# UNITED STATES DISTRICT COURT MIDDLE DISTRICT OF LOUISIANA

PINNACLE MEDICAL SOLUTIONS, LLC, and DIABETES MANAGEMENT & SUPPLIES, LLC,

Plaintiffs,

v.

LOUISIANA HEALTHCARE CONNECTIONS, CENTENE CORPORATION, and RALPH L. ABRAHAM, in his official capacity as Secretary, Louisiana Department of Health

Defendants.

CIVIL ACTION NO. 3:24-cv-00430

# <u>VERIFIED AMENDED COMPLAINT FOR DECLARATORY AND</u> INJUNCTIVE RELIEF, COMPENSATORY DAMAGES, AND ATTORNEYS' FEES<sup>1</sup>

Plaintiffs, Pinnacle Medical Solutions, LLC ("Pinnacle") and Diabetes Management & Supplies, LLC ("DMS"), (collectively, "Plaintiffs"), each a wholly-owned subsidiary of AdaptHealth Corp. ("Adapt"), by through undersigned counsel, bring this action against Defendants, Louisiana Healthcare Connections ("LHC"), a Medicaid Managed Care Organization ("MCO") and its parent company, Centene Corporation ("Centene") (collectively, "LHC-Centene,") as well as against Defendant Ralph L. Abraham, M.D., solely in his official capacity as Secretary of the Louisiana Department of Health ("LDH") (each a "Defendant," and collectively, "Defendants"), due to their collective improper and unconstitutional attempts to claw back millions of dollars previously paid to Pinnacle and DMS for providing diabetes management devices and supplies to the citizens of Louisiana, in violation of the Federal Medicaid Act (42)

<sup>&</sup>lt;sup>1</sup> Plaintiffs are filing this Amended Complaint as a matter of course pursuant to Fed. R. Civ. P. 15.

U.S.C. § 1396a(a)(37)) and the Due Process Clause of the Fourteenth Amendment to the U.S. Constitution. For the reasons set forth below, Pinnacle and DMS are entitled to judgment against Defendants.

#### I. PARTIES

- 1. Pinnacle is a Delaware limited liability company with headquarters in Mississippi that is licensed to do business throughout the United States as a supplier of technology-enabled diabetes management devices, including continuous glucose monitors ("CGM"), and insulin pumps.
- 2. DMS is a Louisiana limited liability company with headquarters in Louisiana that is licensed to do business throughout the United States as a supplier of technology-enabled diabetes management devices, including CGMs.
- 3. Adapt, the parent company of Pinnacle and DMS, is a network of full-service medical equipment companies that provide comprehensive products, services, and supplies, and services beneficiaries of Medicare, Medicaid, and commercial insurance payors, reaching approximately 4 million patients annually in all 50 states through its network of approximately 710 locations in 47 states.
- 4. Ralph L. Abraham, M.D. is the Secretary of LDH,<sup>2</sup> which is a Louisiana state health agency with its headquarters in Baton Rouge, Louisiana that contracts with Medicaid MCOs like LHC-Centene to provide coverage for services in the State of Louisiana.
- 5. LHC is, and at all times relevant to this Complaint was, an entity contracted with LDH to serve as a Medicaid MCO for the Louisiana Medicaid program. LHC is incorporated in the State of Louisiana with its principal place of business in Baton Rouge, Louisiana.

2

<sup>&</sup>lt;sup>2</sup> To the extent applicable, any references to LDH in this Complaint are intended to also refer to Defendant, Ralph L. Abraham, M.D., solely in his capacity as the Secretary of LDH.

6. Centene is, and at all times relevant to this Complaint was, the parent company of LHC. Centene is incorporated in the State of Delaware with its principal place of business in St. Louis, Missouri.

#### II. JURISDICTION AND VENUE

- 7. This Court has subject-matter jurisdiction over this case pursuant to 28 U.S.C. § 1331, because this action arises under the U.S. Constitution and 42 U.S.C. § 1396a(a)(37).
- 8. Venue is proper in this Court under 28 U.S.C. § 1391(b)(2) as this is a judicial district in which a substantial part of the events or omissions giving rise to the claims occurred.

### III. STATEMENT OF FACTS

# A. Facts Relevant to Both Plaintiffs' Causes of Action

- i. LHC-Centene's Contract with LDH
- 9. At all times relevant to this Complaint, LHC-Centene was contracted with the State of Louisiana via the LDH Bureau of Health Services Financing to provide Medicaid MCO services to Louisiana Medicaid beneficiaries (the "MCO Contract"). See generally Exhibit 1, MCO Contract.
- 10. The MCO Contract was renewed for the period of January 1, 2023 through December 31, 2025.<sup>3</sup>
- 11. The MCO Contract requires that LHC-Centene must "adhere to Federal and State laws, regulations, rules, policies, procedures, and guidelines, as well as industry standards and best practices for systems or functions required to support the requirements of [the MCO Contract]."
  - 12. The MCO Contract requires that LHC-Centene comply with all LDH-issued

3

<sup>&</sup>lt;sup>3</sup> Exhibit 1, MCO Contract. All citations to the MCO Contract in this Amended Complaint are to the version of the Contract in effect at the time of the relevant audits, that is, the contract effective as of January 1, 2023.

<sup>&</sup>lt;sup>4</sup> *Id.* at Attachment A, Model Contract, § 2.19.1.12.

policies, including the Louisiana Medicaid MCO Manual (the "MCO Manual").<sup>5</sup>

13. The MCO Manual requires that LHC-Centene carry out its obligations in a commercially reasonable manner and in accordance with federal and state law. *See generally* Exhibit 2, MCO Manual.

- 14. The MCO Manual also requires that LHC-Centene request and obtain prior approval from LDH to utilize statistical extrapolation methods for overpayment determination and follow the Centers for Medicare and Medicaid Services' ("CMS") guidelines, including the Medicare Program Integrity Manual ("MPIM"), when implementing statistical sampling and extrapolation methodologies.<sup>6</sup>
- 15. The MCO Manual also explicitly provides that "[u]nless prior approval is obtained from LDH, the MCO must not employ extrapolation methods to derive an overpayment in a provider audit."<sup>7</sup>

### B. Facts Relevant to Pinnacle's Causes of Action

#### i. Pinnacle's Enrollment with Louisiana Medicaid

- 16. At all times relevant to this Complaint, Pinnacle was enrolled with the Louisiana Medicaid program as a durable medical equipment ("DME") supplier.
- 17. On October 1, 2020, Pinnacle was re-enrolled in the Louisiana Medicaid program subject to a Change of Ownership following Pinnacle's acquisition by Adapt.

#### ii. Pinnacle and LHC-Centene's Provider Agreement

18. On January 1, 2013, Pinnacle entered into a Provider Agreement with LHC-Centene (the "Pinnacle Provider Agreement") to provide DME to LHC-Centene members.

<sup>&</sup>lt;sup>5</sup> *Id.* at § 6.1.4.

<sup>&</sup>lt;sup>6</sup> Exhibit 2, MCO Manual, at Part 15: Program Integrity, p. 244.

<sup>&</sup>lt;sup>7</sup> *Id*.

# **Exhibit 3, Pinnacle Provider Agreement**, at 1.

19. The Pinnacle Provider Agreement states, in relevant part:

### **Provider Agreement**

- **1.11** *Payor* means CCN<sup>8</sup> or another entity that is responsible for funding Covered Services to Covered Persons.
- **1.13** *Provider Manual* means the CCN manual of policies, procedures, and requirements to be followed by Participating Health Care Providers. The Provider Manual includes, but is not limited to, utilization management, quality management, grievances and appeals, and Payor-specific program requirements, and may be changed from time to time by CCN.
- **2.1** <u>Administration.</u> Administration. CCN shall be responsible for the administrative activities necessary or required for the commercially reasonable operation of a coordinated care network. Such activities shall include, but are not limited to, quality improvement, utilization management, grievances and appeals, claims processing, and maintenance of provider directory and records.
- **2.2** <u>Provider Manual.</u> CCN shall make the Provider Manual available to Provider via CCN's website and upon Provider's request. CCN shall post changes to the Provider Manual on CCN's website or provide Provider with prior written notice of material changes to the Provider Manual.
- **4.1.** Compliance with Law and Payor Contracts. Compliance with Law and Payor Contracts. Provider and CCN agree that each party shall carry out its obligations in accordance with terms of the Payor Contract and applicable federal and State laws and regulations, including, but not limited to, the requirements of the Stark law (42 U.S.C. § 1395nn) and applicable federal and State self-referral and fraud and abuse statutes and regulations. If, due to Provider's noncompliance with law, the Payor Contract or this Agreement, sanctions or penalties are imposed on CCN, CCN may, in its sole discretion, offset sanction or penalty amounts against any amounts due Provider from CCN or require Provider to reimburse CCN for the amount of any such sanction or penalty.

5

.

<sup>&</sup>lt;sup>8</sup> "CCN," as named in the Pinnacle Provider Agreement, is the same as LHC-Centene for purposes of this Complaint.

<sup>&</sup>lt;sup>9</sup> Exhibit 3, Pinnacle Provider Agreement, at §§ 1.11, 1.13, 2.1, 2.2, 4.1.

