	Perpetual Inventory	Report detailing the number of packages currently in stock by dispensing location / department for each in-scope NDC-11 used during the audit in-scope period.
Drug Purchasing Documents	Dispensing locations	A listing of all clinics and locations where health care services are provided to individuals for which the CE deems itself responsible for the health care services provided for purposes of meeting 340B eligibility. Include indication of inventory model utilized at each location (*e.g.*, virtual inventory model vs physical inventory model)
340B Samples **Note:** This would be part of a supplemental documentation and data request to be issued upon sample selection	Screenshots of Patient Medical Records	For selected hospital-based and contract pharmacy transactions samples provide screenshots from the EHR of the following: • applicable drug dispense / administration supporting documentation, including (1) administered NDC-11 and quantity, (2) dispensing / administering provider, department, and time stamp • inpatient admission order, as applicable • outpatient prescriptions, including (1) ordering provider and department (2) written date (3) drug name, quantity, and applicable refills

*Covered Entity is requested to provide documentation and data to auditors limiting the amount of protected health information ("PHI") and personally identifiable information ("PII") to that which is specifically requested (*e.g.*, prescription number, patient ID number). J&J respects Covered Entity's responsibility to protect patient confidentiality and proprietary information. Therefore, confidential patient information and / or proprietary information which auditors may access in the performance of an audit will not be disclosed to J&J.

Deloitte.

Deloitte & Touche LLP
350 South Grand Avenue
Suite 200
Los Angeles, CA 90071-3462
USA

Tel: (213) 553-1642
Fax: (213) 673-6082
www.deloitte.com

June 20, 2024

Carrie Fuller Spencer, Chief Financial Officer, Authorizing Official[1]
Katy Lees, Director 340B Policy and Business Strategy, Primary Contact[1]
Strong Memorial Hospital
601 Elmwood Avenue
Rochester, NY 14642
340B ID: DSH330285
LETTER SENT VIA EMAIL: carrie_fullerspencer@urmc.rochester.edu, Katy_Lees@URMC.Rochester.edu

Re: 340B Performance Audit of Strong Memorial Hospital on behalf of Johnson & Johnson

Dear Carrie and Katy:

On June 19, 2024, the Health Resources and Services Administration ("HRSA") Office of Pharmacy Affairs ("OPA") approved Johnson & Johnson Health Care Systems Inc.'s ("J&J's") request to audit Strong Memorial Hospital ("SMH"), based on the reasonable cause letter and audit work plan submitted to HRSA. J&J has engaged Deloitte and Touche LLP ("Deloitte & Touche") as an independent audit organization to conduct the audit ("340B Performance Audit").

Objective & Scope

The objective of the audit is to determine the SMH's compliance with Section 340B(a)(5)(A) and (B) of the Public Health Service Act ("PHSA"), from March 01, 2023 – March 31, 2024 for the following J&J Products:

- STELARA 45 MG/0.5 ML ULTRASAFE PFS (57894-0060-03)
- STELARA 45 MG/VIAL 24 CT (57894-0060-02)
- STELARA 90 MG/1.0 ML ULTRASAFE PFS (57894-0061-03)
- STELARA IV 1X130MG VIAL USA (57894-0054-27)
- TREMFYA 1X100MG ONE PR. USA (57894-0640-11)
- TREMFYA 1X100MG USAFEPL USA (57894-0640-01)

The objectives of the approved 340B Performance Audit Work Plan are to:

- Gain an understanding of the SMH's policies, procedures, operations and internal controls to mitigate the risk of product diversion.
- Obtain and assess various procurement, inventory, distribution, dispensing, replenishment, and billing records to determine whether the SMH was and remains in compliance with section 340B(a)(5)(B) of the Public Health Service Act related to product diversion for the in-scope audit period.