# iii. LHC-Centene's Medical Records Request and Findings

- 20. On June 8, 2022, LHC-Centene issued its June 2022 Request for records to Pinnacle, requesting the medical records for 79 claim lines representing services to 65 LHC-Centene members to whom Pinnacle previously furnished DME during the audit review period from February 1, 2021 to February 14, 2022. Exhibit 4, LHC-Centene's June 2022 Request to Pinnacle ("June 2022 Request").
- 21. On April 27, 2023, LHC-Centene's Special Investigations Unit ("SIU") issued its Initial Proposed Action for Pinnacle and findings related to the June 2022 Request, stating that Pinnacle did not submit any records in response to the June 2022 Request and identifying an alleged overpayment of \$5,836,923.25. Exhibit 5, LHC-Centene's Initial Proposed Action Pinnacle (Redacted).
- 22. On May 4, 2023, LHC-Centene received Pinnacle's May 2023 Response producing documents responsive to the June 2022 Request and appealing the \$5,836,923.25 overpayment demand asserted in LHC-Centene's Initial Proposed Action for Pinnacle.
- 23. On July 3, 2023, LHC-Centene issued its July 2023 Final Proposed Action and set the revised overpayment demand amount at \$5,769,627.75. *See* Exhibit 6, LHC-Centene's July 2023 Final Proposed Action Pinnacle; Exhibit 7, LHC-Centene's July 2023 Audit Findings Attachment Pinnacle (Redacted).
- 24. Upon information and belief, on August 22, 2023, LHC-Centene had an educational call with Pinnacle in relation to its findings.
- 25. Upon information and belief, during that meeting, Pinnacle requested to supplement their May 2023 document production, and subsequently submitted supplemental

documentation for 15 of the 78 claims lines at still issue. 10

- 26. LHC-Centene conducted a second appeal review of the supplemental records and on September 21, 2023, revised its July 2023 Final Proposed Action ("September 2023 Final Proposed Action"). *See* Exhibit 8, LHC-Centene's September 2023 Final Proposed Action Pinnacle.
- 27. The September 2023 Final Proposed Action contained no changes to the overpayment demand amount in the July 2023 Final Proposed Action and upheld the original denial for those 15 claim lines. *See* Exhibit 9, LHC-Centene's September 2023 Audit Findings Attachment Pinnacle (Redacted). As such, the overpayment demand amount remained at \$5,769,627.75.<sup>11</sup>

# iv. <u>LHC-Centene's Document Productions</u>

- 28. On October 17, 2023, LHC-Centene produced the following three documents to Pinnacle:
  - a. "The SAS System"
  - b. "Re-Appeal Audit Sheet Pinnacle Medical Solutions"
  - c. "Re-Appeal Overpayment Letter Pinnacle Medical Solutions."

#### See Exhibit 10, LHC-Centene's October 17, 2023 Production.

29. On October 19, 2023, counsel for Pinnacle requested additional documents from LHC-Centene related to LDH's authorization to LHC-Centene approving the extrapolation and recoupment at issue (as required by LDH), as well as their statistical sampling methodology and

<sup>&</sup>lt;sup>10</sup> Exhibit 6, LHC-Centene's July 2023 Final Proposed Action – Pinnacle.

<sup>&</sup>lt;sup>11</sup> Exhibit 8, LHC-Centene's September 2023 Final Proposed Action – Pinnacle.

extrapolated overpayment, including documents needed to recreate the sampling frame, sample, and extrapolated overpayment. *See* Exhibit 11, Pinnacle's Document Request to LHC-Centene.

- 30. On October 20, 2023, LHC-Centene provided a subset of the requested documents, which have the following file names:
  - a. "03.01.2022\_-\_Preliminary\_Investigation\_Report\_-Pinnacle Medical Solutions"
  - b. "SAMPLE FRAME 20220125 50535 MEDICAID"
  - c. "Replication Package" containing:
    - i. "Centene SVRS and Extrapolation"
    - ii. "extrap input MCD"
    - iii. "sample\_frame\_MCD"
    - iv. "Steps to replicate the SVRS and Extrapolation"
    - v. "strata info MCD"
  - d. "Claim Sampling Project 20220125 50535 Medicaid"
  - e. "Overpaid 20220125-50535 29JUN2023"
  - f. "Statistical Sampling and Extrapolation Provider"

See Exhibit 12, LHC-Centene's October 20, 2023 Production – Pinnacle.

- v. Scope of LHC-Centene's Audit of Pinnacle and Alleged Findings
  - a. Target Universe of Claims
- 31. In its "3.01.2022\_Preliminary Investigation Report" ("Preliminary Investigation Report"), LHC-Centene indicated that the scope of the target universe of claims consisted of 9,716 claim lines, involving 17 Healthcare Common Procedure Coding System ("HCPCS") codes, with dates of service dates ranging from February 1, 2021 to February 21, 2022 ("Target Universe of

Claims").

### b. Sample Frame

- 32. In its "Sample Frame\_20220125" ("Sample Frame"), LHC-Centene indicated that the sampled claims were drawn from a sampling frame which consisted of 9,178 claim lines, involving 14 HCPCS codes, with dates of service dates ranging from February 1, 2021 to February 21, 2022.
- 33. As compared to the Target Universe of Claims described in the section above, the following codes and claim lines were excluded from the Sample Frame:
  - a. Three HCPCS Codes Excluded, which included:
    - i. A4232 (18 claim lines);
    - ii. K0553 (72 claim lines); and
    - iii. K0554 (5 claim lines).
  - b. 538 Claim Lines Excluded, which included:
    - i. 488 claim lines that were \$0.00 paid claims; and
    - 50 paid claim lines of K0553, with payments that ranged from \$178.58 -\$234.60 per claim line.

#### c. <u>Sampled Claims</u>

- 34. LHC-Centene's June 2022 Request consisted of an audit sample of 79 claim lines for 65 beneficiaries, involving nine HCPCS codes, with dates of service ranging from February 1, 2021 to February 14, 2022 (the "LHC-Centene Audit"). 12
- 35. 40 of the 79 claim lines in the LHC-Centene Audit were for CGM sensors (A9276), representing 50.63% of the claim lines under review. 13

<sup>&</sup>lt;sup>12</sup> Exhibit 4, LHC-Centene's June 2022 Request to Pinnacle.

<sup>&</sup>lt;sup>13</sup> Exhibit 7, LHC-Centene's July 2023 Audit Findings Attachment – Pinnacle.

- 36. LHC-Centene denied 100% of the 40 claim lines for A9276. 14
- 37. The remaining 39 claim lines in the sampled claims covered eight additional HCPCS codes.<sup>15</sup>
  - 38. LHC-Centene denied 38 of the 39 remaining claim lines described above. 16
  - 39. Pinnacle was originally paid \$53,022.46 for the 79 sampled claim lines. 17
- 40. After Pinnacle's appeal of LHC-Centene's April 2023 Proposed Action findings, LHC-Centene issued its July 2023 Final Proposed Action, allowing one claim line, which amounted to \$518.60.<sup>18</sup>
- 41. In its July 2023 Final Proposed Action, LHC-Centene denied the remaining 78 claim lines, which amounted to \$52,503.86.<sup>19</sup>
- 42. When LHC-Centene projected the \$52,503.86 it denied for the sampled claims to the sampling frame, the extrapolated overpayment calculation amounted to \$5,769,627.75 (the "Pinnacle \$5.7 Million Overpayment Demand").<sup>20</sup>

# vi. Pinnacle's Formal Rebuttal and Factual Findings

- 43. On November 14, 2023, Pinnacle submitted its Formal Rebuttal to the Pinnacle \$5.7 Million Overpayment Demand in LHC-Centene's July 2023 Final Proposed Action.

  Exhibit 13, Pinnacle's Formal Rebuttal to LHC-Centene.
- 44. On November 17, 2023, LHC-Centene alleged that it had reviewed Pinnacle's November 14, 2023 Formal Rebuttal and stated that LHC-Centene would neither revise nor

<sup>&</sup>lt;sup>14</sup> *Id*.

<sup>&</sup>lt;sup>15</sup> *Id*.

<sup>&</sup>lt;sup>16</sup> *Id*.

<sup>17</sup> I.A

<sup>&</sup>lt;sup>18</sup> *Id.* at 5; Exhibit 6, LHC-Centene's July 2023 Final Proposed Action – Pinnacle.

<sup>19</sup> Id

 $<sup>^{20}</sup>$  Exhibit 6, LHC-Centene's July 2023 Final Proposed Action – Pinnacle.

overturn its extrapolated \$5.7 Million Overpayment Demand. Exhibit 14, LHC-Centene's November 17, 2023 Correspondence re: Pinnacle's Formal Rebuttal.

- 45. Between November 2023 and April 2024, Pinnacle and LHC-Centene negotiated and exchanged settlement offers.
- 46. LHC-Centene subsequently sent a Notice of Recoupment for the Pinnacle \$5.7 Million Overpayment Demand, with recoupment starting effective April 30, 2024. Exhibit 15, LHC-Centene Notice of Recoupment Pinnacle.
- 47. Additionally, LHC-Centene conducted an onsite visit of Pinnacle's facilities on May 14, 2024.
- 48. The relevant facts from Pinnacle's Formal Rebuttal and its ongoing dispute of LHC-Centene's findings as set forth in the July 2023 Final Proposed Action are further described in the sections below.

# a. Sampled Claims Were Medically Necessary and Properly Payable

- 49. For the majority of claims at issue in the Pinnacle \$5.7 Million Overpayment Demand, LHC-Centene did not appear to allege the DME furnished to LHC-Centene members were not medically reasonable and necessary. Instead, LHC-Centene's denial rationales related to alleged documentation deficiencies or raised irrational bases for denial, as set forth further below.
- 50. However, there was conspicuous documentation in the members' medical records to substantiate the medical necessity of the provided DME, and the documents submitted were in compliance with the coverage criteria outlined in Local Coverage Article ("LCA") A55426, "Standard Documentation Requirements for All Claims Submitted to DME MACs." *See also*

# Exhibit 16, LHC-Centene's Provider Manual.<sup>21</sup>

- 51. LCA A55426 sets out the requirements that are applicable to all DME claims, and thus is the controlling guidance relevant to whether Pinnacle has provided the information necessary to justify payment.<sup>22</sup>
- 52. In support of its finding that the sampled claims involved the dispensing of physician-ordered DME that were reasonable, medically necessary, appropriately documented and properly payable, Pinnacle's Formal Rebuttal provided member-specific responses to LHC-Centene for all 65 members included in the LHC-Centene's review, including the denial rationales for each member and Pinnacle's member-specific analysis in response. *See* Exhibit 17, Pinnacle's Member-Specific Responses to LHC-Centene Audit (Redacted).<sup>23</sup>
- 53. The members' medical records demonstrated that the requirements of LCA A55426 were met, namely, that these records detailed: 1) the DME requested; 2) the quantity and type of DME received; and 3) Proof of Delivery in conformity with the allowable delivery methods.
- 54. Thus, proper documentation existed for each member demonstrating the member's receipt of the DME that was billed by Pinnacle.
  - b. LHC-Centene's Denial Bases Lacked Specificity and Failed to Provide Pinnacle with Adequate Notice of the Alleged Deficiencies
  - 55. As set forth above, Pinnacle's medical records for the sample claims contain clear

<sup>&</sup>lt;sup>21</sup> The LHC Provider Manual specifically states that LHC-Centene's SIU utilizes the Medicaid Coverage Database in its investigations, which includes National Coverage Determinations ("NCDs"), Local Coverage Determinations ("LCDs"), and Local Coverage Articles ("LCAs"). Exhibit 16, LHC-Centene's Provider Manual, April 2023 Version at 173; *see also id.*, September 2023 Version at 159; December 2023 Version at 160.

<sup>&</sup>lt;sup>22</sup>Id.; see also LCA A55426, available at https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=55426.

<sup>&</sup>lt;sup>23</sup> Note that Exhibit 17, Pinnacle's Member-Specific Responses to LDH-Centene Audit (Redacted) was provided to LHC-Centene with Pinnacle's Formal Rebuttal.

documentation to support that the DME was provided as billed.<sup>24</sup>

- 56. However, in its Audit Findings Attachment to the July 2023 Final Proposed Action, LHC-Centene denied 78 of the 79 claim lines at issue.<sup>25</sup>
- 57. In denying such claims, LHC-Centene failed to provide Pinnacle with any individual patient-specific denial rationales.<sup>26</sup>
- 58. Instead, for each of the denied claims, LHC-Centene merely assigned one or more the following primary denial reasons, without further explanation:
  - a. Billed Service Not Supported by Legible Evidence;
  - b. Claim Form Incomplete/Requirements Not Met;
  - c. Missing Documentation for DOS;
  - d. Service Not Supported Per Policy;
  - e. Unable to Verify Provider; and/or
  - f. Unable to Verify Units Rendered.<sup>27</sup>
- 59. Several of these denial bases, including but not limited to: "billed service not supported by legible evidence," "service not supported per policy," and "unable to verify units rendered" were ambiguous, vague, or otherwise lacked specificity and failed to provide Pinnacle with adequate notice of the alleged deficiencies.<sup>28</sup>
- 60. For example, when denying a claim on the basis of "service not supported per policy," LHC-Centene wholly failed to specify which policy(ies) were not supported by the documentation.

<sup>&</sup>lt;sup>24</sup> Exhibit 17, Pinnacle's Member-Specific Responses to LHC-Centene Audit (Redacted).

<sup>&</sup>lt;sup>25</sup> Exhibit 7, LHC-Centene's July 2023 Audit Findings Attachment – Pinnacle.

<sup>&</sup>lt;sup>26</sup> See id.

<sup>&</sup>lt;sup>27</sup> *Id; see also* Exhibit 6, LHC-Centene's July 2023 Final Proposed Action – Pinnacle.

<sup>&</sup>lt;sup>28</sup> *Id*.

- 61. Upon information and belief, after Pinnacle received the July 2023 Final Proposed Action findings, Pinnacle sought further clarification of these denials and requested individual patient-specific denial rationales from LHC-Centene.
- 62. However, LHC-Centene refused to provide such information, and instead stated that any questions would be answered during the educational call with LHC-Centene.
  - c. LHC-Centene Apparently and Improperly Used Software Tool-Based Prediction in its Claims Review
- 63. Upon information and belief, based on the facts set forth herein and based upon Pinnacle's observations in the substantially similar DMS matter (*see infra* Section III.C), Pinnacle contends that LHC-Centene used a predictive algorithm, generative artificial intelligence model, or some other software-based prediction tool (collectively, "software tool"), with minimal human intervention, as the sole or primary basis to deny many or all of Pinnacle's otherwise properly supported claims for reimbursement.
- 64. First, LHC-Centene has policies indicating (1) that its SIU "utilizes software tools that help find and prevent health care fraud;" and (2) that the Optum Comprehensive Payment Integrity system ("Optum CPI") supports Centene's contractual and regulatory obligations by "perform[ing] claim editing on both a pre-pay and post-pay basis as part of Centene's Fraud, Waste, and Abuse (FWA) program." **Exhibit 18, Centene, Payment Policy: Optum Comprehensive Payment Integrity (CPI) (CPP-136)**.

<sup>&</sup>lt;sup>29</sup> Exhibit 16, LHC-Centene's Provider Manual, April 2023 Version at 173; *see also id.*, September 2023 Version at 159: December 2023 Version at 160.

- 65. Likewise, at times relevant to LHC-Centene's post-payment audit of Pinnacle, Centene owned Apixio, an AI platform that has capabilities to conduct medical record review and analysis.<sup>30</sup>
- 66. Despite these software tools, LHC-Centene is required—under its contract and regulatory guidance—to utilize qualified human auditors in its post-payment claim reviews.<sup>31</sup>
- 67. Likewise, § 3.3.1.1(C) of the MPIM<sup>32</sup> requires auditors to "ensure that the credentials of their reviewers are consistent with the requirements in their respective [Statements of Work]."<sup>33</sup>
- 68. However, as set forth herein, LHC-Centene's July 2023 Final Proposed Action findings were not patient-specific, and were ambiguous, vague, illogical, or otherwise improper,

<sup>&</sup>lt;sup>30</sup> See, e.g., Centene, Press Release, "Centene Corporation Completes Divestiture of Apixio," INVESTORS.CENTENE.COM (June 13, 2023), available at https://investors.centene.com/2023-06-13-CENTENE-CORPORATION-COMPLETES-DIVESTITURE-OF-APIXIO.

September 2023 Version at 143; December 2023 Version at 149; see also id., September 2023 Version at 143; December 2023 Version at 143 (each noting that "post-processing claims audit consists of a review of clinical documentation and claims submissions" and that "[a]uditors review cases.") A software tool is not an "auditor." Similarly, under the MCO Contract, LHC-Centene must "have adequate staffing and resources to investigate unusual incidents and develop and implement Corrective Action Plans to assist [LHC-Centene] in preventing and detecting potential Fraud, Waste, and Abuse. At a minimum, [LHC-Centene] shall have one (1) full-time investigator physically located within Louisiana for every fifty thousand (50,000) Enrollees or fraction thereof." MCO Contract, Attachment A, § 2.20.1.10; see also MCO Contract, Attachment A, § 2.20.2.2.4 (requiring LHC-Centene to implement a "system for training and education . . . for the Federal and State standards and requirements under the [MCO] Contract"); § 2.20.2.2.4.1 (noting that Fraud, Waste, and Abuse training must include "[a]nnual training of all employees" and "[n]ew hire training"); § 2.20.2.2.4.2 (mandating LHC-Centene to require new employees to complete and attest to the completion of training modules in accordance with federal and state laws, regulations, rules, and policies).

<sup>&</sup>lt;sup>32</sup> All MPIM Chapter 3 citations are to Rev. 12056 (Issued 05-25-23; Implemented: 06-26-2023) and all MPIM Chapter 8 citations are to Rev. 11962 (Issued: 04-21-23; Implemented: 05-22-23), which were the applicable versions of the MPIM in effect during the audits at issue in this matter.

MPIM, § 3.3.1.1(C); see also MPIM § 3.3.1.1(E) (requiring auditors to "include inter-rater reliability assessments in their [Quality Improvement] process and [to] report these results as directed by CMS"). Collectively, these provisions indicate that LHC-Centene is required to utilize qualified human auditors in its post-payment claim reviews.

which indicate that LHC-Centene inappropriately used software tool-based predictions (with minimal human intervention).<sup>34</sup>

- 69. For example, there were multiple claims denied for "Claim Form Incomplete/Requirements Not Met" and in its July 2023 Final Proposed Action Findings, LHC-Centene set forth that "no ordering provider documentation was provided; 'DME' was not written at the top of claim forms, and/or prior authorization numbers were not always documented."<sup>35</sup>
- 70. In denying these claims, LHC-Centene applied standards unique to paper submission of claim forms, whereas Pinnacle electronically submitted the claims at issue and paper claims were not even produced and part of the review.
- 71. The standards for electronically submitted DME claims are materially different than those LHC-Centene applied.
- 72. For instance, the finding that Pinnacle had failed to write "DME" at the top of claim forms is a requirement specific to paper claims; however, because all claims in question had been submitted electronically, this was a wholly and plainly inapplicable requirement.
- 73. These denials strongly suggest such errors were not the result of flawed human reasoning, but rather, that LHC-Centene likely used software tool-based predictions (with minimal human intervention) as the basis to improperly deny Plaintiffs' otherwise proper claims for reimbursement.
  - d. LHC-Centene Used Improper Statistical Sampling and Extrapolation Methodologies
  - 74. In its MCO Manual, LDH has established two threshold criteria that an MCO must

<sup>35</sup> *Id*.

<sup>&</sup>lt;sup>34</sup> See Exhibit 6, LHC-Centene's July 2023 Final Proposed Action – Pinnacle; Exhibit 7, LHC-Centene's July 2023 Audit Findings Attachment – Pinnacle.

satisfy in order to use statistical sampling and extrapolation methodologies.<sup>36</sup>

- 75. Specifically, LDH requires that all MCOs, including LHC-Centene, must: 1) request and obtain prior approval from LDH to utilize extrapolation methods for the purpose of deriving an overpayment in a provider or supplier audit; and 2) follow CMS guidelines when implementing statistical sampling and extrapolation methodologies.<sup>37</sup>
- Despite multiple requests by Pinnacle's counsel, neither LHC-Centene nor LDH 76. have provided Pinnacle with written evidence that LHC-Centene appropriately requested and received written prior approval from LDH before it employed statistical sampling and extrapolation methods that resulted in the Pinnacle \$5.7 Million Overpayment Demand.
- 77. Failure by LHC-Centene to comply fully with LDH's pre-approval requirements pertaining to the use of statistical sampling and extrapolation would entirely invalidate the Pinnacle \$5.7 Million Overpayment Demand as a failure of mandated process.
- 78. LHC-Centene also failed to adhere to the CMS guidelines in this matter, as required by LDH.<sup>38</sup>
- 79. The statistical sampling and extrapolation methods used to determine the Overpayment Demand did not comport with several of the mandatory requirements of the MPIM,

<sup>&</sup>lt;sup>36</sup> Exhibit 2, MCO Manual, Part 15: Program Integrity, at 244.

<sup>&</sup>lt;sup>37</sup> *Id*.