[1] As noted on the Office of Pharmacy Affairs Information System ("OPAIS")

- Gain an understanding of the SMH's operations and procedures to mitigate the risk of manufacturer duplicate discounts and impact of entity's decision to carve out or carve in Medicaid prescriptions and the related impact on inventory monitoring.
- Obtain and assess records for 340B and Medicaid activity, including purchasing, inventory, and dispense data to determine if the SMH was in compliance with section 340B(a)(5)(A) of the Public Health Service Act related to non-provision of duplicate discounts for the in-scope audit period.
- Communicate results in a formal report.

Data and Documentation Request List ("DRL")

In order to facilitate the 340B Performance Audit we have prepared – and attached – an initial DRL, which lists the documentation necessary in order to execute our audit procedures. Please note that additional information may be requested based on our initial review of DRL items, following sample selection, and throughout the audit.

Any and all requested DRL items that are available and able to be provided before the start of our field work will expedite the 340B Performance Audit and may potentially decrease the number of days required from SMH. Please provide the requested DRL items by July 5, 2024.

Fieldwork

Our fieldwork will be completed virtually and include interviews of SMH's 340B stakeholders and walkthroughs of applicable 340B processes. We are targeting the fieldwork to begin the week of July 8, 2024 and are committed to limiting interruptions to SMH's operations to the extent possible. Additionally, we have controls in place to ensure privacy requirements are upheld throughout the 340B Performance Audit.

Upon completing the 340B Performance Audit, Deloitte & Touche will prepare a draft audit report communicating the results to J&J. J&J will be responsible for submitting the draft audit report to SMH, and SMH will have an opportunity to provide a response to the report within 30 days of receipt. Upon receipt of the response from SMH, Deloitte & Touche reserves the right to incorporate this response into the draft report, making any final updates, as needed. J&J will submit copies of the 340B Performance Audit report to HRSA and the Office of Inspector General.

Immediate Next Steps

We would like to schedule a call with you for the week of June 24, 2024 to identify the appropriate SMH point of contact for the 340B Performance Audit, confirm your understanding of our DRL, answer any questions or concerns that you might have, and discuss timeline and logistics. Please contact me at mimada@deloitte.com at your earliest convenience to confirm receipt of audit notification and to schedule this call.

We look forward to working with you on the 340B Performance Audit and thank you in advance for your time and participation.

Sincerely,

Marcy Imada

Marcy Imada
Managing Director, Deloitte & Touche LLP

Initial Documentation and Data Request List ("DRL")

This is the initial documentation and data request list for the 340B Performance Audit. As fieldwork progresses and samples are selected, there may be supplemental documents and data requested. We ask that you provide all documents and data via Deloitte Connect, a secure and efficient platform, for managing our DRL. Following is a link to our user demo video: Deloitte Connect User Video

Please email Abel Haile at abhaile@deloitte.com with a list of contacts from your organization for whom access needs to be provided to Deloitte Connect. Once we receive this information, we will add each user to the Deloitte Connect page and an automated email will be sent, to each user, with instructions to create a username and password credentials. After completing the necessary steps, each user will be able to access Deloitte Connect and start using it for document/data provision. **Please provide the requested DRL items by July 5, 2024.**

Request Category	Request Area	Request Description

340B Program Overview	Policies and Procedures
	
	Note: Provide all versions of the policy that were effective within the audit period
		Documentation related to existing 340B policies and procedures, including:
		• Definition of "eligible site", process of determining what sites are eligible and list of 340B drug dispensing locations
		• Definition of "eligible patient"
		• Definition of "eligible provider" and medical staff relationships
		• Mechanism to prevent diversion and duplicate discounts at CE, off-site facilities, and retail / contract pharmacy dispenses
		• Medicaid billing requirements & carve-in / out status (by state)
		• Process for ensuring that the 340B OPAIS record is up to date/accurate for the parent, applicable off-site outpatient facilities and contract pharmacies
		• Process for procuring, distributing, and billing 340B drugs (including purchases made outside 340B software, borrow and loan processes, as applicable)
		• Processes to manage 340B physical and / or virtual inventory (including applicable 340B software maintenance activities)
		• Processes designed to prevent non-compliance with 340B Program requirements and guidelines, specifically as it relates to diversion and duplicate discount compliance (including monitoring activities utilized to detect non-compliance of diversion and duplicate discount)
		• Processes to prevent the resale or transfer of drugs to a person that is not a patient of the CE (*i.e.*, diversion) and contract pharmacy processes to confirm the following:
		  ○ Patient eligibility (including status change)
		  ○ Site eligibility location
		  ○ Referral / responsibility of care remained with CE
		  ○ Medical / patient health record