<sup>&</sup>lt;sup>38</sup> The MCO Contract indicates that LHC-Centene is required to follow the MPIM in conducting its sampling, reviewing, and extrapolation procedures in calculating overpayments during postpayment claims reviews. See Exhibit 1, MCO Contract, Attachment A, § 6.1.4 (requiring that LHC-Centene must "comply, to the satisfaction of LDH, with: (1) all requirements set forth in [the MCO] Contract; (2) all provisions of State and Federal laws, rules, regulations, policies, and procedures, the State Plan, and Waivers applicable to the Managed Care Program; and (3) the MCO Manual" (emphasis in original); see also Exhibit 2, MCO Manual, at 244(noting that the Louisiana Medicaid program "follows published CMS guidelines used by Medicare recovery audit contractors to determine whether an extrapolation is permissible"). LHC-Centene likewise acknowledges that it is bound by the requirements of the MPIM.

which, as referenced by LDH in its MCO Manual, contains the published guidelines that its MCOs are required to follow.<sup>39</sup>

- 80. These procedural failures invalidate the statistical sampling and extrapolation methodologies used by LHC-Centene in determining the Pinnacle \$5.7 Million Overpayment Demand.
- 81. Pinnacle has identified two separate and specific violations of the MPIM by LHC-Centene.
- 82. First, LHC-Centene intentionally excluded zero-paid claims from the composition of the sampling frame.<sup>40</sup>
- 83. Second, LHC-Centene failed to provide the documentation necessary for Pinnacle to appropriately determine the validity of the statistical sampling and extrapolation methodologies utilized by LHC-Centene to calculate the alleged overpayment amount.<sup>41</sup>
- 84. Each violation is independently sufficient to invalidate the calculation of an extrapolated overpayment amount.
- 85. Taken together, these violations necessitate a finding that the Pinnacle \$5.7 Million Overpayment Demand is invalid and unenforceable.<sup>42</sup>

<sup>&</sup>lt;sup>39</sup> See Exhibit 13, Pinnacle's Formal Rebuttal to LHC-Centene; see also Exhibit 2, MCO Manual, at 244.

<sup>&</sup>lt;sup>40</sup> See MPIM §§ 8.4.3.2.1, 8.4.1.3, 8.4.7.1, 8.4.6.3, 8.4.5.2; see also Goose Creek Physical Med., LLC, v. Becerra, No. 2:22-CV-03932-DCN, 2024 WL 942918 at \*2 (D.S.C. Mar. 5, 2024); Exhibit 13, Pinnacle's Formal Rebuttal to LHC-Centene, at 8-16.

<sup>&</sup>lt;sup>41</sup> See MPIM §§ 8.4.3.1; 8.4.3.2; 8.4.4.4.1; see also Goose Creek, 2024 WL 942918 at \*2, 10-11; MedEnvios Healthcare, Inc. v. Becerra, No. 23-cv-20068, 2024 WL 1252264, at \*4-5 (S.D. Fla. Mar. 25, 2024) (invalidating extrapolated overpayment demands because CMS and its contractors failed to provide the plaintiff-supplier with documentation sufficient to determine the validity of the sample as drawn and conducted); Exhibit 13, Pinnacle's Formal Rebuttal to LHC-Centene, at 8-16.

<sup>&</sup>lt;sup>42</sup> See Cent. La. Home Health Care, LLC v. Price, No. 17-cv-00346, 2018 WL 7888523, at \*16-20 (W.D. La. Dec. 28, 2018) ("[F]ailure to adhere to several or all of these safeguards should eliminate the presumption that the statistical analysis is valid.").

#### vii. LDH's Related Audit of Pinnacle

- 86. Close in time to the LHC-Centene Audit, LDH performed its own audit of Pinnacle ("LDH Audit") for claims submitted to Louisiana Medicaid MCOs.
- 87. Notably, LDH's audit was solely a review of claims data, not a review of medical record documentation, and LDH did not request any records from Pinnacle at that time.
- 88. On November 3, 2023, LDH sent Pinnacle a letter alleging that Pinnacle improperly billed the number of CGM sensor units supplied to beneficiaries (HCPCS Code A9276) for claims submitted to Louisiana Medicaid from January 1, 2019 through July 31, 2023 ("LDH Audit Review Period"). **Exhibit 19, LDH's November 3, 2023 Demand to Pinnacle**.
- 89. LDH alleged that Pinnacle incorrectly billed this code on 11,088 occasions during the LDH Audit Review Period, for quantities allegedly in excess of recipients' needs and/or the coverage policy, and LDH asserted a potential overpayment of \$6,678,967.32 ("LDH's Demand").<sup>43</sup>
- 90. Although the LHC-Centene Audit is carved out of the individual claims within the LDH Audit, 44 LDH's Demand overlaps with LHC-Centene's Pinnacle \$5.7 Million Overpayment Demand in several significant ways, namely:
  - a. 100% of the claims in the LDH Audit were for CGM sensors (A9276) and 50.63%(40 of the 79 claim lines) in the LHC-Centene Audit were for CGM sensors.
  - b. Centene's counsel stated during the January 17, 2024 meeting that approximately
     \$2.8 million of the Pinnacle \$5.7 Million Overpayment Demand relates to LDH's Demand.

<sup>&</sup>lt;sup>43</sup> Exhibit 19, LDH's November 3, 2023 Demand to Pinnacle.

<sup>&</sup>lt;sup>44</sup> The LDH Audit included claims from four MCOs and none of the LHC-Centene claims in the LDH Audit were for dates of service February 1, 2021 to February 14, 2022.

- c. The LHC-Centene Audit Review Period covers claims from February 1, 2021 to February 14, 2022, which overlaps with LDH's Audit Review Period (January 1, 2019 to July 31, 2023).
- d. The LHC-Centene Audit included denial rationales based on the same flawed billing guidance produced by LDH and used by LDH to assert denials in the LDH Audit.
- 91. Pinnacle was not aware of LDH's Demand until January 17, 2024, when Centene's counsel raised the existence of a demand letter in a meeting with Pinnacle's counsel.
- 92. On January 26, 2024, Pinnacle's counsel met virtually with LDH's counsel and LDH agreed to restart the audit process.
- 93. On February 2, 2024, LDH sent Pinnacle a follow-up letter with the reissued demand. Exhibit 20, LDH's Follow-up Letter to Pinnacle.
- 94. Also on February 2, 2024, Pinnacle's counsel sent LDH a position letter regarding billing for CGM sensors and the use of HCPCS Code A9276. Exhibit 21, Pinnacle's LDH Position Paper.
- 95. On February 5, 2024, Pinnacle received a flash drive from LDH with the audit data and spreadsheet supporting LDH's Demand against Pinnacle ("LDH's Audit Data").
- 96. On February 29, 2024, Pinnacle responded to LDH's Demand, disputing LDH's findings and LDH's Audit Data and analyzing the claim denials in light of changes in LDH and Louisiana MCOs' billing policies and guidance for CGM sensors during the LDH Audit Review Period. Exhibit 22, Pinnacle's LDH Audit Response Letter.
- 97. As set forth in Pinnacle's LDH Audit Response Letter, and upon information and belief, LDH previously had a "per sensor" CGM billing policy in place, which was applicable to

claims for dates of service from January 1, 2019 to February 22, 2021. 45

- 98. LDH's overpayment audit contractor—Gainwell Technologies ("Gainwell")—did not correctly apply this policy for the applicable time period.<sup>46</sup>
- 99. Rather, Gainwell appeared to improperly apply the "per month" policy that was applicable to dates of service on or after February 23, 2021 to all claims in the LDH Audit Review Period, regardless of the actual date of service.<sup>47</sup>
- 100. Upon information and belief, this improper application of the "per month" policy led to an improper overpayment of more than \$5.5 million relevant to the claims that fell between January 1, 2019 and February 22, 2021 in the LDH Audit.<sup>48</sup>
- 101. On March 18, 2024, an informal, in-person hearing was held between LDH Program Integrity and Pinnacle's counsel.
- 102. Following that hearing, LDH requested additional documentation which Pinnacle produced on April 24, 2024.
  - 103. To date, the results of the LDH Investigation remain pending.

# C. Facts Relevant to DMS' Causes of Action

#### i. DMS' Enrollment with Louisiana Medicaid

104. At all times relevant to this Complaint, DMS was enrolled with the Louisiana Medicaid program as a DME supplier.

#### ii. DMS' and LHC-Centene's Provider Agreement

105. At all times relevant to this Complaint, DMS had a Provider Agreement ("DMS Provider Agreement") with LHC-Centene to provide DME to LHC-Centene members.

<sup>&</sup>lt;sup>45</sup> Exhibit 22, Pinnacle's LDH Audit Response Letter, at 5-10.

<sup>&</sup>lt;sup>46</sup> *Id.* at 16-17.

<sup>&</sup>lt;sup>47</sup> *Id*.

<sup>&</sup>lt;sup>48</sup> *Id*.at 17.

- 106. Upon information and belief, DMS no longer has a copy of the DMS Provider Agreement and has been unable to obtain a copy of this DMS Provider Agreement from LHC-Centene.
- 107. Upon information and belief, the DMS Provider Agreement has similar provisions to those detailed in the Pinnacle Provider Agreement, including n relevant part (1) that LHC-Centene shall be responsible for the administrative activities necessary or required for the commercially reasonable operation of a coordinated care network, including, but not limited to, quality improvement, utilization management, grievances and appeals, claims processing, and maintenance of provider directory and records, and (2) that DMS and LHC-Centene agree that each party shall carry out its obligations in accordance with terms of the Payor Contract and applicable federal and State laws and regulations, including, but not limited to, the requirements of the Stark law (42 U.S.C. § 1395nn) and applicable federal and State self-referral and fraud and abuse statutes and regulations.

#### iii. Scope of LHC-Centene's Audit of DMS and their Alleged Findings

- 108. Close in time to the LHC-Centene Audit of Pinnacle, LHC-Centene also audited DMS for claims submitted to Louisiana Medicaid for DME.
- 109. Specifically, on August 10, 2023, and again on August 16, 2023, LHC-Centene issued a request for records (the "August 2023 DMS Request") to DMS, requesting the medical records of 64 LHC members to support certain DME services furnished by DMS between December 7, 2020 and July 26, 2023 (the "DMS Review Period"). **Exhibit 23, LHC-Centene August 2023 Request to DMS**.
- 110. On September 25, 2023, LHC-Centene issued its "Proposed Action Findings" regarding the August 2023 Request (the "September 2023 DMS Proposed Action"). **Exhibit 24**,

# **LHC-Centene's Initial Proposed Action – DMS.**

- 111. The September 2023 DMS Proposed Action stated that DMS did not submit any records in response to the August 2023 DMS Request and identified an overpayment of \$4,771,190.49.<sup>49</sup>
- 112. On October 27, 2023, an audit manager from DMS' parent company Adapt, informed LHC-Centene that Adapt had never received the August 2023 Request and indicated that DMS would like to appeal LHC-Centene's September 2023 Proposed Action.
- 113. LHC-Centene stated that a 30-day window to submit "appeal records" would open on October 30, 2023, with a deadline of November 30, 2023; however, on November 17, 2023, DMS requested and received an extension from LHC-Centene to produce the relevant medical records by December 7, 2023.
- 114. DMS produced the requested medical records to LHC-Centene on December 6, 2023 (the "December 2023 DMS Medical Records Production").
- DMS Medical Records Production; in the same letter confirming receipt, LHC-Centene also referred to this production as an appeal and stated that "[n]o further documentation [would] be accepted for review." Exhibit 25, LHC-Centene's Confirmation of DMS Medical Records Production.
- 116. On January 26, 2024, LHC-Centene issued its revised "Proposed Action Findings" regarding the December 2023 DMS Medical Records Production (the "January 2024 DMS Proposed Action"), which set the revised overpayment demand amount at \$2,747,549.37 (the "DMS \$2.7 Million Overpayment Demand"). *See* Exhibit 26, LHC-Centene's January 2024

<sup>&</sup>lt;sup>49</sup> Exhibit 24, LHC-Centene's Initial Proposed Action – DMS.

Proposed Action for DMS; Exhibit 27, LHC-Centene's Proposed Action for DMS – Overpayment Projection (Redacted); Exhibit 28, LHC-Centene's Proposed Action for DMS – Original Audit Spreadsheet (Redacted); Exhibit 29, LHC-Centene's Proposed Action for DMS – Corrected Audit Spreadsheet (Redacted).

- 117. On January 30, 2024, DMS' counsel reached out to LHC-Centene to confirm the timeline for filing an appeal of the January 2024 DMS Proposed Action.
- 118. On January 31, 2024, Ms. Guidetta stated that "[t]here is no 2nd level of appeal or Independent Review available for SIU audits" and further stated that payment would be due 30 days from the date of the January 2024 DMS Proposed Action, with LHC-Centene open to settlement negotiations during that time. Exhibit 30, LHC-Centene's January 31, 2024 Email Regarding DMS Appeal.
- 119. On February 7, 2024, DMS met with Ms. Guidetta and others from LHC-Centene; during this meeting, Ms. Guidetta asserted that the claims analysis underlying the January 2024 DMS Proposed Action was performed in-house and not by a software tool.
- 120. During this same February 7, 2024 meeting, Ms. Guidetta agreed that LHC-Centene would treat the December 2023 DMS Medical Records Production as a medical records production and would accept a response from DMS appealing the January 2024 DMS Proposed Action, with any such response to be filed by February 29, 2024, which later was extended to March 8, 2024.
- 121. On February 7, 2024, DMS requested from Ms. Guidetta all materials relevant to the statistical sampling and extrapolation LHC-Centene conducted to issue the DMS \$2.7 Million Overpayment Demand assessed in the January 2024 DMS Proposed Action.
- 122. On February 14, 2024, LHC-Centene responded to DMS' request by providing a subset of the requested documents, which have the following file names:

- a. "Claim Sampling Project 20230801 59975 MEDICAID"
- b. "Overpaid 20230801-59975 24JAN2024"
- c. "Replication Package" containing:
  - i. "Centene SVRS and Extrapolation MCD"
  - ii. "extrap input MCD"
  - iii. "sample frame MCD"
  - iv. "Steps To replicate the SVRS and Extrapolation"
  - v. "strata info MCD"
- d. "Sampling and Extrapolation Procedures for Determination of Overpayments"
- e. "Sampling Plan 20230801-59975 MCD"
- f. "SVRS Data"
- g. "Statistical Sampling and Extrapolation Provider."

#### See Exhibit 31, LHC-Centene's DMS Production.

#### iv. DMS' Formal Rebuttal and Factual Findings

- DMS Letter"), contesting LHC-Centene's findings, and detailing LHC-Centene's improper statistical sampling and extrapolation methodology, its findings that claims at issue were medically necessary and properly payable, and further alleging, upon information and belief, that LHC-Centene improperly used software tool-based predictions (i.e. artificial intelligence), with minimal human intervention, as the sole or primary basis to improperly deny DMS' otherwise properly supported claims for reimbursement, as further set forth in the sections below. **Exhibit 32**, **DMS' Formal Rebuttal to LHC-Centene**.
  - 124. On March 19, 2024, representatives of LHC-Centene requested to meet with DMS'

counsel to discuss the March 8, 2024 DMS Letter.

- 125. On March 25, 2024, Ms. Guidetta emailed DMS' counsel regarding DMS' Formal Rebuttal and LHC-Centene provided its "Corrected Audit Sheet" due to a column misalignment error in the prior audit spreadsheet that LHC-Centene became aware of during its review of the March 8, 2024 DMS Letter.<sup>50</sup>
- 126. Notably, the "Corrected Audit Spreadsheet" merely corrected a formatting error and did not materially change DMS' prior findings.<sup>51</sup>
- 127. On April 2, 2024, representatives of LHC-Centene met with DMS' counsel and confirmed that LHC-Centene did not change any of its positions from the January 2024 DMS Proposed Action following its review of the March 8, 2024 DMS Letter, and instead indicated that LHC-Centene would be moving forward with recoupment, starting effective April 30, 2024. *See* Exhibit 33, LHC-Centene Notice of Recoupment DMS.
- 128. The relevant facts from the March 8, 2024 DMS Letter and DMS' ongoing dispute of LHC-Centene's findings, as set forth in the January 2024 DMS Proposed Action, are further described in the sections below.

### i. Sampled Claims Were Medically Necessary and Properly Payable

- 129. As noted above, LHC-Centene's SIU review involved 80 claims lines regarding services rendered to 64 members and LHC-Centene found that all 80 claim lines should be disallowed.
- 130. In January 2024, LHC-Centene provided the following documentation: Exhibit 26, LHC-Centene January 2024 Proposed Action for DMS; Exhibit 27, LHC-Centene's Proposed

<sup>&</sup>lt;sup>50</sup> Exhibit 29, LHC-Centene's Proposed Action for DMS – Corrected Audit Spreadsheet (Redacted).

<sup>&</sup>lt;sup>51</sup> *Id*.

Action for DMS – Overpayment Projection (Redacted); and Exhibit 28, LHC-Centene's Proposed Action for DMS – Original Audit Spreadsheet (Redacted); additionally, as mentioned above, LHC-Centene subsequently produced Exhibit 29, LHC-Centene's Proposed Action for DMS – Corrected Audit Spreadsheet (Redacted).

- 131. Notably, these findings did not allege the DME services that DMS furnished to LHC-Centene members were not medically reasonable and necessary. Instead, LHC-Centene's denial rationales related to alleged documentation deficiencies or raised irrational bases for denial, as set forth further below.
- 132. However, as evidenced by the December 2023 DMS Medical Records Production, the DME services that DMS furnished for the audited sample claims were reasonable, medically necessary, appropriately documented and properly payable.

# b. LHC-Centene Apparently and Improperly Used Software Tool-Based Prediction in its Claims Review

- 133. Upon information and belief, LHC-Centene used a predictive algorithm, generative artificial intelligence model, or some unknown software-based prediction tool (collectively, "software tool") as the sole or primary basis to deny many or all of DMS' otherwise properly supported claims for reimbursement.
- 134. As set forth above in Section III.B.vi.c, LHC-Centene is required—under its contract and regulatory guidance—to utilize qualified human auditors in its post-payment claim reviews and the MPIM requires auditors to ensure their credentials are adequate for their scope of work.
- 135. While Ms. Guidetta of LHC-Centene stated that it was her belief that no such software tool-based prediction was used, the following evidence supports DMS' conclusion to the contrary.

- 136. First, LHC-Centene has policies indicating (1) that its SIU "utilizes software tools that help find and prevent health care fraud;"<sup>52</sup> and (2) that Optum CPI supports Centene's contractual and regulatory obligations by "perform[ing] claim editing on both a pre-pay and post-pay basis as part of Centene's Fraud, Waste, and Abuse (FWA) program."<sup>53</sup>
- 137. Second, and as similar to LHC-Centene's findings in the LHC-Centene Audit of Pinnacle (*see infra* Section III.B.vi.c), LHC-Centene's January 2024 DMS Proposed Action findings state that multiple claims were denied for "Claim Form Incomplete/Requirements Not Met" and LHC-Centene set forth that "DME claim forms were incomplete and incorrectly submitted per LA MCD DME Claim requirements."<sup>54</sup>
- 138. However, claim forms were neither required by LHC-Centene in its documentation request nor provided by DMS in the December 2023 DMS Medical Records Production, and there is nothing within the submitted documentation that would support the specific deficiencies LHC-Centene cites in the denial.
- 139. In denying these claims, LHC-Centene applied standards unique to paper submission of claim forms, whereas DMS electronically submitted the claims at issue.
- 140. The standards for electronically submitted DME claims are materially different than those LHC-Centene applied.
- 141. For instance, for multiple specific claim denials, LHC-Centene stated that DMS had failed to write "DME" at the top of paper claim forms (and cited to the Louisiana Medicaid DME claim requirements for paper claim submission); however, because all claims in question

<sup>&</sup>lt;sup>52</sup> Exhibit 16, LHC-Centene's Provider Manual, April 2023 Version at 173; *see also id.*, September 2023 Version at 159; December 2023 Version at 160.

<sup>&</sup>lt;sup>53</sup> Exhibit 18, Centene, Payment Policy: Optum Comprehensive Payment Integrity (CPI) (CPP-136).