Request Category	Request Area	Request Description
		○ Provider eligibility (relationship) ○ Service in the scope of grant (if applicable/non-hospital) ○ Documenting and accounting for wastage of a drug not administered • When and how CE would self-disclose and CE's definition of noncompliance material breach • CE's process for conducting oversight of its contract pharmacy(ies), including Internal audits and independent audits
340B Personnel	340B Personnel Names and Contact Information	Personnel involved in 340B activities, to participate in audit interviews and process walkthroughs including, but not limited to, the following (as applicable): • Roles identified in 340B Enrollment (i.e., Authorizing Official, Primary Contact, Grant Manager, etc.) • 340B Point of Contact (e.g., Pharmacy Director) • Systems Owners (e.g., split-billing software) • Individuals involved in patient intake/handling/processing, purchasing, dispensing, or billing of applicable drugs • Individuals with relevant clinical and admissions responsibilities, for example: • Hospital Admissions Personnel
340B Oversight	Independent Audits and Corrective Action Plans ("CAP"), as applicable	If independent audit(s) are performed – to evaluate for 340B diversion and compliance with the prohibition of duplicate discounts – provide: • documentation of the methodology applied • any corrective action related to the NDC-11s and time period subject to this manufacturer audit.
340B Oversight	Communications with State Medicaid Agencies	Communications with state Medicaid Agencies related to Medicaid billing, including potential duplicate discounts CAPs
340B Oversight	Internal Monitoring Activities and CAPs, as applicable	If internal monitoring activities are performed - to evaluate for 340B diversion and compliance with the prohibition of duplicate discounts - provide: • documentation of the methodology applied • any corrective action related to the NDC-11s and time period subject to this manufacturer audit.
340B Agreements	TPA Agreement	Current contract in place with 340B TPA (*i.e.*, software vendor used for 340B operations) **Note:** Proprietary business-related information within the contract not related to the prevention of diversion and/or duplicate discounts may be redacted by CE.
340B Agreements	Pharmacy Service Agreements ("PSA")	A listing of contract pharmacies utilized, and the current contracts individually identifying in-scope contract pharmacy (this is for purposes of confirming compliance with diversion and duplicate discounting through contract pharmacy relationships).

Request Category	Request Area	Request Description
		Note: Proprietary business-related information within the contract not related to the prevention of diversion and/or duplicate discounts may be redacted by CE.
340B Data Universe*	Data universe	For the audit in-scope time period and NDC-11s, a listing of applicable drug orders or prescriptions (include all account types: Wholesale Acquisition Cost ("WAC"), Group Purchasing Order ("GPO") and 340B) for both hospital-based and contract pharmacy transactions in Excel format. The following data elements should be included: • Unique identifying number – this is likely the prescription (Rx) number, but can be any number you assign that will allow tracking through your system to retrieve all information associated with the order • The drug / product name / NDC • The acquisition price • The type of account the drug was purchased through and the associated 340B ID number • The quantity issued • The patient ID number (*e.g.*, Medical Record Number ("MRN")) • The payer (All payers including Medicaid) • The date of the order and date it was dispensed or administered • The ordering provider • The location / site drug was administered / ordered / prescribed • Whether the drug was dispensed / or used, reversed, or returned to stock • Any modifiers indicating use of 340B drugs, as applicable
340B Data Universe	Description of universe	A narrative describing the methodology by which the data was gathered, and any limitations or exclusions (*e.g.*, whether reversed transactions, or any other elements, were excluded or other drug orders or dispenses, were direct purchases included or other purchasing mechanisms).
340B Data Universe	NPI and MPN	Copy of the CE's Medicaid provider enrollment verification letters, including NPI, Medicaid ID number(s) or Provider Number for all entities, including out-of-state billing numbers
340B Data Universe	Prescriber file	A listing of all providers, employed and contracted with the CE, that include start dates and termination dates.
340B Data Universe	EHR departmental crosswalk	Full listing of Electronic Health Record ("EHR") department classifications including Department ID and Description.
340B Software Documents	Patient eligibility configuration settings	A report/screenshot of existing patient eligibility settings for hospital-based and retail/contract pharmacy transactions.
340B Software Documents	Split-billing software accumulator report	List of the most current accumulations of 340B and GPO drugs for each in-scope NDC-11 by accumulation repository.
340B Software Documents	CDM-NDC Crosswalk	Listing of each in-scope NDC-11 assigned to a specific Charge Data Master ("CDM") and applicable Billing Units Per Package ("BUPP"), as applicable

Request Category	Request Area	Request Description
340B Software Documents	Split-billing software adjustments	List of adjustments made in split-billing software that would impact in-scope drugs (*e.g.*, manual adjustments, updates to crosswalks and BUPPs, etc.)
Drug Purchasing Documents	Drug purchasing accounts	For the in-scope period a listing of all accounts used to purchase drugs for the parent and off-site outpatient facilities, which includes locations dispensing or distributing 340B drugs and a description of the applicable pricing (340B, GPO, WAC). This applies to wholesaler, direct purchases (made outside of the wholesaler), and any materials management accounts that are used to support 340B drug procurement.
Drug Purchasing Documents	Drug purchase history	For the in-scope period a listing of applicable wholesaler drug purchase orders, including price paid. This is for all account types including 340B, GPO and WAC.
Drug Purchasing Documents	Drugs purchased outside of wholesaler	For the in-scope period a report of applicable drugs purchased outside of wholesaler, including price paid. This is for all account types including 340B, GPO and WAC.
Drug Purchasing Documents	Perpetual Inventory	Report detailing the number of packages currently in stock by dispensing location / department for each in-scope NDC-11 used during the audit in-scope period.
Drug Purchasing Documents	Dispensing locations	A listing of all clinics and locations where health care services are provided to individuals for which the CE deems itself responsible for the health care services provided for purposes of meeting 340B eligibility. Include indication of inventory model utilized at each location (*e.g.*, virtual inventory model vs physical inventory model)
340B Samples **Note:** This would be part of a supplemental documentation and data request to be issued upon sample selection	Screenshots of Patient Medical Records	For selected hospital-based and contract pharmacy transactions samples provide screenshots from the EHR of the following: • applicable drug dispense / administration supporting documentation, including (1) administered NDC-11 and quantity, (2) dispensing / administering provider, department, and time stamp • inpatient admission order, as applicable • outpatient prescriptions, including (1) ordering provider and department (2) written date (3) drug name, quantity, and applicable refills

*Covered Entity is requested to provide documentation and data to auditors limiting the amount of protected health information ("PHI") and personally identifiable information ("PII") to that which is specifically requested (*e.g.*, prescription number, patient ID number). J&J respects Covered Entity's responsibility to protect patient confidentiality and proprietary information. Therefore, confidential patient information and / or proprietary information which auditors may access in the performance of an audit will not be disclosed to J&J.

HRSA
Health Resources & Services Administration
Office of Special Health Initiatives
5600 Fishers Lane
Rockville, MD 20857

July 10, 2024

BY EMAIL
Todd Nova
Attorney
Hall, Render, Killian, Heath & Lyman P.C.
tnova@hallredner.com

Dear Todd Nova:

Johnson & Johnson (J&J) brought its concerns to HRSA's attention through its request to audit Maine General Medical Center, Oregon Health Science Center University Hospital, and Strong Memorial Hospital. After careful review, including review of the work plans, good faith timelines, and the "reasonable cause" bases applicable to each covered entity, HRSA determined that J&J satisfied the procedures to conduct an audit identified in HRSA's Manufacturer Audit Guidelines and Dispute Resolution Process, 61 Fed. Reg. 65,406 (Dec. 12,1996) and Clarification of Manufacturer Audits of 340B Covered Entities, 340B Drug Pricing Program Notice 2011-3 (Nov. 21, 2011).