<sup>&</sup>lt;sup>54</sup> See Exhibit 26, January 2024 Proposed Action for DMS.

had been submitted electronically, this was a wholly and plainly inapplicable requirement.<sup>55</sup>

- 142. Additionally, the January 2024 Proposed Action for DMS states that several claims were denied, in part, because of an inability to "verify the units to be billed;" and that "[t]he provider did not appropriately document, complete, or submit the refill request form. The review could not verify the units invoiced, shipped, and billed were consistent with the DME device and quantities requested by the patient." 56
- 143. However, the documentation DMS submitted to LHC-Centene provided clear evidence of the specific DME supply requested, including: the manufacturer, the quantity requested, the quantity dispensed to the patient, and the quantity dispensed to the patient, in sufficient detail to allow an auditor to determine the billing units supported.
- 144. For example, in one instance in which LHC-Centene denied a patient's claims due to being "unable to verify units rendered," LHC-Centene's findings noted that the "item requested appears to be sold in 10-packs, but invoiced/billed individual units; no item SKU documented to verify if infusion set invoiced was a 30 x 10-packs (300 infusion sets) or 30 x individual units;" however, DMS' documentation clearly indicates that 30 sets were dispensed and 30 units were billed, in accordance with the applicable HCPCS code definition that 1 unit = 1 set. <sup>57</sup>
- 145. Nothing in the records indicated 300 infusion sets were dispensed; therefore, the assertion that the number of units could not be verified was illogical and nonsensical.
  - 146. LHC-Centene improperly denied the majority of infusion set claims as well as

<sup>&</sup>lt;sup>55</sup> See Exhibit 26, January 2024 Proposed Action for DMS; Exhibit 28, LHC-Centene's Proposed Action for DMS – Original Audit Spreadsheet (Redacted); Exhibit 29, LHC-Centene's Proposed Action for DMS – Corrected Audit Spreadsheet (Redacted).

<sup>&</sup>lt;sup>56</sup> See Exhibit 26, January 2024 Proposed Action for DMS.

<sup>&</sup>lt;sup>57</sup>See Exhibit 29, LHC-Centene's Proposed Action for DMS – Corrected Audit Spreadsheet (Redacted) at 3.

claims for related products in a similar manner.

147. Likewise, LHC-Centene's Proposed Action for DMS – Corrected Audit Spreadsheet included multiple similar findings for CGM sensor claims, which failed to account for the differences in the various manufacturer sensor lifespans in determining the number of units dispensed and billed.<sup>58</sup>

148. The nature and extent of these errors indicate they are not the result of flawed human reasoning, but rather, that LHC-Centene used software tool-based predictions (with minimal human intervention) (i.e. artificial intelligence) as the basis to improperly deny DMS' otherwise proper claims for reimbursement.

# c. LHC-Centene Used Improper Statistical Sampling and Extrapolation Methodologies

- 149. The calculation of the DMS \$2.7 Million Overpayment Demand was the result of LHC-Centene's use of statistical sampling and extrapolation methodologies that violate the MPIM.
- 150. In its MCO Manual, LDH established two threshold criteria that an MCO must satisfy in order to use statistical sampling and extrapolation methodologies.<sup>59</sup>
- 151. Specifically, LDH requires that all MCOs, including LHC-Centene, must: 1) request and obtain prior approval from LDH to utilize extrapolation methods for the purpose of deriving an overpayment in a provider or supplier audit; and 2) follow CMS guidelines when implementing statistical sampling and extrapolation methodologies.<sup>60</sup>
- 152. Upon information and belief, despite requests by DMS, neither LHC-Centene nor LDH have provided DMS with written evidence that LHC-Centene appropriately requested and

<sup>&</sup>lt;sup>58</sup>See generally, id.

<sup>&</sup>lt;sup>59</sup> Exhibit 2, MCO Manual, Part 15: Program Integrity, at 244.

<sup>&</sup>lt;sup>60</sup> *Id*.

received written prior approval from LDH before it employed statistical sampling and extrapolation methods that resulted in the DMS \$2.7 Million Overpayment Demand.

- 153. Failure by LHC-Centene to comply fully with LDH's pre-approval requirements pertaining to the use of statistical sampling and extrapolation would entirely invalidate the DMS \$2.7 Million Overpayment Demand.
- 154. LHC-Centene also failed to adhere to the CMS guidelines in this matter, as required by LDH.
- 155. The statistical sampling and extrapolation methods used to determine the DMS \$2.7 Million Overpayment Demand did not comport with several of the requirements of the MPIM, which, as referenced by LDH in its MCO Manual, contains the published guidelines that its MCOs are required to follow.<sup>61</sup>
- 156. This procedural failure not only invalidates the specific statistical sampling and extrapolation methodologies used by LHC-Centene in determining the DMS \$2.7 Million Overpayment Demand, but also invalidates the use of statistical sampling and extrapolation altogether in this matter.
- 157. DMS has identified two separate and specific violations of the MPIM by LHC-Centene.
- 158. First, LHC-Centene intentionally excluded zero-paid claims from the composition of the sampling frame.<sup>62</sup>
- 159. Second, LHC-Centene failed to provide the information necessary for DMS to appropriately determine the validity of the statistical sampling and extrapolation methodologies

<sup>&</sup>lt;sup>61</sup> See Exhibit 32, DMS' Formal Rebuttal to LHC-Centene (Redacted).

<sup>&</sup>lt;sup>62</sup> *Id*.

utilized by LHC-Centene to calculate the alleged overpayment amount. <sup>63</sup>

- 160. Each violation is independently sufficient to invalidate the calculation of an extrapolated overpayment amount.
- 161. Taken together, these violations necessitate a finding that the DMS \$2.7 Million Overpayment Demand is invalid and unenforceable.

# IV. CAUSES OF ACTION

#### **COUNT ONE**

#### (DUE PROCESS VIOLATION UNDER THE UNITED STATES CONSTITUTION)

#### A. <u>LHC-Centene Violated Plaintiffs' Procedural Due Process Rights</u>

- 162. Plaintiffs re-allege and incorporate by reference the allegations set forth in the preceding paragraphs as if fully set forth herein.
- 163. As further set forth in the Memorandum in Support of Plaintiffs' Motion for Preliminary Injunction ("Memorandum") filed contemporaneously herewith, Plaintiffs satisfy the three requirements for demonstrating a procedural due process violation against Defendants: (1) there was a state action; (2) that plaintiff has a cognizable liberty or property interest; and (3) the administrative procedures provided to the plaintiff were constitutionally inadequate.<sup>64</sup>

### i. LHC-Centene is a State Actor

- 164. Plaintiffs re-allege and incorporate by reference the allegations set forth in the preceding paragraphs as if fully set forth herein.
- 165. The list of services that LHC must provide—as set forth in the MCO Contract and in the MCO Manual—suggest that the state effectively assigns to LHC-Centene the entire responsibility

<sup>&</sup>lt;sup>63</sup> *Id*.

<sup>&</sup>lt;sup>64</sup> Mathews v. Eldridge, 424 U.S. 319, 332-335 (1976); see also J.K v. Dillenberg, 836 F. Supp. 694, 698-99 (D. Ariz. 1993) (analyzing the issue of state action in the context of regional behavioral health authorities).

for the Medicaid program for a subset of Louisiana Medicaid beneficiaries. <sup>65</sup>

- 166. In addition, LHC-Centene is subject to extensive state involvement, as seen in the MCO Contract's requirement that LHC-Centene comply with all applicable requirements of state and federal laws or regulations relating to receipt of state and federal funds.<sup>66</sup>
- 167. Accordingly, and as further set forth in the Memorandum filed contemporaneously herewith, in carrying out its duties as an MCO of the Louisiana State Medicaid program, LHC-Centene is a state actor.

# ii. Plaintiffs Have a Constitutionally Protected Property Interest in Their Own Money

- 168. Plaintiffs re-allege and incorporate by reference the allegations set forth in the preceding paragraphs as if fully set forth herein.
- 169. The function of the Medicaid program makes clear that Pinnacle and DMS have a cognizable property interest in payment for services rendered to Medicaid beneficiaries.
- 170. Federal courts have long-recognized that individual beneficiaries have a "constitutionally protected property interest in social welfare benefits" such as Medicaid "when a statute entitles them to the benefits if they satisfy eligibility criteria."<sup>67</sup>
- 171. While beneficiaries are the primary parties in interest to the Medicaid program, providers and suppliers are likewise parties in interest as assignees of beneficiaries.
- 172. Providers generally collect an Assignment of Benefits ("AOB") at the time the first item or service is furnished to a beneficiary, and this AOB is used in submissions of claims

<sup>&</sup>lt;sup>65</sup> See generally Exhibit 1, MCO Contract; Exhibit 2, MCO Manual.

<sup>&</sup>lt;sup>66</sup> See Exhibit 1, MCO Contract, at § 17; see also id., Attachment A, Model Contract, § 2.19.1.12.

<sup>&</sup>lt;sup>67</sup>Harrison v. Young, 48 F.4th 331, 341 (5th Cir. 2022) (citations omitted); see also Goldberg v. Kelly, 397 U.S. 254, 261-62 (1970) (recognizing property interest in state welfare payments when a statute entitles a recipient to such payments).

thereafter. Medicare providers are then subrogated to the statutory entitlement of reimbursement for services rendered to Medicaid beneficiaries.<sup>68</sup>

- 173. The Fifth Circuit has previously held that a Medicaid provider did not have a constitutionally-protected right to Medicaid reimbursements that were withheld pending a fraud investigation, including future claims to offset potential overpayment, where Texas state law explicitly allowed such holds.<sup>69</sup>
- 174. However, Pinnacle and DMS have a cognizable property interest in their own money that is distinct from any actual overpayment.<sup>70</sup>
- 175. Pinnacle and DMS face extrapolated overpayment demands that are "over and above" the actual overpayment amounts that were calculated by LHC-Centene and interest charged on the whole debt, which do not involve a pending fraud investigation.<sup>71</sup>
- 176. Moreover, the extrapolated overpayment demands at issue are fundamentally flawed estimations based on biased and improper statistical sampling methodologies and impermissible determinations by a software-based tool (i.e. artificial intelligence).
- 177. Pinnacle and DMS have, at minimum, a constitutional right to challenge the fines assessed against them: the extrapolated overpayment demands and interest accrued on those portions, which constitute penalties against their "own money."<sup>72</sup>
- 178. The Medicaid program itself supports that Pinnacle and DMS also have right to challenge the entirety of the overpayments (including the actual and extrapolated portions of each).

<sup>&</sup>lt;sup>68</sup> See La. Rev. Stat. §§ 46:460.73, 460.75 (addressing provider claim payments).

<sup>&</sup>lt;sup>69</sup> Personal Care Products, Inc. v. Hawkins, 635 F.3d 155, 159 (5th Cir. 2011).

<sup>&</sup>lt;sup>70</sup> Zen Group, Inc. v. Fla. Agency for Health Care Admin., 80 F.4th 1319 (11th Cir. 2023).

<sup>&</sup>lt;sup>71</sup> Id. at 1326 (emphasis in original); Cf. Personal Care Products, 635 F.3d at 158.

<sup>&</sup>lt;sup>72</sup> *See id.* 

179. Accordingly, and as further set forth in the Memorandum filed contemporaneously herewith, Pinnacle and DMS have constitutionally-protected property interests in payment for services rendered to Louisiana Medicaid beneficiaries.

# iii. LHC-Centene's Actions Violated Mandatory Procedural Safeguards and were Constitutionally Inadequate

- 180. Plaintiffs re-allege and incorporate by reference the allegations set forth in the preceding paragraphs as if fully set forth herein.
- 181. In assessing whether the administrative procedures at issue violated mandatory procedural safeguards or were otherwise constitutionally inadequate, courts consider: (1) the private interest affected by the state action; (2) the risk of an erroneous deprivation of that interest given the procedures used, as well as the probable value of additional or substitute safeguards; and, (3) the Government's interest, including the fiscal and administrative burden that the additional or substitute procedural requirement would entail.<sup>73</sup>
- 182. As further set forth in the Memorandum filed contemporaneously herewith, LHC-Centene violated Plaintiffs' due process rights through its:
  - a. Improper use of software tool-based predictions (with minimal human intervention)
     in conducting the claims reviews underlying the extrapolated overpayment demands; and
  - b. Noncompliance with applicable statistical sampling and extrapolation procedures set forth in statutory, regulatory, and sub-regulatory guidance.
- 183. Further, as specific to Pinnacle, LHC-Centene violated Pinnacle's due process rights through its failure to provide Pinnacle with notice of all applicable denial bases for the

<sup>&</sup>lt;sup>73</sup> *Mathews*, 424 U.S. at 335.

individual claims at issue.

- 184. With regard to LHC-Centene's noncompliance with applicable statistical sampling and extrapolation procedures contained in the MPIM, this caused two fundamental due process violations: bias and failure of notice.
- 185. Specifically, and as further set forth in the Memorandum filed contemporaneously herewith, in auditing Plaintiffs' claims LHC-Centene:
  - Improperly executed the statistical sampling and extrapolation processes by failing to objectively review claims that could have been in Plaintiffs' favor (i.e., zero-paid claims); and
  - Failed to produce primary evidence that is essential for raising a due process challenge.
- 186. Each of these violations is an independently sufficient ground to vacate the extrapolated portions of LHC-Centene's overpayment demands.
- 187. Further, each of LHC-Centene's above-noted acts separately amounted to violations of Plaintiffs' rights to due process under the U.S. Constitution.<sup>74</sup>
- 188. For these reasons, Plaintiffs' constitutionally-protected property interests are subject to immediate deprivation (i.e., recoupment) through procedures that were not constitutionally adequate.
- 189. By reason of LHC-Centene's foregoing conduct, Plaintiffs have been damaged and are entitled to monetary and equitable relief as set forth in the Prayer for Relief below.

<sup>&</sup>lt;sup>74</sup> U.S. Const. amend. XIV; *see also MedEnvios*, 2024 WL 1252264, at \*4-5 (invaliding extrapolated overpayments on due process grounds where CMS and its contractors failed to provide the plaintiff-provider with documentation sufficient to determinate the validity of the sample as drawn and conducted).

#### B. LDH Violated Plaintiffs' Procedural Due Process Rights

- i. Plaintiffs' Action Against LDH Falls Under the *Ex Parte Young* Exception to Sovereign Immunity
- 190. Plaintiffs re-allege and incorporate by reference the allegations set forth in the preceding paragraphs as if fully set forth herein.
- 191. The Supreme Court has held that a suit may proceed against a state official, notwithstanding the Eleventh Amendment, when a plaintiff alleges an ongoing violation of federal law, including the U.S. Constitution, and seeks relief properly characterized as prospective.<sup>75</sup>
- 192. As further set forth in the Memorandum filed contemporaneously herewith, Plaintiffs' action falls under the *Ex Parte Young* exception to sovereign immunity because (1) Plaintiffs allege continuing violations of the Fourteenth Amendment to the U.S. Constitution, and (2) Plaintiffs seek injunctive relief to prevent that continuing violation.<sup>76</sup>
- 193. Accordingly, and as further set forth in the Memorandum filed contemporaneously herewith, Plaintiffs' due process allegations against LDH can appropriately be brought in this suit against Defendant, Ralph L. Abraham, M.D.

# ii. Plaintiffs Have a Constitutionally Protected Property Interest in Their Own Money

- 194. Plaintiffs re-allege and incorporate by reference the allegations set forth in the preceding paragraphs as if fully set forth herein.
- 195. As set forth in Section IV.A.ii above and in the Memorandum filed contemporaneously herewith, Plaintiffs have a protected property interest in their own money.

<sup>&</sup>lt;sup>75</sup> Ex Parte Young, 209 U.S. 123, 159-60 (1908).

<sup>&</sup>lt;sup>76</sup> See Women's Hosp. Found. v. Townsend, No. 07-cv-00711, 2008 WL 2743284, at \*3-4 (M.D. La. July 10, 2008); see also CIGNA Healthplan of La., Inc. v. Louisiana ex rel. Ieyoub, 82 F.3d 642, 645 (5th Cir. 1996).

196. Accordingly, and as further set forth in the Memorandum filed contemporaneously herewith, Pinnacle and DMS have constitutionally-protected property interests in payment for services rendered to Louisiana Medicaid beneficiaries.

# iii. LDH's Actions Violated Mandatory Procedural Safeguards and were Constitutionally Inadequate

- 197. Plaintiffs re-allege and incorporate by reference the allegations set forth in the preceding paragraphs as if fully set forth herein.
- 198. As further set forth in the Memorandum filed contemporaneously herewith, LDH's failure to properly oversee LHC-Centene in LHC-Centene's assessment of its overpayment demands violated mandatory procedural safeguards, or was otherwise constitutionally inadequate.
- 199. As further set forth in the Memorandum filed contemporaneously herewith, LHC-Centene violated Plaintiffs' due process rights through its:
  - a. Failure to properly oversee its contractor, LHC-Centene, in LHC-Centene's conduct of its post-payment review and resultant statistical sampling and extrapolation;<sup>77</sup> and
  - b. Improper authorization for LHC-Centene to conduct its statistical sampling and extrapolation.<sup>78</sup>
- 200. Both of LDH's above-noted acts separately amounted to violations of Plaintiffs' right to due process under the U.S. Constitution.<sup>79</sup>

<sup>&</sup>lt;sup>77</sup> See, e.g., Exhibit 2, MCO Manual, at 244.

<sup>&</sup>lt;sup>78</sup> *Id*.

<sup>&</sup>lt;sup>79</sup> U.S. Const. amend. XIV; *see also MedEnvios*, 2024 WL 1252264, at \*4-5 (invaliding extrapolated overpayments on due process grounds where CMS and its contractors failed to provide the plaintiff-provider with documentation sufficient to determinate the validity of the sample as drawn and conducted).

- 201. For these reasons, Plaintiffs' constitutionally-protected property interests are subject to immediate deprivation (i.e., recoupment) through procedures that were not constitutionally adequate.
- 202. By reason of LDH's foregoing conduct, Plaintiffs have been damaged and are entitled to monetary and equitable relief as set forth in the Prayer for Relief below.

#### **COUNT TWO**

### (VIOLATION OF THE FEDERAL MEDICAID ACT)

203. Plaintiffs re-allege and incorporate by reference the allegations set forth in the preceding paragraphs as if fully set forth herein.

#### A. Plaintiffs Have a Private Right of Action Under 42 U.S.C. § 1396a(a)(37)

- 204. Pinnacle and DMS re-allege and incorporate by reference the allegations set forth in the preceding paragraphs as if fully set forth herein.
- 205. As further set forth in the Memorandum filed contemporaneously herewith, Plaintiffs have private right of action under 42 U.S.C. § 1983 to enforce a violation of 42 U.S.C. § 1396a(a)(37) of the Federal Medicaid Act.
- 206. Congress intended 42 U.S.C. § 1396a(a)(37) to benefit providers and suppliers. The language in that statutory provision speaks directly to "provider[s] of a service" and is intended to ensure that a State Medicaid Plan provides for post[-]payment claims review that ensures "the proper and efficient payment of claims[.]"<sup>80</sup>
- 207. 42 U.S.C. § 1396a(a)(37) creates a right—to receive proper payment of claims—that is not so "vague and amorphous" as to render the provision unenforceable. 81

<sup>&</sup>lt;sup>80</sup> 42 U.S.C. § 1396a(a)(37).

<sup>&</sup>lt;sup>81</sup> *Id*.

208. 42 U.S.C. § 1396a(a)(37) imposes a binding obligation to provide procedures for post-payment claims review that ensure proper payment of claims, "including review of appropriate data with respect to the recipient and provider of a service and the nature of the service for which payment is claimed" and the statute uses the mandatory language "must," indicating Congress' intent to impose a binding obligation on those enforcing the state plan. 82

# B. LHC-Centene Violated 42 U.S.C. § 1396a(a)(37)

- 209. Plaintiffs re-allege and incorporate by reference the allegations set forth in the preceding paragraphs as if fully set forth herein.
- 210. In issuing its extrapolated overpayment demands to Plaintiffs, LHC-Centene engaged in several processes that failed to ensure the proper and efficient payment of claims under the Louisiana Medicaid program.
- 211. Specifically, and as further set forth above and in the Memorandum filed contemporaneously herewith, LHC-Centene:
  - a. Conducted improper claim reviews of the individual claims underlying the extrapolations, including, upon information and belief, the use of software tool-based predictions with minimal human intervention (i.e. AI);
  - b. Upon information and belief, conducted its extrapolations without prior written approval from LDH; and
  - c. Utilized statistical sampling and extrapolation methodologies that violated the MPIM and contractual obligations.
- 212. Individually and collectively, LHC-Centene's actions therefore violated 42 U.S.C. § 1396a(a)(37)'s mandate that claims be properly and efficiently paid to providers and suppliers

<sup>&</sup>lt;sup>82</sup> *Id*.

and Plaintiffs are entitled to monetary and equitable relief as set forth in the Prayer for Relief below.

# C. <u>LDH Violated 42 U.S.C. § 1396a(a)(37)</u>

- 213. Plaintiffs re-allege and incorporate by reference the allegations set forth in the preceding paragraphs as if fully set forth herein.
- 214. As set forth above in Paragraphs 190-193 and as further set forth above and in the Memorandum filed contemporaneously herewith, Plaintiffs' action against LDH, via a suit against Secretary Ralph L. Abraham M.D., falls under the *Ex Parte Young* exception to sovereign immunity.
- 215. As further set forth above and in the Memorandum filed contemporaneously herewith, LDH's actions and omissions violated the mandates of 42 U.S.C. § 1396a(a)(37):
  - a. In issuing its own overpayment demand to Pinnacle, LDH conducted an improper review of the claims at issue; and
  - b. As relevant to LHC-Centene's extrapolated overpayment demands assessed to Plaintiffs, LDH failed to properly oversee LHC-Centene in LHC-Centene's procedures for the post-payment claims reviews and statistical sampling and extrapolation processes.
- 216. Individually and collectively, LDH's actions therefore violated 42 U.S.C. § 1396a(a)(37)'s mandate that claims be properly and efficiently paid to providers and suppliers; as such, Plaintiffs are entitled to monetary and equitable relief as set forth in the Prayer for Relief below.

#### **COUNT THREE**

# (INJUNCTIVE RELIEF PROHIBITING RECOUPMENT OF THE OVERPAYMENT DEMANDS)

- 217. Plaintiffs re-allege and incorporate by reference the allegations set forth in the preceding paragraphs as if fully set forth herein.
- 218. As further set forth in the Memorandum filed contemporaneously herewith, Plaintiffs satisfy the four requirements for injunctive relief under Federal Rule of Civil Procedure 65: (1) a substantial likelihood of success on the merits; (2) a substantial threat of irreparable injury if the injunction is not issued; (3) that the threatened injury if the injunction is denied outweighs any harm that will result if the injunction is granted; and (4) that the grant of an injunction will not disserve the public interest.<sup>83</sup>

# A. <u>Likelihood of Success on the Merits</u>

- 219. Plaintiffs re-allege and incorporate by reference the allegations set forth in the preceding paragraphs as if fully set forth herein.
- 220. As set forth in Paragraphs 162-189 and 209-212, and as further set forth in the Memorandum filed contemporaneously herewith, Plaintiffs can make a prima facie case that LHC-Centene violated Plaintiffs' procedural due process rights and 42 U.S.C. § 1396a(a)(37) of the Federal Medicaid Act via LHC-Centene's actions in conducting its post-payment claims reviews and statistical samplings (resulting in the extrapolated overpayment demands).
- 221. As set forth in Paragraphs 190-202 and 213-216 above, and as further set forth in the Memorandum filed contemporaneously herewith, Plaintiffs can make a prima facie case that LDH violated Plaintiffs' procedural due process rights and 42 U.S.C. § 1396a(a)(37) in failing to

<sup>&</sup>lt;sup>83</sup> Benisek v. Lamone, 138 S. Ct. 1942, 1943 (2018) (citing Winter v. NRDC, Inc., 555 U.S. 7, 24 (2008)); see also Byrum v. Landreth, 566 F.3d 442, 445 (5th Cir. 2009); Deep S. Commc'ns, LLC v. Fellegy, 652 F. Supp. 3d 636, 667 (M.D. La. 2023).

properly oversee LHC-Centene in LHC-Centene's procedures for post-payment claims reviews and statistical sampling; and, specific to Pinnacle, LDH conducted an improper claims review of the individual claims at issue in violation of 42 U.S.C. § 1396a(a)(37).

222. Accordingly, and as further set forth in the Memorandum filed contemporaneously herewith, Plaintiffs are likely to succeed on the merits against Defendants.

# B. <u>Irreparable Harm</u>

- 223. Plaintiffs re-allege and incorporate by reference the allegations set forth in the preceding paragraphs as if fully set forth herein.
- 224. The Fifth Circuit has recognized that constitutional violations inflict irreparable harm, regardless of availability of monetary damages.<sup>84</sup>
- 225. As set forth in Count One above, and as further set forth in the Memorandum filed contemporaneously herewith, Defendants' improper and unconstitutional recoupments will irreparably harm Plaintiffs in ways that are incapable of ascertainment in monetary terms.<sup>85</sup>
- 226. Accordingly, and as further set forth in the Memorandum filed contemporaneously herewith, Plaintiffs can demonstrate that Defendants' actions will cause irreparable harm unless enjoined by this Court.

#### C. Balance of the Equities

227. Plaintiffs re-allege and incorporate by reference the allegations set forth in the

<sup>&</sup>lt;sup>84</sup> See, e.g., BST Holdings, LLC v. OSHA, 17 F.4th 604, 618 (5th Cir. 2021) (finding that "dollars and cents" cannot capture the damage that the government inflicts when it deprives rights that it exists to defend); see also Elrod v. Burns, 427 U.S. 347, 373 (1976) (holding that the loss of constitutional freedoms "for even minimal periods of time unquestionably constitutes irreparable injury").

<sup>85</sup> See, e.g., Johnson Controls, Inc. v. Guidry, 724 F. Supp. 2d 612, 626 (W.D. La. 2010) (citing Allied Mktg. Grp, Inc. v. CDL Mktg., Inc., 878 F.2d 806 (5th Cir. 1989)); see also Air Prods. Blue Energy, LLC v. Livingston Parish Gov't, No. 22-cv-00809, 2022 WL 17904535, at \*7 (M.D. La. Dec. 26, 2022).

preceding paragraphs as if fully set forth herein.

- 228. As set forth generally above, and as further set forth in the Memorandum filed contemporaneously herewith, the threatened injuries to Plaintiffs far outweigh any threatened harm to Defendants.
- 229. Further, district courts within the Fifth Circuit have held that this factor is automatically satisfied in cases where a movant seeks correct application of the law and has shown a likelihood of success on the merits, both of which Plaintiffs have done.<sup>86</sup>
- 230. Accordingly, and as further set forth in the Memorandum filed contemporaneously herewith, Plaintiffs can demonstrate that the balance of equities favor injunctive relief against Defendants.

# D. <u>Public Interest</u>

- 231. Plaintiffs re-allege and incorporate by reference the allegations set forth in the preceding paragraphs as if fully set forth herein.
- 232. As further set forth in the Memorandum filed contemporaneously herewith, Plaintiffs seek to enforce the correct application of the law as it relates to LHC-Centene and LDH.<sup>87</sup>
- 233. Accordingly, and as further set forth in the Memorandum filed contemporaneously herewith, Plaintiffs can demonstrate that the public interest will be served by a grant of preliminary injunction.

<sup>&</sup>lt;sup>86</sup> See, e.g., Air Prods., 2022 WL 17904535, at \*7; Helpful Hound, LLC v. New Orleans Bldg. Corp., 331 F. Supp. 3d 581, 604 (E.D. La. 2018).

<sup>&</sup>lt;sup>87</sup> See Centurum Info. Tech. Inc. v. Geocent, LLC, No. 21-cv-00082, 2021 WL 533707, at \*15 (E.D. La. Feb. 12, 2021)("An injunction to enforce the correct application of the law, in and of itself, serves the public interest.")(internal citations omitted).

#### V. PRAYER FOR RELIEF

WHEREFORE Plaintiffs demand an award in its favor against Defendants as follows:

- A preliminary injunction prohibiting recoupment of the Overpayment Demands; A.
- B. Awarding direct and consequential damages;
- C. Awarding costs of the litigation;
- Awarding pre-judgment and post-judgment interest as provided by common law, D. statute or rule, or equity; and
- E. Awarding all other relief to which Plaintiffs are entitled.

June 7, 2024

Respectfully submitted,

#### GOLD WEEMS BRUSER SUES & RUNDELL

/s/ Bradley L. Drell Bradley L. Drell LA State Bar No. 24387 P.O. BOX 6118 2001 Macarthur Dr. Alexandria, LA 71307 Email: bdrell@goldweems.com Telephone: 318-445-6471

#### **K&L GATES LLP**

Stephen D. Bittinger\* SC State Bar No. 104550 134 Meeting Street, Suite 500 Charleston, SC 29401 Email: stephen.bittinger@klgates.com

Telephone: 843-579-5694

Anthony P. La Rocco\* NJ State Bar No. 023491982 One Newark Center, Tenth Floor Newark, NJ 07102 Email: anthony.larocco@klgates.com

Telephone: 973-848-4014

Daniel M. Glassman\* CA State Bar No. 179302 1 Park Plaza, Twelfth Floor Irvine, CA 92614

Email: dan.glassman@klgates.com

Telephone: 949-623-3565

Counsel for Plaintiffs
Pinnacle Medical Solutions, LLC and
Diabetes Management & Supplies, LLC

<sup>\*</sup>Admission pro hac vice pending

# **CERTIFICATE OF SERVICE**

I hereby certify that on June 7, 2024, the foregoing Plaintiffs' Amended Complaint was served on the following by depositing it in the U.S. Mail addressed as below:

Ralph L. Abraham, M.D. Secretary Louisiana Department of Health 628 N. 4th Street Baton Rouge, LA 70802 Kimberly Humbles General Counsel Louisiana Department of Health 628 N. 4th Street Baton Rouge, LA 70802

Louisiana Healthcare Connections, Inc. c/o CT Corporation System 3867 Plaza Tower Dr. Baton Rouge, LA 70816

Centene Corporation c/o CT Corporation System 3867 Plaza Tower Dr. Baton Rouge, LA 70816

This this 7<sup>th</sup> day of June, 2024

/s/ Bradley L. Drell