HRSA declines to reconsider its prior determination that J&J may conduct these audits pursuant to section 340B(a)(5)(A) of the Public Health Service Act. HRSA encourages the covered entities you are representing to cooperate with the auditors working on behalf of J&J to ensure that the audits commence in a timely manner. If any of the covered entities determines that it needs additional time to review J&J's data request and gather the necessary documents, it should ask J&J for an extension.

With regard to the request for communications between J&J and HRSA, HRSA encourages the covered entities to work with J&J for access to J&J's audit work plans and any related correspondence that was a part of HRSA's review. Alternatively, covered entities may submit a Freedom of Information Act (FOIA) request to obtain records that may be available and not subject to a FOIA exemption. Access to the requested documents, is neither a requirement in the 340B statute nor the Manufacturer Audit Guidelines, therefore HRSA respectfully declines to supply these documents through its Office of Pharmacy Affairs.

Sincerely,

Chantelle V. Britton, M.P.A., M.S.
Director, Office of Pharmacy Affairs

JS 44 (Rev. 08/18)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *SEE INSTRUCTI NS N NE T PAGE THIS RM.*

I. (a) PLAINTIFFS

MaineGeneral Medical Center

(b) County of Residence of First Listed Plaintiff 88888
E CEPT IN U.S. PLAINTI CASES

(c) Attorneys *irm Name, Address, and Telephone Number*
Hall, Render, Killian, Heath & Lyman, PC
330 E. Kilbourn Ave., Suite 1250
Milwaukee, WI 53202 (414) 721-0442

DEFENDANTS

CAROLE JOHNSON, Administrator, Health Resources and Services Administration; and XAVIER BECERRA, Secretary, U.S. Dept. of Health and Human Services

County of Residence of First Listed Defendant
IN U.S. PLAINTI CASES NL

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *If no n*

II. BASIS OF JURISDICTION *Place an in ne Box nly*

- ❒ 1 U.S. Government Plaintiff
- ❒ 3 Federal uestion *U.S. Government Not a Party*
- ☒ 2 U.S. Government Defendant
- ❒ 4 Diversity *Indicate Citi enship of Parties in Item III*

III. CITI ENSHIP OF PRINCIPAL PARTIES *Place an in ne Box for Plaintiff or Diversity Cases nly and ne Box for Defendant*

	PTF	DEF		PTF	DEF
Citizen of This State	❒ 1	❒ 1	Incorporated *or* Principal Place of Business In This State	❒ 4	❒ 4
Citizen of Another State	❒ 2	❒ 2	Incorporated *and* Principal Place of Business In Another State	❒ 5	❒ 5
Citizen or Subject of a Foreign Country	❒ 3	❒ 3	Foreign Nation	❒ 6	❒ 6

IV. NATURE OF SUIT *Place an in ne Box nly*

Click here for: Nature of Suit Code Descriptions.

CONTRACT
- ❒ 110 Insurance
- ❒ 120 Marine
- ❒ 130 Miller Act
- ❒ 140 Negotiable Instrument
- ❒ 150 Recovery of Overpayment & Enforcement of Judgment
- ❒ 151 Medicare Act
- ❒ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ❒ 153 Recovery of Overpayment of Veteran's Benefits
- ❒ 160 Stockholders' Suits
- ❒ 190 Other Contract
- ❒ 195 Contract Product Liability
- ❒ 196 Franchise

REAL PROPERTY
- ❒ 210 Land Condemnation
- ❒ 220 Foreclosure
- ❒ 230 Rent Lease & Ejectment
- ❒ 240 Torts to Land
- ❒ 245 Tort Product Liability
- ❒ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ❒ 310 Airplane
- ❒ 315 Airplane Product Liability
- ❒ 320 Assault, Libel & Slander
- ❒ 330 Federal Employers' Liability
- ❒ 340 Marine
- ❒ 345 Marine Product Liability
- ❒ 350 Motor Vehicle
- ❒ 355 Motor Vehicle Product Liability
- ❒ 360 Other Personal Injury
- ❒ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ❒ 365 Personal Injury - Product Liability
- ❒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ❒ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ❒ 370 Other Fraud
- ❒ 371 Truth in Lending
- ❒ 380 Other Personal Property Damage
- ❒ 385 Property Damage Product Liability

CIVIL RIGHTS
- ❒ 440 Other Civil Rights
- ❒ 441 Voting
- ❒ 442 Employment
- ❒ 443 Housing/ Accommodations
- ❒ 445 Amer. w/Disabilities - Employment
- ❒ 446 Amer. w/Disabilities - Other
- ❒ 448 Education

PRISONER PETITIONS

Habeas Corpus
- ❒ 463 Alien Detainee
- ❒ 510 Motions to Vacate Sentence
- ❒ 530 General
- ❒ 535 Death Penalty

Other
- ❒ 540 Mandamus & Other
- ❒ 550 Civil Rights
- ❒ 555 Prison Condition
- ❒ 560 Civil Detainee - Conditions of Confinement

FORFEITURE PENALTY
- ❒ 625 Drug Related Seizure of Property 21 USC 881
- ❒ 690 Other

LABOR
- ❒ 710 Fair Labor Standards Act
- ❒ 720 Labor/Management Relations
- ❒ 740 Railway Labor Act
- ❒ 751 Family and Medical Leave Act
- ❒ 790 Other Labor Litigation
- ❒ 791 Employee Retirement Income Security Act

IMMIGRATION
- ❒ 462 Naturalization Application
- ❒ 465 Other Immigration Actions

BANKRUPTCY
- ❒ 422 Appeal 28 USC 158
- ❒ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ❒ 820 Copyrights
- ❒ 830 Patent
- ❒ 835 Patent - Abbreviated New Drug Application
- ❒ 840 Trademark

SOCIAL SECURITY
- ❒ 861 HIA (1395ff)
- ❒ 862 Black Lung (923)
- ❒ 863 DIWC/DIWW (405(g))
- ❒ 864 SSID Title XVI
- ❒ 865 RSI (405(g))

FEDERAL TA SUITS
- ❒ 870 Taxes (U.S. Plaintiff or Defendant)
- ❒ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ❒ 375 False Claims Act
- ❒ 376 ui Tam (31 USC 3729(a))
- ❒ 400 State Reapportionment
- ❒ 410 Antitrust
- ❒ 430 Banks and Banking
- ❒ 450 Commerce
- ❒ 460 Deportation
- ❒ 470 Racketeer Influenced and Corrupt Organizations
- ❒ 480 Consumer Credit
- ❒ 485 Telephone Consumer Protection Act
- ❒ 490 Cable/Sat TV
- ❒ 850 Securities/Commodities/ Exchange
- ❒ 890 Other Statutory Actions
- ❒ 891 Agricultural Acts
- ❒ 893 Environmental Matters
- ❒ 895 Freedom of Information Act
- ❒ 896 Arbitration
- ☒ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ❒ 950 Constitutionality of State Statutes

V. ORIGIN *Place an in ne Box nly*

☒ 1 Original Proceeding ❒ 2 Removed from State Court ❒ 3 Remanded from Appellate Court ❒ 4 Reinstated or Reopened ❒ 5 Transferred from Another District *specify* ❒ 6 Multidistrict Litigation - Transfer ❒ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing ***(Do not cite jurisdictional statutes unless diversity)*** :
5 U.S.C. § 706(2)

Brief description of cause:
Plaintiff challenges HRSA's decision to permit a drug manufacturer to audit Plaintiff's business records

VII. RE UESTED IN COMPLAINT

❒ CHECK IF THIS IS A **CLASS ACTION** UNDER RULE 23, F.R.Cv.P.

DEMAND

CHECK ES only if demanded in complaint:
JURY DEMAND ❒ es ☒ No

VIII. RELATED CASE(S) IF ANY

See instructions

JUDGE DOCKET NUMBER 1:24-cv-2184

DATE 07/24/2024

SIGNATURE OF ATTORNE OF RECORD /s/ James Junger

FOR OFFICE USE ONLY

RECEIPT AMOUNT APPL ING IFP JUDGE MAG. JUDGE

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

MAINEGENERAL MEDICAL CENTER

Plaintiff(s)

v.

CAROLE JOHNSON, Administrator, Health Resources and Services Administration, and XAVIER BECERRA, Secretary, U.S. Department of Health and Human Services

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Carole Johnson, Administrator
Health Resources and Services Administration
5600 Fishers Lane
Rockville, MD 20852

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: T. James Junger
Hall, Render, Killian, Heath, & Lyman, P.C.
330 E. Kilbourn Ave., Suite 1250
Milwaukee, WI 53202

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. ou also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(is section s ould not e iled it t e court unless re uired y ed iv (l

This summons for *(name of individual and title, if any)* _____
was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____
_____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____
_____ , a person of suitable age and discretion who resides there,
on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is
designated by law to accept service of process on behalf of *(name of organization)* _____
_____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

MAINEGENERAL MEDICAL CENTER

Plaintiff(s)

v.

CAROLE JOHNSON, Administrator, Health Resources and Services Administration, and XAVIER BECERRA, Secretary, U.S. Department of Health and Human Services

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Xavier Becerra, Secretary
U.S. Department of Health and Human Services
200 Independence Ave., S.W., Room 700-E
Washington, DC 20201-0004

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: T. James Junger
Hall, Render, Killian, Heath, & Lyman, P.C.
330 E. Kilbourn Ave., Suite 1250
Milwaukee, WI 53202

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. ou also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(is section s ould not e iled it t e court unless re uired y ed iv (l

This summons for *(name of individual and title, if any)* _____

was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____

_____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____

_____ , a person of suitable age and discretion who resides there,

on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is

designated by law to accept service of process on behalf of *(name of organization)* _____

_____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____

Server's signature

_____

Printed name and title

_____

Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

MAINEGENERAL MEDICAL CENTER

Plaintiff(s)

v.

CAROLE JOHNSON, Administrator, Health Resources and Services Administration, and XAVIER BECERRA, Secretary, U.S. Department of Health and Human Services

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Merrick B. Garland, U.S. Attorney General
U.S. Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530-0001

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: T. James Junger
Hall, Render, Killian, Heath, & Lyman, P.C.
330 E. Kilbourn Ave., Suite 1250
Milwaukee, WI 53202

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. ou also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

PROOF OF SERVICE

(is section s ould not e iled it t e court unless re uired y ed iv (l

This summons for *(name of individual and title, if any)* _____
was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____
_____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____
_____ , a person of suitable age and discretion who resides there,
on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is
designated by law to accept service of process on behalf of *(name of organization)* _____
_____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

MAINEGENERAL MEDICAL CENTER

Plaintiff(s)

v.

CAROLE JOHNSON, Administrator, Health Resources and Services Administration, and XAVIER BECERRA, Secretary, U.S. Department of Health and Human Services

Defendant(s)

Civil Action No.

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* Matthew M. Graves
U.S. Attorney for the District of Columbia
601 D Street, NW
Washington, DC 20530

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: T. James Junger
Hall, Render, Killian, Heath, & Lyman, P.C.
330 E. Kilbourn Ave., Suite 1250
Milwaukee, WI 53202

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. ou also must file your answer or motion with the court.

CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No.

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_____ , a person of suitable age and discretion who resides there,
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❒ I served the summons on *(name of individual)* _____ , who is
designated by law to accept service of process on behalf of *(name of organization)* _____
_____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

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I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc: