

STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS
FOR THE DEPARTMENT OF HUMAN SERVICES

In the Matter of the SIRS Appeal of
The Lazarus Project

**FINDINGS OF FACT,
CONCLUSIONS OF LAW,
AND RECOMMENDATION**

The above-entitled matter came before Administrative Law Judge Jeanne M. Cochran for an evidentiary hearing on April 12-13, 2017.¹ The parties filed written closing arguments and proposed findings of fact on June 9, 2017. On June 29, 2017, the Department of Human Services (Department) filed a Motion to Seal, requesting an order sealing portions of the record. On July 11, 2017, The Lazarus Project (Lazarus) filed its response to the Motion. The record closed on that date, upon receipt of the response.²

Brett O. Terry, Assistant Attorney General, appeared on behalf of the Department. Samuel D. Orbovich and Catherine E. London, Fredrikson & Byron, P.A., appeared on behalf of Lazarus.

STATEMENT OF THE ISSUE

Whether the Department may recover \$369,979 in payments made to Lazarus pursuant to Minn. Stat. § 256B.064, subd. 1c (2016), and Minn. R. 9505.0465, .2215, .2220 (2015), based on an audit which used sampling and extrapolation?

SUMMARY OF CONCLUSIONS AND RECOMMENDATION

The Department has established by a preponderance of the evidence that it is entitled to recover \$6,620.85 (Base Claim), the amount of overpayments identified in the sample of 150 claims reviewed. The Department has failed to establish that it is entitled to recover \$369,979, the total amount that it seeks from Lazarus, based on extrapolation of the Base Claim to the universe of claims from which the sample was drawn. The Department has not established that the sampling and extrapolation methodology used to calculate the \$369,979 amount is statistically valid. Nor has it established that the sampling and extrapolation methodology meets the requirements of Minn. R. 9505.2220. Therefore, the Administrative Law Judge recommends that the Commissioner limit the amount recovered from Lazarus to \$6,620.85.

¹ Exhibits 1-35 and Exhibits 2000-2014 were received into the record pursuant to the stipulation of the parties. The parties also agreed that the documents submitted with the cross motions for partial summary disposition filed prior to the evidentiary hearing could be used in preparation of this report.

² A separate order addressing the Motion to Seal is being issued simultaneously.

Based on the evidence in the hearing record, the Administrative Law Judge makes the following:

FINDINGS OF FACT

I. Regulatory Background

A. Medicaid Program and Recovery of Improper Payments

1. Medicaid is a program to provide necessary medical care to individuals with insufficient resources, which is jointly financed by the federal and state governments.³ The federal government shares the costs of providing medical assistance with states that elect to participate in the Medicaid program.⁴

2. In return for federal funding, participating states must comply with the federal requirements, including the rules of the United States Department of Health and Human Services' Centers for Medicare and Medicaid (CMS).⁵

3. Minnesota has elected to participate in the Medicaid program. In Minnesota, the state Medicaid program is administered by the Department and is referred to as Medical Assistance or MA.⁶

4. As a condition of the state's receipt of federal funds, the Department has implemented a statewide surveillance and utilization control program to safeguard against unnecessary or inappropriate use of MA funds.⁷

5. If the Department discovers that payment to a provider of MA services was the result of fraud, theft, abuse or error, the Department "shall" seek monetary recovery.⁸ The Department is authorized to obtain recovery from a provider who has been improperly paid as a result of provider or Department error, regardless of whether the error was intentional.⁹

B. Sampling and Extrapolation Requirements

6. For purposes of seeking recovery of MA payments that were improperly paid to a MA vendor, Minn. R. 9505.2220 authorizes the Department "to calculate the amount of monetary recovery from a vendor based upon extrapolation from a

³ See 42 U.S.C. §§ 1396-1396v, 1396-1 (2012); 42 C.F.R § 430.0 (2016); *Ark. Dep't of Health and Human Servs. v. Ahlborn*, 547 U.S. 268, 275 (2006) (stating the "Medicaid program, . . . provides joint federal and state funding of medical care for individuals who cannot afford to pay their own medical costs....").

⁴ See 42 U.S.C. §§ 1396a, 1396b; 42 C.F.R. § 430.0.

⁵ See 42 U.S.C. § 1396a; 42 C.F.R. § 430.10.

⁶ See Minn. Stat. §§ 256B.01-.0949 (2016).

⁷ 42 C.F.R. § 456.3(a) (2016); see also Minn. Stat. § 256B.04, subds. 4, 15(a) (2016)

⁸ Minn. R. 9505.0465, .2215; see also Minn. Stat. § 256B.064, subd. 1c.

⁹ Minn. Stat. § 256B.064, subd. 1c.

systematic random sample of claims submitted by the vendor and paid by the [MA] program....”¹⁰

7. Minnesota Rules part 9505.2220 further specifies that the Department may use sampling and extrapolation if: (1) the claims to be reviewed represent services to 50 or more recipients; or (2) there are more than 1,000 claims to be reviewed.¹¹

8. In conducting the sampling and extrapolation, the Department is authorized to use simple random samples and “may choose to employ other sampling designs, such as the stratified random sampling, if it determines that those designs are more likely to lead to greater precision, or a closer approximation to the population mean.”¹²

9. In addition, Minn. R. 9505.2220, subp. 3, provides that “[t]he sampling method, including drawing the sample, calculating values, and extrapolating from the results of the sample, shall be performed according to statistical procedures published in the following text: W. Cochran, Sampling Techniques, John Wiley and Sons, New York 3rd Ed. (1977).”¹³ This text, hereinafter referred to as the Cochran Treatise, is incorporated by reference into the Minnesota rules.¹⁴

10. The statistical procedures discussed in the Cochran Treatise are not specific to health care or Medicaid, but are general in their applicability.¹⁵

II. The Lazarus Project

11. Lazarus is a provider of therapeutic services and supports to children diagnosed with autism.¹⁶ Lazarus provides early intervention applied behavior analysis services for these children.¹⁷

12. Lazarus serves approximately 20 children at a time.¹⁸

13. Lazarus provides these services to children who are eligible for MA.¹⁹

14. Lazarus received \$3,235,775.95 in MA reimbursement between December 1, 2007 and December 31, 2011, from the Department.²⁰

¹⁰ Minn. R. 9505.2220, subp. 1.

¹¹ *Id.*, subp. 2.

¹² *Id.*, subp. 3A.

¹³ *Id.*, subp. 3B.

¹⁴ *Id.*, subp. 3C.

¹⁵ Transcript (Tr.) at 139 (Dr. Keller); Tr. at 267 (Dr. Wachs).

¹⁶ Tr. at 178 (Peggy Howell); Stipulation of Facts at ¶ 1 (Jan. 18, 2017).

¹⁷ Tr. at 178 (P. Howell).

¹⁸ *Id.* at 179.

¹⁹ *Id.* at 178-79.

²⁰ Ex. 29 at 11 (Final Audit Report).

15. Lazarus had a total annual income of approximately \$700,000 to \$1.5 million per year between 2007 and 2011.²¹

III. General Overview of the Audit

16. Health Integrity, a Medicaid contractor, was hired by the federal government to conduct an audit of Lazarus and determine Lazarus's compliance with applicable federal and state laws related to its provision of therapeutic services to children with autism.²²

17. The objectives of the audit were to: (1) "determine if services billed and paid under the State Medicaid program were provided"; (2) "determine compliance with State and Federal Medicaid laws and regulations"; and (3) "identify Provider billing and/or payment irregularities within the State's Medicaid program."²³

18. Health Integrity obtained medical and business records from Lazarus to determine if claims were coded appropriately, services were rendered, and claims were billed and paid appropriately.²⁴

19. In conducting the audit, Health Integrity used statistical sampling and extrapolation to determine the estimated overpayment to Lazarus and the amount to be recouped.²⁵

IV. Sampling and Extrapolation Used in the Lazarus Audit

20. In conducting its audit of Lazarus, Health Integrity utilized the guidelines set forth in the CMS Program Integrity Manual (PIM), and consulted applicable federal and state statutes and rules.²⁶ The PIM has been in existence for a number of years and fully corresponds with the Cochran Treatise.²⁷

21. The PIM includes six major steps for conducting an audit: (1) selecting the provider or supplier; (2) selecting the period to be reviewed; (3) defining the universe, the sampling unit, and the sampling frame; (4) designing the sampling plan and selecting the sample; (5) reviewing each of the sampling units and determining if there was an overpayment or underpayment; and as applicable (6) estimating the overpayment.²⁸

22. Health Integrity followed these six steps in conducting the Lazarus audit.²⁹

²¹ Tr. at 181 (P. Howell).

²² Stipulation at ¶ 2; Ex. 29 at 1.

²³ Ex. 29 at 1 (Final Audit Report).

²⁴ *Id.*

²⁵ *Id.* at 1-7.

²⁶ Tr. at 30-31, 33 (Dr. Keller); Ex. 29 at 1 (Final Audit Report).

²⁷ Tr. at 25-26 (Dr. Keller).

²⁸ Ex. 33 at 4 (Outline for Health Integrity, LLC's Sampling and Extrapolation Methodologies Used in the Lazarus Audit prepared by Dr. Keller).

²⁹ *Id.*

A. Step 1- Selecting the Provider

23. Health Integrity selected Lazarus as the provider to be audited. Lazarus was identified through a referral from the Department to the federal government, which contracted with Health Integrity.³⁰

B. Step 2 – Selecting the Period to be Reviewed

24. The time period to be reviewed was December 1, 2007 through December 31, 2011.³¹ This time period was chosen by the Department.³²

C. Step 3 – Defining the Universe, the Sample Unit, and the Sampling Frame

25. The universe is the population from which the sample is drawn.³³

26. In the Lazarus audit, the universe consisted of Medicaid claims with a paid amount greater than zero and service dates from December 1, 2007, through December 31, 2011. The universe was limited to procedures codes H2014 (Skills Training and Development) and H0046 (Provider Travel Time).³⁴

27. The resulting universe consisted of 15,009 claim lines for 49 recipients (patients).³⁵

28. Health Integrity did not use claim lines as the sampling unit. Instead, Health Integrity used the combination of “Recipient ID plus Date of Service” as the sampling unit.³⁶ Health Integrity also referred to this sampling unit as a “claim.”³⁷ A sampling unit or claim could potentially consist of multiple claim lines if Lazarus billed for skills training and travel time on the same day, or multiple instances of skills training on the same day.³⁸

29. Health Integrity chose “Recipient ID plus Date of Service” rather than claim lines as the sampling unit to avoid pseudoreplication.³⁹ Pseudoreplication is a dependency where the outcome of any given claim gives more than random odds of knowing the outcome of any other given claim. In the case of the Lazarus audit, outcome means whether a claim was denied or approved.⁴⁰

³⁰ *Id.*

³¹ *Id.*; Ex. 1 at 1 (Sample Design Summary).

³² Ex. 33 at 4 (Outline for Health Integrity, LLC’s Sampling and Extrapolation Methodologies Used in the Lazarus Audit prepared by Dr. Keller); Ex. 29 at 1 (Final Audit Report).

³³ Tr. at 38.

³⁴ Ex. 1 at 1 (Sample Design Summary); Ex. 29 at 1 (Final Audit Report); Tr. at 38-39 (Dr. Keller).

³⁵ Ex. 1 at 1 (Sample Design Summary); Ex. 3 (Excel Spreadsheet with universe).

³⁶ Ex. 29 at 2 (Final Audit Report); Tr. at 41-42 (Dr. Keller).

³⁷ Ex. 29 at 2.

³⁸ *Id.*

³⁹ Tr. at 40-41 (Dr. Keller).

⁴⁰ See Tr. at 41, 93 (Dr. Keller).

30. The universe of 15,009 claim lines translated into 13,531 sampling units or claims.⁴¹

31. The 13,531 claims comprised the sampling frame.⁴² The sampling frame is “the collection of transformed eligible universe elements” from which the sample is drawn.⁴³ In establishing a sampling frame, the sum of the dollars in the sampling frame must equal the sum of the dollars in the eligible universe so that all data is considered and not counted twice.⁴⁴

D. Step 4 – Designing the Sampling Plan and Selecting the Sample

32. After defining the universe, the sampling unit, and the sampling frame, Health Integrity undertook the fourth step: designing the sampling plan and selecting the sample.⁴⁵

33. The two most common type of sampling plans used in Medicaid audits are the simple random sample and the stratified sample.⁴⁶

34. A simple random sample means every sampling unit in the sample frame has an equal chance of being selected for the sample.⁴⁷ The simple random sample forms what is known as a probability sample.⁴⁸

35. A stratified sample involves dividing the claims into groups, and then taking a sample from each of the groups.⁴⁹ It is a grouping technique.⁵⁰

36. Health Integrity decided to use a simple random sample, rather than a stratified sample.⁵¹ Health Integrity chose a simple random sample because, in its view, a simple random sample is more consistent with Minn. R. 9505.2220.⁵²

37. To determine how many sampling units to include in the simple random sample, Health Integrity used a computer program known as RAT-STATS.⁵³

38. RAT-STATS is a software program developed by the Office of the Inspector General (OIG) of the U.S. Department of Health and Human Services for use in Medicare and Medicaid audits.⁵⁴ It is the “primary statistical tool for OIG’s Office of Audit

⁴¹ *Id.*; Ex. 1 at 1 (Sample Design Summary); Ex. 29 at 5 (Final Audit Report).

⁴² Ex. 29 at 5 (Final Audit Report); Tr. at 42 (Dr. Keller).

⁴³ Tr. at 42 (Dr. Keller).

⁴⁴ *Id.*; Ex. 29 at 2.

⁴⁵ Tr. at 44 (Dr. Keller).

⁴⁶ *Id.*

⁴⁷ *Id.* at 45 (Dr. Keller).

⁴⁸ *Id.*

⁴⁹ Tr. at 217 (Dr. Wachs).

⁵⁰ Tr. at 154 (Dr. Keller).

⁵¹ *Id.* at 45-46 (Dr. Keller); Ex. 1 at 2 (Sample Design Summary).

⁵² Tr. at 44-45 (Dr. Keller).

⁵³ *Id.* at 47.

⁵⁴ *Id.* at 33-35.

Services.”⁵⁵ RAT-STATS has been in use since the late 1970s for Medicare and Medicaid audits.⁵⁶ RAT-STATS has been “vetted” by numerous statisticians since that time.⁵⁷

39. RAT-STATS can be used to generate recommended sample sizes for these types of audits, and also to generate random numbers.⁵⁸ RAT-STATS incorporates relevant statistical equations and principles from the Cochran Treatise.⁵⁹

40. RAT-STATS generates a sample size based on the parameters input into the program.⁶⁰ The parameters are values needed to calculate the sample size using the equations in the Cochran Treatise.⁶¹ The parameters are functional assumptions, not predictions.⁶²

41. One of parameters that is input into RAT-STATS is the expected error rate.⁶³ The error rate reflects an assumption about the percentage of time the provider billed Medicaid incorrectly.⁶⁴

42. The expected error rate is an important parameter because it affects the sample size.⁶⁵ The larger the error rate, the smaller the sample assuming all other parameters are held the same. Conversely, the smaller the error rate, the larger the sample.⁶⁶ According to Dr. Keller, the Department’s expert who is familiar with RAT-STATS, a larger error rate results in a smaller sample because it is easier to find a sample with an erroneous payment.⁶⁷

43. The expected error rate is chosen by the auditor.⁶⁸ In this case, Health Integrity used an expected error rate of 50 percent, meaning it was assumed that 50 percent of claims submitted by Lazarus to the Department included billing errors.⁶⁹

44. The other parameters used in RAT-STATS to determine the sample size are all empirical, based on the data itself.⁷⁰

⁵⁵ Ex. 33 at 1 (Outline for Health Integrity, LLC’s Sampling and Extrapolation Methodologies Used in the Lazarus Audit prepared by Dr. Keller).

⁵⁶ *Id.*

⁵⁷ Tr. at 26 (Dr. Keller).

⁵⁸ *Id.* at 35, 47.

⁵⁹ *Id.* at 36, 47-48.

⁶⁰ *Id.* at 47.

⁶¹ *Id.* at 47-48.

⁶² *Id.*

⁶³ *Id.* at 48.

⁶⁴ See *id.* at 47-50, 283.

⁶⁵ *Id.* at 48.

⁶⁶ *Id.*

⁶⁷ *Id.*

⁶⁸ See *id.* at 48-50.

⁶⁹ Ex. 1 at 1 (Sample Design Summary); Tr. at 48, 79, 165-66 (Dr. Keller).

⁷⁰ Tr. at 50 (Dr. Keller).

45. Using the 50 percent assumed error rate, RAT-STATS derived a sample size of 206 claims.⁷¹

46. Next, Health Integrity used RAT-STATS and SAS, another computer program, to generate random numbers and to select the random sampling units based on the random numbers. This produced a random sample of 206 claims from the universe of 13,531 eligible claims.⁷² The 206 claims were comprised of 215 claim lines.⁷³

47. Health Integrity then conducted a “probe” of 50 of the 206 claims.⁷⁴ A probe is a random slice or subset of a sample used to see whether completing the audit is worthwhile.⁷⁵ If the error rate in a probe is sufficiently small, the government may cease its work and instead issue a “low-no-findings” letter.⁷⁶

48. Health Integrity used RAT-STATS to draw 50 claims for the probe.⁷⁷

49. Health Integrity reviewed the 50 claims in the probe, and found an 18.4 percent error rate in the 50 claims sampled.⁷⁸

50. Based on these probe results, Health Integrity decided to move forward with the audit.⁷⁹

51. Health Integrity decided to review an additional 100 claims from the random sample of 206, for a total of 150 claims reviewed.⁸⁰ The additional 100 sample units were randomly drawn by RAT-STATS.⁸¹

52. In deciding to limit the final sample size to 150 claims rather than the full 206 derived from RAT-STATS, Health Integrity did not apply any specific criteria or standards.⁸²

53. Instead, after conducting the probe, Health Integrity considered the level of error found in the probe and weighed the time and expense required to review additional claims.⁸³ Health Integrity also ran Monte Carlo studies to determine the “optimal balance

⁷¹ Ex. 1 at 2 (Sample Design Summary); Tr. at 113-114 (Dr. Keller). If Health Integrity had used a smaller expected error rate, RAT-STATS would have derived a larger sample size all else being equal. Tr. at 48 (Dr. Keller).

⁷² Tr. at 33 (Dr. Keller); Ex. 33 at 6 (Outline for Health Integrity, LLC’s Sampling and Extrapolation Methodologies Used in the Lazarus Project Audit); Ex. 1 (Sample Design Summary).

⁷³ Ex. 1 at 2 (Sample Design Summary); Ex. 33 at 6 (Outline for Health Integrity, LLC’s Sampling and Extrapolation Methodologies Used in the Lazarus Project Audit); Tr. at 52, 114 (Dr. Keller).

⁷⁴ Tr. at 50-53, 114 (Dr. Keller); Ex. 16.

⁷⁵ Tr. at 114.

⁷⁶ *Id.* at 51.

⁷⁷ Ex. 1; Tr. at 52 (Dr. Keller).

⁷⁸ Tr. at 115 (Dr. Keller).

⁷⁹ *Id.* at 51.

⁸⁰ *Id.* at 51-53 (Dr. Keller); Ex. 2 (Updated Sample Design Summary).

⁸¹ Tr. at 53 (Dr. Keller); Ex. 17.

⁸² Tr. at 319 (Dr. Keller).

⁸³ *Id.* at 51-52, 319.

of provider burden and government effort.”⁸⁴ Based on these considerations, Health Integrity decided to limit the final sample size to 150 claims even though it had 206 available for review.⁸⁵

54. During this process, Health Integrity did not consult with Lazarus regarding the final sample size or the burden that a larger sample size would impose on the provider.⁸⁶ Lazarus was willing to produce documentation for additional claims if requested by Health Integrity, even up to 1000.⁸⁷ Lazarus never indicated that it was unwilling to produce more information.⁸⁸

55. Health Integrity viewed the decision regarding the final sample size as a management decision, not a statistical question.⁸⁹

56. There is no evidence in the record that either Health Integrity or the Department informed Lazarus of the sampling method to be used before the samples were drawn.

E. Step 5 – Reviewing the Sampling Units to determine if there was an Overpayment or Underpayment

57. Health Integrity reviewed each of the 150 claims to determine if there was an overpayment or underpayment. Health Integrity’s review of the 150 claims (comprised of 158 claim lines) showed that 31 claims (comprised of 33 claim lines), or approximately 20 percent, were improperly paid.⁹⁰

58. Of the 31 claims (33 claim lines) that were identified as improperly paid: 26 claim lines involved payments for non-covered services; 4 claim lines had the incorrect number of units billed; and 3 were identified as missing record specific service.⁹¹ The total overpayment amount for the 31 claims (33 claim lines) amounted to \$6,620.85.⁹² There were no underpayments identified.⁹³ The \$6,620.85 overpayment amount is also known as the Base Claim.⁹⁴

⁸⁴ *Id.* at 52. Monte Carlo methods are any “generating of random values (most often with a computer) in order to study statistical models. Monte Carlo methods involve producing several sets of artificial data and using these to study the properties of estimators.” W. Paul Vogt, *Dictionary of Statistics & Methodology: A Nontechnical Guide for the Social Sciences* (4th ed.).

⁸⁵ Tr. at 51-52 (Dr. Keller).

⁸⁶ See *id.* at 52, 120-22; Tr. at 182 (P. Howell).

⁸⁷ Tr. at 182 (P. Howell).

⁸⁸ *Id.*

⁸⁹ Tr. at 127 (Dr. Keller stating that choice of a sample size of 150 is “not a statistical question” and noting that the decision was made by “management” after consulting the Monte Carlo study results and considering the error rate).

⁹⁰ Tr. at 61, 284 (Dr. Keller); Ex. 22 (RAT-STATS report); Ex. 29 at 5 (Final Audit Report).

⁹¹ Ex. 29 (Final Audit Report).

⁹² Tr. at 61 (Dr. Keller); Ex. 22 (RAT-STATS report); Stipulation at ¶3.

⁹³ Tr. at 284 (Dr. Keller).

⁹⁴ Stipulation at ¶3.

59. Based on these results, Health Integrity determined that the level of payment error was sufficiently high to warrant extrapolation.⁹⁵ In reaching this conclusion, Health Integrity relied on the CMS PIM § 8.4.1.2 which provides that extrapolation should only be used to determine overpayment amounts where there is a “determination of sustained or high level of payment error....”⁹⁶ Health Integrity considered the sample results to show a “sustained or high level of payment error.”⁹⁷

F. Step 6 – Estimating the Overpayment

60. Health Integrity then completed the final step in the audit: estimating the total overpayment amount.⁹⁸

61. Health Integrity used RAT-STATS to extrapolate from the sample of 150 claims to the universe of 13,531 claims.⁹⁹

62. A key step in the process is calculating the point estimate.¹⁰⁰ The point estimate equals the average overpayment from the sample of 150 claims (sample mean) multiplied by the total number of units in the universe.¹⁰¹

63. RAT-STATS calculated a sample mean of \$44.14.¹⁰²

64. Based on the sample mean of \$44.14 and a universe of 13,531 units, Health Integrity calculated a point estimate of \$597,245 (\$44.14 * 13,531).¹⁰³

65. In addition to calculating the point estimate, Health Integrity used RAT-STATS to calculate two-sided confidence intervals at 80 percent, 90 percent, and 95 percent.¹⁰⁴ Confidence intervals are a range of values for which there is a specified probability that the value of the parameter lies within it.¹⁰⁵

66. Confidence intervals are derived using the Central Limit Theorem.¹⁰⁶

67. The Central Limit Theorem is a statistical proposition to the effect that the larger the sample size, the more closely a sampling distribution of a statistic (in this case the mean overpayment amount) will approach a normal distribution (i.e. “bell-shaped”

⁹⁵ Tr. at 59-60 (Dr. Keller).

⁹⁶ Ex. 33 at 7-8 (Outline for Health Integrity, LLC’s Sampling and Extrapolation Methodologies Used in the Lazarus Project); Tr. at 59 (Dr. Keller).

⁹⁷ Tr. at 60 (Dr. Keller).

⁹⁸ *Id.* at 60 (Dr. Keller); Ex. 22 (RAT-STATS report).

⁹⁹ Tr. at 60 (Dr. Keller); Ex. 22 (RAT-STATS report).

¹⁰⁰ Tr. at 60 (Dr. Keller); Ex. 22 (RAT-STATS report).

¹⁰¹ Tr. at 63, 69 (Dr. Keller).

¹⁰² Tr. at 63 (Dr. Keller); Ex. 22 (RAT-STATS report); Ex. 33 (Outline for Health Integrity, LLC’s Sampling and Extrapolation Methodologies Used in the Lazarus Project). This sample mean is calculated as \$6,620.85 (total sample overpayment amount)/150 (the sample size)= \$44.14.

¹⁰³ Ex. 22 (RAT-STATS report); Tr. at 63 (Dr. Keller).

¹⁰⁴ Ex. 22 (RAT-STATS report); Tr. at 61 (Dr. Keller).

¹⁰⁵ Tr. at 68 (Dr. Keller).

¹⁰⁶ *Id.* at 76-77; Tr. at 206-08 (Dr. Wachs).

curve). "This is true even if the population from which the sample is drawn is not normally distributed."¹⁰⁷

68. Confidence intervals are based on the expectation from the Central Limit Theorem that the sampling distribution of the mean is normal or "bell-shaped."¹⁰⁸

69. RAT-STATS calculated the following results for the 80, 90, and 95 confidence intervals from the Lazarus audit results:¹⁰⁹

SAMPLE SIZE	VALUE OF SAMPLE	NONZERO ITEMS
150	6,620.85	31
----- DIFFERENCE -----		
MEAN / UNIVERSE	44.14	13,531
STANDARD DEVIATIONS	104.68	
SKEWNESS	2.83	
KURTOSIS	11.63	
STANDARD ERROR (MEAN)	8.50	
STANDARD ERROR (TOTAL)	115,012	
POINT ESTIMATE	597,245	
CONFIDENCE LIMITS		
80% CONFIDENCE LEVEL		
LOWER LIMIT	449,194	
UPPER LIMIT	745,296	
PRECISION AMOUNT	148,051	
PRECISION PERCENT	24.79%	
T-VALUE USED	1.287259135403	
90% CONFIDENCE LEVEL		
LOWER LIMIT	406,883	
UPPER LIMIT	787,607	
PRECISION AMOUNT	190,362	
PRECISION PERCENT	31.87%	
T-VALUE USED	1.655144533798	

¹⁰⁷ Tr. at 76 (Dr. Keller) (quoting from *Dictionary of Statistics & Methodology: A Nontechnical Guide for the Social Sciences*); see also Tr. at 206-08, 266 (Dr. Wachs).

¹⁰⁸ Tr. at 135 (Dr. Keller).

¹⁰⁹ Ex. 22 (RAT-STATS report).

95% CONFIDENCE LEVEL	
LOWER LIMIT	369,979
UPPER LIMIT	824,511
PRECISION AMOUNT	227,266
PRECISION PERCENT	38.05%
T-VALUE USED	1.976013177689

70. The lower limit confidence intervals are calculated by subtracting the precision amount for a given confidence level from the point estimate.¹¹⁰ The upper limit confidence intervals are calculated by adding the precision amount for a given confidence level to the point estimate.¹¹¹ The precision interval amount is calculated by multiplying the point estimate by the precision percentage.¹¹²

71. The precision percentage is really a measurement of how imprecise the point estimate is at a given confidence level.¹¹³

72. For example, the results above show that, at the 95 percent confidence level, the precision estimate is 38.05 percent. This means the lower confidence limit at the 95 percent level is 38.05 percent below the point estimate of \$597,245, resulting in a lower confidence limit of \$369,979.¹¹⁴

73. The PIM does not set boundaries on the allowable size for the precision percentage or precision amount.¹¹⁵

74. In addition to calculating the 80, 90, and 95 percent confidence levels, RAT-STATS also produced several other statistical measures for the sample results including: standard deviation, skewness, and kurtosis.¹¹⁶

75. Standard deviation is a measure of the dispersion of a set of results.¹¹⁷ In this case, the standard deviation indicates how widely the payment error values vary in the sample results.¹¹⁸ RAT-STATS calculated a standard deviation of 104.68 for the Lazarus sample results.¹¹⁹

¹¹⁰ Ex. 33 at 11 (Outline for Health Integrity, LLC's Sampling and Extrapolation Methodologies Used in the Lazarus Project); Ex. 22 (RAT-STATS report).

¹¹¹ Ex. 22 (RAT-STATS report).

¹¹² See *id.*

¹¹³ Ex. 33 at 11 (Outline for Health Integrity, LLC's Sampling and Extrapolation Methodologies Used in the Lazarus Project); Ex. 22 (RAT-STATS report); Tr. at 151 (Dr. Keller).

¹¹⁴ See Ex. 22 (RAT-STATS report). The point estimate of \$597,245- the precision amount of \$227,266= the lower limit of \$369,979 at the 95 percent confidence level. *Id.*

¹¹⁵ Ex. 33 at 11(Outline for Health Integrity, LLC's Sampling and Extrapolation Methodologies Used in the Lazarus Project).

¹¹⁶ Ex. 22 (RAT-STATS report).

¹¹⁷ Tr. at 69 (Dr. Keller).

¹¹⁸ *Id.* at 69-70.

¹¹⁹ Ex. 22.

76. Skewness is a measure of asymmetry of the distribution of the data results.¹²⁰ Skewness looks at how normally or abnormally the data results are distributed.¹²¹ A bell-shaped curve has a skewness measure of zero.¹²² In this case, the overpayment results from the sample of 150 claims have a skewness value of 2.83.¹²³ A skewness value of 2.83 is typical for this type of payment data, but is very far from zero statistically.¹²⁴

77. Kurtosis is a measure of how peaky the curve is and how flattened or fat the tails or ends are.¹²⁵ If a set of data results are highly kurtotic, the curve showing the results will tend to have a big peak in the center and flat ends.¹²⁶ Conceptually, kurtosis is an indicator of whether one can expect extreme values in the data set.¹²⁷ In this case, the measure of kurtosis by RAT-STATS was 11.63.¹²⁸ This value is expected in an audit of MA payments.¹²⁹

78. After reviewing the RAT-STATS results, Health Integrity also tested to see if the null hypothesis that the mean overpayment is less than or equal to zero could be rejected with a probability of being wrong of less than 0.05.¹³⁰

79. Health Integrity tested the null hypothesis because it is required by Minn. R. 9505.2220.¹³¹ The null hypothesis is calculated to ensure that net overpayments are statistically different from zero.¹³²

80. The null hypothesis results for the three tests run by Health Integrity all rejected the null hypothesis with a probability of less than 0.0001.¹³³

81. Based on these results, the Department decided to seek recovery of the lower limit of the 95 percent confidence level or \$369,979.¹³⁴

¹²⁰ Tr. at 210 (Dr. Wachs).

¹²¹ Tr. at 70 (Dr. Keller).

¹²² Tr. at 210-221 (Dr. Wachs).

¹²³ Ex. 22 (RAT-STATS report); Tr. at 70, 312 (Dr. Keller).

¹²⁴ Tr. at 70 (Dr. Keller); Tr. at 211 (Dr. Wachs).

¹²⁵ Tr. at 70, 137 (Dr. Keller).

¹²⁶ *Id.* at 70 .

¹²⁷ Tr. at 212 (Dr. Wachs).

¹²⁸ Ex. 22 (RAT-STATS report); Tr. at 70 (Dr. Keller).

¹²⁹ Tr. at 70 (Dr. Keller).

¹³⁰ *Id.* at 72-74; Ex. 24 (SAS System results).

¹³¹ Tr. at 72 (Dr. Keller).

¹³² *Id.* at 168-169, 291.

¹³³ *Id.* at 74; Ex. 24 (SAS System results); Tr. at 207-08 (Dr. Wachs).

¹³⁴ Ex. 22 (RAT-STATS report); Ex. 30 (Notice of Agency Action).

V. Sample Size, Confidence Intervals, and Extrapolation According to Cochran Treatise

82. Health Integrity used the confidence intervals to estimate the amount of overpayment in the universe.¹³⁵ In order to have a statistically valid extrapolation using confidence intervals, the sample size must be large enough to approximate a normal distribution of results (a/k/a bell-shaped curve).¹³⁶

83. According to the Cochran Treatise, it is not easy to answer the question of how large the sample size (n) must be for the sample means to produce a bell-shaped curve.¹³⁷ As noted above, the Central Limit Theorem states that with a sufficiently large sample size, the distribution of the averages (or sample means) approaches a normal distribution.¹³⁸ The Cochran Treatise notes “[t]here is no safe general rule as to how large n must be for use of the normal approximation in computing confidence limits.”¹³⁹

84. Cochran goes on to state on page 42 that “[f]or populations in which the principal deviation from normality consists of marked positive skewness, a crude rule that I have occasionally found useful is:

$$n > 25G_1^2$$

where G_1 is Fisher's measure of skewness (Fisher, 1932).

$$G_1 = \frac{E(y_i - \bar{Y})^3}{\sigma^3} = \frac{1}{N\sigma^3} \sum_{i=1}^N (y_i - \bar{Y})^3$$

This rule is designed so that a 95% confidence probability statement will be wrong not more than 6% of the time.”¹⁴⁰

85. In other words, where the underlying data (here the overpayment amounts) demonstrate a marked positive skewness, this rule provides a formula by which to determine the minimum sample size needed for a normal distribution of sample means.¹⁴¹

86. Use of this formula is appropriate for determining the minimum sample size needed for the Lazarus audit because the sample overpayment results show marked positive skewness.¹⁴² The results for the 150 claims sampled show a skewness of positive 2.83.¹⁴³ If the sample data analyzed by Health Integrity had been normal, it would

¹³⁵ Ex. 29 (Final Audit Report - Overpayment Calculation Summary); Ex. 22 (RAT-STATS report showing confidence levels with upper and lower limits); Tr. at 61, 64-66 (Dr. Keller).

¹³⁶ See Tr. at 76, 85 (Dr. Keller), 207-08 (Dr. Wachs); see also Cochran Treatise at 37, 39-42.

¹³⁷ Cochran Treatise at 40.

¹³⁸ Tr. at 76 (Dr. Keller), 207 (Dr. Wachs).

¹³⁹ Cochran Treatise at 42.

¹⁴⁰ *Id.*; see also, Tr. at 238-40 (Dr. Keller explaining formula).

¹⁴¹ See Cochran Treatise at 42.

¹⁴² Ex. 22 (RAT-STATS report); Ex. 2005 (graph of overpayment distribution for sample of 150 claims).

¹⁴³ Ex. 22.

have generated a skewness factor at or near zero.¹⁴⁴ A skewness of 2.83 is “very far from zero statistically.”¹⁴⁵

87. Using data from the Lazarus audit, the equation in the Cochran Treatise produces a result of $n >$ greater than 203.¹⁴⁶ In other words, to ensure a statistically valid extrapolation, the equation on page 42 of the Cochran Treatise instructs that the sample size must exceed 203 claims in order for the extrapolation to be statistically valid.¹⁴⁷

88. The minimum sample size calculated using this formula is very similar to the sample size of 206 derived from RAT-STATS, which incorporates relevant Cochran equations.¹⁴⁸

89. In this case, the sample size formula from the Cochran Treatise could not be calculated until after the audit was complete because the skewness measure comes from the results of the audit.¹⁴⁹

VI. Procedural Facts

90. On November 15, 2013, Health Integrity issued a “Draft Audit Report of Lazarus Project.”¹⁵⁰ The Draft Audit Report summarized the audit process discussed above and presented preliminary results.¹⁵¹ Lazarus and the Department were each provided an opportunity to comment on the Draft Audit Report and identify any concerns with it.¹⁵²

91. On March 25, 2014, the Department sent Health Integrity a letter regarding the Draft Audit Report. The Department stated that “it did not disagree with the monetary findings on the sampled claims reviewed by Health Integrity” but requested that Health Integrity compare Health Integrity’s sampling and extrapolation methodology to the requirements in Minn. R. 9505.2220.¹⁵³

92. On July 3, 2014, attorneys for Lazarus sent a letter to Health Integrity raising a number of concerns with the findings in the Draft Audit Report and disputing the preliminary results.¹⁵⁴ Lazarus provided information in support of its position.¹⁵⁵

¹⁴⁴ Tr. at 211 (Dr. Wachs).

¹⁴⁵ *Id.*

¹⁴⁶ Tr. at 209, 240-41 (Dr. Wachs).

¹⁴⁷ *Id.* at 209.

¹⁴⁸ *Id.* at 240-41; Tr. at 113-114 (Dr. Keller); Ex. 1 at 2 (Sample Design Summary).

¹⁴⁹ Tr. at 278 (Dr. Keller).

¹⁵⁰ Ex. 25.

¹⁵¹ *Id.*

¹⁵² Tr. at 162 (Dr. Keller).

¹⁵³ Ex. 27 (Letter from Department to Health Integrity dated March 25, 2014).

¹⁵⁴ Ex. 28 (Letter from Samuel Orbovich and Catherine London, Fredrickson and Byron, to Health Integrity dated July 3, 2014).

¹⁵⁵ *Id.*

93. Health Integrity reviewed Lazarus's response and revised some of its findings.¹⁵⁶

94. On February 26, 2015, Health Integrity issued its "Final Audit Report of Lazarus Project."¹⁵⁷ The final report concluded that a "review of the 150 claims (158 claim lines) revealed 31 claims (33 claim lines) with recoupable billing errors."¹⁵⁸ The final report stated the identified overpayments for the discrepant claims totaled \$6,620.85. The final report further stated: "When extrapolated to the universe of claims from which the sample was drawn, the calculated overpayment is \$369,979.00."¹⁵⁹ The \$369,979 amount is the lower limit of the 95 percent confidence level as calculated by RAT-STATS, based on the sample of 150 claims reviewed by Health Integrity.¹⁶⁰

95. On August 26, 2015, the Department issued a Notice of Agency Action to Lazarus.¹⁶¹ Based on the final audit report, the Department informed Lazarus that the Department was seeking recovery of \$369,979 in funds paid by the Department to Lazarus for services rendered between December 1, 2007, and December 31, 2011. The Notice informed Lazarus of its right to appeal the Department's decision by submitting a written request within 30 days of the date of the Notice.¹⁶² The Notice also gave Lazarus the option to request an installment payment schedule if it did not appeal.¹⁶³

96. By a letter dated September 25, 2015, Lazarus filed an appeal of the Department's Notice of Agency Action.¹⁶⁴

97. On February 25, 2016, the Department issued the Notice and Order for Prehearing Conference and Hearing.

98. On December 15, 2016, Lazarus and the Department each filed a motion for partial summary disposition. The parties' cross motions addressed only the issue of whether the Department had demonstrated that it was entitled to recovery of the Base Claim (\$6,620.85), not the issue of the propriety of the sampling methodology or extrapolation used to arrive at the proposed total recovery amount of \$369,979.

99. On January 18, 2017, the parties filed responsive briefs. Also, on January 18, 2017, the parties filed a Stipulation of Facts.

¹⁵⁶ Ex. 29 at 8 (Final Audit Report).

¹⁵⁷ Ex. 29 (Final Audit Report).

¹⁵⁸ *Id.* at 5.

¹⁵⁹ *Id.* at 7.

¹⁶⁰ See Ex. 22 (RAT-STATS report).

¹⁶¹ Ex. 30 (Notice of Agency Action).

¹⁶² *Id.*

¹⁶³ *Id.*

¹⁶⁴ Ex. 31 (Lazarus Appeal Letter and Request for Contested Case Hearing).

100. A hearing on the cross motions for partial summary disposition was held on January 26, 2017, at the Office of Administrative Hearings. Supplemental briefs were filed by the parties on February 9, 2017, at the request of the Administrative Law Judge.

101. On March 7, 2017, the Administrative Law Judge issued an Order on Cross Motions for Partial Summary Disposition. The Order granted the Department's Motion for Partial Summary Disposition, concluding that the Department is entitled to recovery of the Base Claim of \$6,620.85. The Order noted that the issue of the extrapolation of the Base Claim would be addressed at the evidentiary hearing in this matter.

102. An evidentiary hearing on the issues of sampling and extrapolation was held on April 12 and 13, 2017, at the Office of Administrative Hearings.

103. Any of the foregoing Findings more properly designated as Conclusions of Law are hereby adopted as such.

Based on these Findings of Fact, the Administrative Law Judge makes the following:

CONCLUSIONS OF LAW

1. The Administrative Law Judge and the Commissioner of Human Services have jurisdiction in this matter pursuant to Minn. Stat. §§ 14.50, 256B.064, subd. 2 (2016).

2. Medicaid is a program established under federal law, jointly financed by the federal and state governments.¹⁶⁵ The purpose of Medicaid is to provide necessary medical assistance to eligible persons who have insufficient income and resources to pay for the cost of the medical care they require.¹⁶⁶

3. In return for federal funding, the participating states must comply with the federal requirements, including the CMS rules.¹⁶⁷

4. As a condition of Minnesota's receipt of federal funds, the Department has implemented a statewide surveillance and utilization control program to safeguard against unnecessary or inappropriate use of Medicaid funds.¹⁶⁸ The state implemented Medicaid program in Minnesota is known as Medical Assistance or MA.¹⁶⁹

5. Minnesota Statute section 256B.064, subdivision 1c, authorizes the Department to obtain monetary recovery from a MA vendor who has been improperly paid as a result of fraud, theft, or abuse, or as a result of a vendor or Department error, regardless of whether the error was intentional.

¹⁶⁵ Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v.

¹⁶⁶ See 42 U.S.C. § 1396 (2012); *Atkins v. Rivera*, 477 U.S. 154, 156 (1986).

¹⁶⁷ See 42 U.S.C. § 1396a; 42 C.F.R. § 430.10.

¹⁶⁸ 42 C.F.R. § 456.3(a); see also Minn. Stat. § 256B.04, subds. 4, 15(a).

¹⁶⁹ See Minn. Stat. §§ 256B.01-0949.

6. Minnesota Rule 9505.0465, subpart 1, provides that the Department “shall recover medical assistance funds paid to a provider if the [D]epartment determines that the payment was obtained fraudulently or erroneously.”

7. Similarly, Minn. R. 9505.2215, subp. 1, requires the Department to seek monetary recovery from a “program” vendor if payments made by the Department to the vendor were the result of “fraud, theft, abuse, or error on the part of the vendor, department, or local agency.”¹⁷⁰ The term “program” includes the MA program.¹⁷¹

8. Where recovery is based on error, the Department may seek recovery from a vendor regardless of whether the error was intentional.¹⁷²

9. In addition, Minn. R. 9505.2220 authorizes the Department “to calculate the amount of monetary recovery from a vendor based upon extrapolation from a systematic random sample of claims submitted by the vendor and paid by the [Department] program or programs.”¹⁷³

10. The Department may use sampling and extrapolation to calculate a monetary recovery from a vendor if there are more than 1,000 claims to be reviewed or the claims to be reviewed represent services to 50 or more recipients.¹⁷⁴

11. If the Department uses sampling and extrapolation to determine the amount of money to recover from a vendor, the Department must use the following sampling and extrapolation methods:

- Samples shall be selected in such a way as they are equally likely to be selected (simple random samples) unless the Department determines that another sampling method is more likely to lead to greater precision or a closer approximation to the population mean.¹⁷⁵ The Department shall “tell the provider the sampling method the [D]epartment is using prior to drawing the sample.”¹⁷⁶
- Samples shall only be selected from claims for health services provided within the interval of time that coincides with the interval during which money allegedly was overpaid and for which recovery will be made.¹⁷⁷
- The sampling method, including drawing the sample, calculating values, and extrapolating from the results of the sample, shall be

¹⁷⁰ Minn. R. 9505.2215; see also Minn. Stat. § 256B.064, subd. 1c.

¹⁷¹ Minn. R. 9505.2165, subp. 8 (2015).

¹⁷² Minn. Stat. § 256B.064, subd. 1c.

¹⁷³ Minn. R. 9505.2220, subp. 1.

¹⁷⁴ *Id.*, subp. 2.

¹⁷⁵ *Id.*, subp. 3A.

¹⁷⁶ *Id.*, subp. 3A.

¹⁷⁷ *Id.*, subp. 3B

performed according to statistical procedures published in the Cochran Treatise.¹⁷⁸ In addition, samples must contain at least 50 claims.¹⁷⁹

- The total amount to be recovered shall equal the mean overpayment multiplied by the number of claims in the population.¹⁸⁰ The Department shall seek to recover the estimated overpayment only if the null hypothesis that the mean overpayment is less than or equal to zero can be rejected with probability less than 0.05.¹⁸¹

12. If the Department uses the methods set forth above, the Department's random sample extrapolation constitutes a rebuttable presumption regarding the calculation of monetary recovery.¹⁸²

13. Lazarus is a vendor within the meaning of Minn. Stat. § 256B.02 and subject to the provisions of Minn. Stat. § 256B.064, and Minn. R. 9505.0465, .2215.

14. The Department bears the burden of proof in this matter to show by a preponderance of the evidence that it is entitled to seek monetary recovery of \$369.979 in payments made by the Department to Lazarus for services provided by Lazarus.¹⁸³

15. For the reasons set forth in the Order on Cross Motions for Partial Summary Disposition dated March 7, 2017, the Department has demonstrated by a preponderance of the evidence that Lazarus was improperly paid for 31 discrepant claims, in an amount totaling \$6,620.85.

16. Pursuant to Minn. R. 9505.2220, subp. 2, the Department is authorized to use sampling and extrapolation to calculate the monetary recovery for the universe of claims because there are more than 1,000 claims from Lazarus to be reviewed.¹⁸⁴

17. The sampling and extrapolation used by the Department and its auditor, Health Integrity, must comply with the requirements in Minn. R. 9505.2220, subp. 3.

18. As noted above, one of the key requirements of the subpart 3 is that the "sampling method, including drawing the sample, calculating values, and extrapolating from the results of the sample, shall be performed according to statistical procedures published in" the Cochran Treatise.¹⁸⁵

¹⁷⁸ *Id.*, subp. 3C.

¹⁷⁹ *Id.*

¹⁸⁰ *Id.*, subp. 3D.

¹⁸¹ *Id.*

¹⁸² *Id.*

¹⁸³ Minn. R. 1400.7300, subp. 5 (2015).

¹⁸⁴ Minn. R. 9505.2220, subp. 2; Ex. 1.

¹⁸⁵ *Id.*, subp. 3C.

19. The Department has failed to demonstrate that the sampling method used by Health Integrity was performed consistent with the procedures in the Cochran Treatise as required by Minn. R. 9505.2220, subp. 3C, or that the sampling and extrapolation was statistically valid.

20. Specifically, the Department has failed to demonstrate that the sample size of 150 claims was sufficiently large to ensure a statistically valid point estimate and statistically valid confidence intervals for purposes of estimating the total overpayment amount for the universe of 13,531 claims. Based on the formula on page 42 of the Cochran Treatise, a sample size exceeding 203 claims is necessary to satisfy the Central Limit Theorem.¹⁸⁶ In addition, RAT-STATS, which incorporates the relevant Cochran Treatise equations, derived a recommended sample size of 206 for the Lazarus audit.¹⁸⁷

21. Even though RAT-STATS derived a sample size of 206, Health Integrity decided to use a final sample size of only 150 sampling units.

22. The evidence shows a sample size of 150 sample units is not sufficient to satisfy the Central Limit Theorem. Nor does the evidence in the record demonstrate that the average overpayment per claim produced by the sample of 150 claims is representative of the average overpayment per claim in the universe of 13,531 claims.

23. As a result, the Department has not demonstrated that the sampling methodology used by Health Integrity is consistent with the Cochran Treatise as required by Minn. R. 9505.2220. Nor has the Department demonstrated that Health Integrity's sampling and extrapolation methodology produced a statistically reliable estimate of the total overpayment to Lazarus for the period December 2007 to December 2011.

24. In addition, there is no evidence in the record showing the Department informed Lazarus about the sampling method being used prior to drawing the sample as required by Minn. R. 9505.2220, subp. 3A.

25. For these reasons, the Department has not demonstrated by a preponderance of the evidence that the methodology used to calculate the \$369,979 in estimated overpayments is statistically valid or that it meets the requirements of Minn. R. 9505.2220.

26. The Department has only demonstrated that Lazarus was improperly paid \$6,620.85, the amount of overpayments identified in the Base Claim.

27. Any of the foregoing Conclusions more properly designated as Findings of Fact are hereby adopted as such.

¹⁸⁶ Tr. at 208-09 (Dr. Wachs).

¹⁸⁷ Ex. 1 at 2 (Sample Design Summary).

Based upon these Conclusions of Law, and for the reasons set forth in the accompanying Memorandum as well as in the Order on Cross Motions for Summary Disposition, the Administrative Law Judge makes the following:

RECOMMENDATION

The Administrative Law Judge respectfully recommends that the Commissioner limit the recovery from Lazarus to \$6,620.85 rather than the \$369,979 amount set forth in the Notice of Agency Action. The Administrative Law Judge further recommends that the Commissioner amend the Notice of Agency Action to be consistent with the Findings of Fact and Conclusions of Law set forth above.

Dated: July 24, 2017


JEANNE M. COCHRAN
Administrative Law Judge

Reported: Digitally Recorded and Transcript Prepared

NOTICE

This Report is a recommendation, not a final decision. The Commissioner of Human Services (the Commissioner) will make the final decision after a review of the record. Under Minn. Stat. § 14.61 (2016), the Commissioner shall not make a final decision until this Report has been made available to the parties for at least ten calendar days. The parties may file exceptions to this Report and the Commissioner must consider the exceptions in making a final decision. Parties should contact Debra Schumacher, Administrative Law Attorney, PO Box 64254, St. Paul, MN 55164-0254, (651) 431-4319 to learn the procedure for filing exceptions or presenting argument.

The record closes upon the filing of exceptions to the Report and the presentation of argument to the Commissioner, or upon the expiration of the deadline for doing so. The Commissioner must notify the parties and Administrative Law Judge of the date the record closes. If the Commissioner fails to issue a final decision within 90 days of the close of the record, this Report will constitute the final agency decision under Minn. Stat. § 14.62, subd. 2a (2016). In order to comply with this statute, the Commissioner must then return the record to the Administrative Law Judge within ten working days to allow the Judge to determine the discipline imposed.

Under Minn. Stat. § 14.62, subd. 1 (2016), the Commissioner is required to serve her final decision upon each party and the Administrative Law Judge by first class mail or as otherwise provided by law.

MEMORANDUM

I. Introduction

On March 7, 2017, the undersigned Administrative Law Judge issued an order addressing the parties' cross motions for partial summary disposition. The motions were limited solely to recovery of the Base Claim. The Administrative Law Judge concluded that the Department had shown that 31 of 150 claims sampled were improperly paid, in an amount totaling \$6,620.85.

The remaining issues in this case relate to the sampling and extrapolation methods used by Health Integrity to calculate the \$369,979 dollar amount, which the Department seeks to recover in this proceeding.¹⁸⁸ A hearing on these issues was held on April 12-13, 2017. At the hearing, both parties presented expert witness testimony on the statistical validity of the sampling and extrapolation methods used, as well as compliance with the requirements of Minn. R. 9505.2220.

II. Positions of the Parties

A. The Department's Position

The Department argues that it is entitled to recover the full \$369,979 pursuant to Minn. Stat. § 256B.064, subd. 1c, and Minn. R. 9505.2215, .2220. The Department notes that under Minnesota law, it is required to obtain monetary recovery from a MA provider who has been "improperly paid as a result of fraud, theft, or abuse in connection with the provision of medical care, or as a result of [Department] or provider error, regardless of whether the error was intentional."¹⁸⁹ In addition, the Department points to Minn. R. 9505.2220, which authorizes the Department to calculate the amount of monetary recovery from a MA provider based upon extrapolation from a systematic random sample of claims paid to the provider.¹⁹⁰

The Department asserts that Health Integrity took a statistically valid random sample of 150 claims over the period from December 1, 2007 through December 31, 2011, reviewed these claims to determine whether they were properly paid, and found 31 were improperly paid. Health Integrity then extrapolated the findings to determine the final overpayment amount.¹⁹¹

The Department argues that the sampling methodology and extrapolation used to calculate the \$369,979 estimated overpayment amount fully complies with Minn. R. 9505.2220.¹⁹²

¹⁸⁸ See Ex. 29 at 7 (Final Audit Report); Ex. 30 at 1 (Notice of Agency Action).

¹⁸⁹ Department of Human Services' Closing Argument (Department Br.) at 2 (citing Minn. Stat. § 256B.064; Minn. R. 9505.2215).

¹⁹⁰ *Id.* (citing Minn. R. 9505.2220).

¹⁹¹ Tr. at 60-61 (Dr. Keller); Exs. 1, 2, 22; Department Br. at 5-10.

¹⁹² Department Br. at 2, 10-17.

In support of its position, the Department called Dr. Dana Keller to testify about the sampling and extrapolation methodology used in the audit and to give his opinion on the validity of the results. Dr. Keller has both a M.A. and a Ph.D. in Measurement, Statistics & Program Evaluation from the University of Delaware.¹⁹³ Dr. Keller has worked as a statistician in the Medicare and Medicaid field since approximately 1997.¹⁹⁴

Dr. Keller is currently employed by Halcyon Research, Inc., which offers statistical and methodological consulting within the health care industry.¹⁹⁵ Halcyon is a subcontractor of Health Integrity, LLC.¹⁹⁶ Dr. Keller worked on the Lazarus audit as it was being conducted. Dr. Keller was responsible for approving the sampling and extrapolation procedures used by Health Integrity during its audit of Lazarus.¹⁹⁷

In Dr. Keller's view, the sampling and extrapolation were performed in accordance with the relevant statistical procedures in the Cochran Treatise.¹⁹⁸ Dr. Keller also stated that sampling methodology and tools used by Health Integrity have been developed over the course of decades for the OIG and have been vetted by hundreds of statisticians at CMS and OIG.¹⁹⁹

According to Dr. Keller, the sample size of 150 sampling units used in the Health Integrity audit was sufficiently large to satisfy the Central Limit Theorem and ensure a statistically valid extrapolation based on a normal distribution.²⁰⁰ He maintains that a sample of 30 or more sampling units would usually result in a sampling distribution for the mean that is very close to a normal distribution.²⁰¹ He also noted that according to OIG, a sample size of 50 is sufficient for this type of audit.²⁰² In addition, Dr. Keller maintained that the sample size of 150 is large enough to be statistically valid because "RAT-STATS, wrote a slipknot clause in there of sorts, so that if your sample size is not appropriate, then the extrapolation comes out negative, as the lower bound, even if the point estimate is positive. You can, in fact, have no underpayment, so there's nothing negative in the sample...."²⁰³ According to Dr. Keller, the very fact the extrapolation is positive is empirical evidence that the sample size of 150 is large enough.²⁰⁴ Dr. Keller disagreed

¹⁹³ Ex. 32 (Dana Keller Curriculum Vitae). Dr. Keller received his undergraduate degree in Sociology from Tufts University. *Id.*

¹⁹⁴ *Id.*

¹⁹⁵ *Id.*

¹⁹⁶ *Id.*

¹⁹⁷ Tr. at 21-22.

¹⁹⁸ *Id.* at 81-82.

¹⁹⁹ *Id.* at 25-27.

²⁰⁰ *Id.* at 138, 279, 281-82.

²⁰¹ *Id.* at 87, 138, 281-282.

²⁰² *Id.* at 280. The Department also maintains that even assuming the sample size is not sufficient to satisfy the Central Limit Theorem, the extrapolation still complies with Minn. R. 9505.2220 because the Central Limit Theorem is used to calculate the confidence intervals. The Department emphasized that it is not required to apply confidence intervals to calculate the overpayment amount but rather can use the point estimate. Department Br. at 17-18 (citing Minn. R. 9505.2220). On this basis, the Department maintains that the extrapolation from the sample mean to the point estimate is still valid even assuming the sample size is too small. Department Br. at 17-18.

²⁰³ Tr. at 81 (Dr. Keller).

²⁰⁴ *Id.*

with the use of the equation on page 42 of the Cochran Treatise in this case. Dr. Keller maintained that this equation is not applicable in the context of a Medicaid audit because the equation uses the results of the audit.²⁰⁵ As such, the formula cannot be used to determine the sample size prior to conducting the audit.²⁰⁶

Dr. Keller also emphasized that the null hypothesis results show the mean overpayment is statistically different from zero.²⁰⁷ According to Dr. Keller, the null hypothesis results demonstrate that the sample is sufficiently large and the results are sufficiently distributed to allow for extrapolation from the sample to the universe.²⁰⁸ Finally, Dr. Keller emphasized that under Minn. R. 9505.2220, the Department is entitled to recover the point estimate amount, or \$597,244.81, but the Department decided instead to recover \$369,979. This amount is based on the lower limit of the two-sided 95 percent confidence interval rather than the point estimate.²⁰⁹ Dr. Keller maintained this decision works to the benefit of Lazarus because the amount that the Department seeks to recover is approximately 38 percent less than amount allowed under the Minnesota rule.²¹⁰

Based on Dr. Keller's testimony, the Department maintains that it has demonstrated the sampling and extrapolation conducted by Health Integrity are statistically valid and comply with Minn. R. 9505.2220.²¹¹ The Department concedes that Lazarus was not notified of the sampling methodology to be used in the audit prior to Health Integrity drawing the sample as required by Minn. R. 9505.2220, subp. 2B, but argues that its failure to notify Lazarus did not prejudice Lazarus.²¹² The Department notes that Lazarus received a copy of the Draft Audit Report, which was issued by Health Integrity to allow Lazarus and the Department an opportunity to provide comments before the final report was issued.²¹³ The Department emphasizes that Lazarus did not mention the lack of timely notice of the sampling methodology in its comments on the Draft Audit Report.²¹⁴ The Department maintains that because there was no prejudice to Lazarus, the Department should be allowed to recover the full \$369,979.²¹⁵

B. Lazarus's Position

According to Lazarus, the Department has failed to demonstrate that the sampling and extrapolation process used by Health Integrity complies with Minn. R. 9505.2220.²¹⁶ Lazarus maintains the sampling and extrapolation methodology used to calculate the

²⁰⁵ *Id.* at 278-79.

²⁰⁶ *Id.*

²⁰⁷ *Id.* at 72-74, 291 (Dr. Keller); Ex. 24 (SAS System results).

²⁰⁸ Tr. at 72 (Dr. Keller).

²⁰⁹ See Tr. at 49, 63-68 (Dr. Keller); Ex. 22 (RAT-STATS report).

²¹⁰ Tr. at 68 (Dr. Keller); Ex. 22; Department Br. at 17-18.

²¹¹ Department Br. at 10-18.

²¹² *Id.* at 11.

²¹³ *Id.* at 12.

²¹⁴ *Id.* at 12-13.

²¹⁵ *Id.* at 11-13.

²¹⁶ The Lazarus Project's Written Argument (Lazarus Br.) at 3.

\$369,979 recovery amount is not statistically valid.²¹⁷ Alternatively, Lazarus argues that the Department lacks subject matter jurisdiction to recover an extrapolated award from any provider of children's therapeutic services including Lazarus.²¹⁸ These two arguments are addressed in turn below.

1. Sampling and Extrapolation Method Issues

In support of its position that the sampling and extrapolation methodology used by Health Integrity is not statistically valid and does not comply with Minn. R. 9505.2220, Lazarus relies on the testimony of Dr. Allise Wachs. Dr. Wachs has a B.S. in Mathematics and Statistics, M.A. in Statistics, M.S. in Industrial Engineering, and a Ph.D. in Applied Mathematics/Operations Research.²¹⁹ She has also completed the course work for a Ph.D. in statistics at the University of Chicago.²²⁰

Dr. Wachs works as a statistician. She is currently the president of Integral Concepts, Inc., which specializes in the quality and reliability of products.²²¹ Dr. Wachs has also taught statistics as an adjunct professor at the University of Michigan.²²²

Dr. Wachs raised several concerns with the sampling and extrapolation methods used by Health Integrity. Dr. Wachs' primary criticism relates to the sample size used in the Health Integrity audit. Dr. Wachs testified that, in her opinion, the sample size of 150 claims is too small to satisfy the Central Limit Theorem.²²³ According to Dr. Wachs, with a sample size of 150 claims, the sample means (averages) will not follow a bell-shaped curve.²²⁴ Dr. Wachs noted that a sample size large enough to approximate a normal distribution of sample means is a requirement in the Cochran Treatise, and is necessary for the confidence intervals and point estimate to be statistically valid.²²⁵

Dr. Wachs clarified that the problem is not that the underlying data (the overpayment amounts for each of the sample claims) are not normally distributed, but that the averages of the overpayment amounts are not normally distributed.²²⁶ Dr. Wachs explained that "[a]verages behave differently than individual measurements."²²⁷ She elaborated that if a statistician keeps taking random samples of a sufficiently large size drawn from the same universe, the averages calculated from those random samples will take on the appearance of a bell-shaped curve reflecting a normal distribution of the

²¹⁷ *Id.*

²¹⁸ *Id.*

²¹⁹ Tr. at 198 (Dr. Wachs); Ex. 2002 (Curriculum Vitae of Dr. Wachs).

²²⁰ Ex. 2002 (Curriculum Vitae).

²²¹ Tr. at 197 (Dr. Wachs); Ex. 2002 (Curriculum Vitae).

²²² Tr. 198-199 (Dr. Wachs); Ex. 2002 (Curriculum Vitae).

²²³ Tr. at 229, 248-49 (Dr. Wachs).

²²⁴ *Id.* at 205, 207.

²²⁵ *Id.* at 270-71.

²²⁶ *Id.* at 204-05.

²²⁷ *Id.* at 204.

averages.²²⁸ She noted that this statistical result is known as the Central Limit Theorem.²²⁹

To determine if the Central Limit Theorem was satisfied in this case, Dr. Wachs used a “bootstrapping” method to calculate averages based on the audit data and on a sample size of 150 claims.²³⁰ According to Dr. Wachs, this “bootstrapping” method showed that averages based on a sample size of 150 were not bell-shaped, but instead followed a highly skewed distribution.²³¹ In other words, the results showed that the sample size of 150 claims was not large enough to satisfy the Central Limit Theorem.²³²

In addition, Dr. Wachs calculated the minimum sample size using the formula on page 42 of the Cochran Treatise.²³³ Using that formula, Dr. Wachs calculated that the minimum sample size needs to exceed 203 in order to satisfy the Central Limit Theorem and produce a bell-shaped curve upon which a statistically valid extrapolation can be calculated.²³⁴ Because the sample size used in the Health Integrity audit of Lazarus was 150, Dr. Wachs concluded the sample size was not large enough to produce statistically valid confidence intervals or a statistically valid point estimate.²³⁵ Dr. Wachs emphasized that the sample was too small to produce averages following a normal distribution.²³⁶

Dr. Wachs also raised concerns about: (1) the assumed error rate of 50 percent used to calculate the sample size;²³⁷ (2) the 38.05 percent imprecision level associated with the 95 percent confidence interval used to calculate the \$369,979 overpayment amount that the Department seeks to recover;²³⁸ (3) use of the mean rather than the median when the results of the audit were highly skewed (79 percent of the overpayment values in the sample of 150 claims were zero);²³⁹ (4) the failure to consider methods for handling of the skewed data such as bootstrapping or use of a stratified sample;²⁴⁰ and (5) failing to appreciate that the extrapolation is heavily dependent on the data from one recipient (patient).²⁴¹

Based on these concerns, Dr. Wachs concluded that the results of the Health Integrity extrapolation are not statistically valid.²⁴²

²²⁸ *Id.* at 207.

²²⁹ *Id.* at 206-07.

²³⁰ *Id.* at 205, 209.

²³¹ *Id.* at 209.

²³² *Id.*

²³³ *Id.* at 208-09.

²³⁴ *Id.* at 209, 240-41, 265.

²³⁵ *Id.* at 205-09, 248-49.

²³⁶ *Id.* at 205, 248.

²³⁷ *Id.* at 201; Lazarus Br. at 9.

²³⁸ Tr. at 232-33, 235 (Dr. Wachs).

²³⁹ *Id.* at 211, 220 229; Ex. 2003; Lazarus Br. at 12-13.

²⁴⁰ Tr. at 231-232 (Dr. Wachs); Lazarus Br. at 11-12.

²⁴¹ Tr. at 229 (Dr. Wachs); Ex. 2003; Lazarus Br. at 12.

²⁴² Tr. at 200 (Dr. Wachs). The Department disagreed with each of these concerns as set forth in its brief. Department Br. at 5-17.

2. Subject Matter Jurisdiction Issue

In its written closing argument, Lazarus argued for the first time that the Department lacks subject matter jurisdiction to use extrapolation to determine the amount Lazarus has been overpaid by the Department for children's therapeutic services.²⁴³ Lazarus maintains that there is no statutory authority allowing the Department to use extrapolation to determine the amount of overpayments to recover from providers of children's therapeutic services like Lazarus.²⁴⁴ On that basis, Lazarus claims that Minn. R. 9505.2220 goes beyond the Department's enabling legislation, and is unlawful to the extent it is being applied to Lazarus to recover funds for children's therapeutic services.²⁴⁵

Lazarus acknowledged in its brief that the legality of Minn. R. 9505.2220 is beyond the scope of this proceeding.²⁴⁶ Lazarus raises this argument solely to preserve the issue for appeal if necessary.²⁴⁷

C. Legal Analysis

Having determined in the Order on Cross Motions for Partial Summary Disposition that the Department is entitled to recover \$6,620.85 for 31 improperly paid claims in the Base Claim, the issue that remains to be decided is whether the sampling and extrapolation methods used to calculate the total estimated overpayment of \$369,979 are consistent with Minn. R. 9505.2220 and are statistically valid.

Minn. R. 9505.2220 authorizes the Department to calculate the amount of "monetary recovery" from a MA vendor for fraud, theft, abuse, or error based upon extrapolation of a systematic random sample of claims submitted by the vendor and paid by the program in certain circumstances.²⁴⁸ If the requirements in the rule are met, the Department's random sample extrapolation constitutes a rebuttal presumption regarding the calculation of monetary recovery.²⁴⁹ If the presumption is not rebutted by the vendor in the appeal process, the Department may recover funds from the vendor based on the extrapolation.²⁵⁰

1. Compliance with Minn. R. 9505.2220, Subp. 2

The rule allows sampling and extrapolation to calculate a monetary recovery if there are more than 1,000 claims to be reviewed or the claims to be reviewed represent services to 50 or more recipients.²⁵¹ In this case, the Department was authorized to use

²⁴³ Lazarus Br. at 13-19.

²⁴⁴ *Id.* at 14.

²⁴⁵ *Id.* at 14-18.

²⁴⁶ *Id.* at 18-19.

²⁴⁷ *Id.*

²⁴⁸ Minn. R. 9505.2220.

²⁴⁹ *Id.*

²⁵⁰ *Id.*

²⁵¹ *Id.*, subd. 2.

sampling and extrapolation because there were 13,531 claims (15,009 claim lines) included in the audit of Lazarus for the applicable time period.²⁵²

2. Compliance with Minn. R. 9505.2220, Subp. 3

The rule also provides the Department must use the following sampling and extrapolation methods:

- Samples shall be selected in such a way as they are equally likely to be selected (simple random samples) unless the Department determines that another sampling method is more likely to lead to greater precision or a closer approximation to the population mean.²⁵³ The Department shall “tell the provider the sampling method the [D]epartment is using prior to drawing the sample.”²⁵⁴
- Samples shall only be selected from claims for health services provided within the interval of time that coincides with the interval during which money allegedly was overpaid and for which recovery will be made.²⁵⁵
- The sampling method, including drawing the sample, calculating values, and extrapolating from the results of the sample, shall be performed according to statistical procedures published in the Cochran Treatise.²⁵⁶ In addition, samples must contain at least 50 claims.²⁵⁷
- The Department shall seek to recover the estimated overpayment only if the null hypothesis that the mean overpayment is less than or equal to zero can be rejected with probability less than 0.05.²⁵⁸

The record shows the Department complied with some, but not all of the requirements of Minn. R. 9505.2220, subp. 3. Consistent with the rule, the Department used simple random samples, and the samples selected were from the time interval covered by the audit. The record also demonstrates that the results of the null hypothesis are less than 0.05.

The Department, however, did not “tell the provider the sampling method the [D]epartment [would be] using prior to drawing the sample” as required by the rule.²⁵⁹

²⁵² Ex. 29 at 10 (Final Audit Report of Lazarus Project); Ex. 1 (Sampling Design Summary).

²⁵³ Minn. R. 9505.2220, subp. 3A.

²⁵⁴ *Id.*

²⁵⁵ *Id.*, subp. 3B

²⁵⁶ *Id.*, subp. 3C.

²⁵⁷ *Id.*

²⁵⁸ *Id.*, subp. 3D.

²⁵⁹ *Id.*, subp. 3A. The Department argues that its failure to comply with this provision in the rule should not bar recovery of funds from Lazarus because there was no prejudice to Lazarus. Department Br. at 11-13.

More importantly, a preponderance of the evidence shows that the “sampling method” was not performed in accordance with the statistical procedures in the Cochran Treatise as required by Minn. R. 9505.2220, subp. 3C.

The Cochran Treatise notes that the “results of sample surveys are always subject to some uncertainty because only part of the population has been measured and because of error of measurement.”²⁶⁰ The Cochran Treatise specifies that the sample size needs to be large enough to approximate a normal distribution of means of random samples in order to extrapolate the sample mean to the universe, and determine the confidence intervals.²⁶¹

Cochran notes that it is not easy to determine how large the sample size must be to produce a normal distribution of means, but provides a “crude rule” for use where the underlying data consists of marked positive skewness.²⁶² The formula, found on page 42 of the Cochran Treatise, is as follows:

$$n > 25G_1^2$$

where G_1 is Fisher’s measure of skewness (Fisher, 1932).

$$G_1 = \frac{E(y_i - \bar{Y})^3}{\sigma^3} = \frac{1}{N\sigma^3} \sum_{i=1}^N (y_i - \bar{Y})^3$$

In this case, the underlying overpayment data from the sample of 150 claims shows marked positive skewness.²⁶³ Therefore, the Cochran Treatise instructs that this formula is applicable to this data set. Using the data from the Lazarus audit, the formula produces a result of $n>203$, where n is the sample size.²⁶⁴ In other words, the formula calculates that the sample size must exceed 203 claims to satisfy the Central Limit Theorem and approach a normal distribution of means.

In addition, the RAT-STATS software derived a sample size of 206 for the Lazarus audit based on the assumptions provided by Dr. Keller.²⁶⁵ According to Dr. Keller, RAT-STATS incorporates the relevant Cochran equations.²⁶⁶

It is unnecessary to address this argument because the sample size of 150 fails to comply with the procedures included in the Cochran Treatise for sample size, and the sample is too small to produce a statistically valid estimated overpayment amount.

²⁶⁰ Cochran Treatise at 5.

²⁶¹ See *id.* at 27, 39-40.

²⁶² *Id.* at 40.

²⁶³ Tr. at 211 (Dr. Wachs).

²⁶⁴ *Id.* at 209, 238-240; see also Tr. at 278 (Dr. Keller; agreeing that the formula produces a result of $n>203$).

²⁶⁵ Ex. 1 (Sample Design Summary).

²⁶⁶ Tr. at 36, 47-48, 62, 82, 301 (Dr. Keller).

Health Integrity, however, decided to sample only 150 claims.²⁶⁷ Because the sample used by Health Integrity did not exceed 203 claims as instructed by the formula, the Health Integrity audit was not performed according to the statistical procedures published in the Cochran Treatise. This conclusion is reinforced by the RAT-STATS recommended sample size of 206, which incorporates the relevant Cochran principles. The sampling and extrapolation, therefore, fail to meet the requirements of Minn. R. 9505.2220.

Moreover, the record shows that the sample size of 150 claims was too small to produce a statistically valid extrapolation because it was not big enough to satisfy the Central Limit Theorem. As both experts explained, the Central Limit Theorem is a statistical proposition to the effect that the larger the sample size, the more closely the sampling distribution of a mean will approach a bell-shaped curve or normal distribution.²⁶⁸ A normal distribution is necessary to be able to extrapolate from the sample mean to the universe.²⁶⁹ With a bell-shaped curve or normal distribution of results, the confidence levels can be determined as well as the amount of precision (or imprecision) at the various confidence levels.²⁷⁰ If the sample size is not large enough to approach a normal distribution, then the confidence limits cannot be reliably determined.²⁷¹ Nor is there any basis to use the point estimate as the total overpayment in universe because there is no evidence the sample of 150 claims is truly representative of the universe of claims.²⁷²

Here, the record shows that the sample of 150 claims is insufficient to ensure a normal distribution of sample means (a/k/a bell-shaped curve). The formula in Cochran instructs that a sample size exceeding 203 claims is necessary in order to approach a normal distribution upon which a statistically valid extrapolation can be derived.²⁷³ In addition, the bootstrapping conducted by Dr. Wachs showed that averages based on a sample size of 150 were not bell-shaped, but instead followed a highly skewed distribution.²⁷⁴ In other words, the results showed that the sample size of 150 was not large enough to satisfy the Central Limit Theorem.²⁷⁵ Because the sample size of 150 was not large enough to produce averages that form a normal distribution, the extrapolation from the sample of 150 claims to the universe of 13,531 claims is not statistically valid.²⁷⁶

The Department's arguments to the contrary with regard to the minimum sample size are not persuasive. The Department's own expert, Dr. Keller, agreed that the formula on page 42 of the Cochran Treatise calculates that the sample size must exceed 203.

²⁶⁷ *Id.* at 51-53 (Dr. Keller); Ex. 2 (Final Sample Design Summary).

²⁶⁸ Tr. at 76 (Dr. Keller); Tr. at 206-08 (Dr. Wachs).

²⁶⁹ Tr. at 213-14 (Dr. Wachs); see also Cochran Treatise at 40.

²⁷⁰ Cochran Treatise at 27, 43; Tr. at 202-05, 214-15 (Dr. Wachs).

²⁷¹ See Tr. at 205, 209, 223 (Dr. Wachs).

²⁷² See *id.* at 248-49 (Dr. Wachs).

²⁷³ *Id.* at 209, 240-41, 265 (Dr. Wachs).

²⁷⁴ *Id.* at 209 (Dr. Wachs).

²⁷⁵ *Id.*

²⁷⁶ See *id.* at 209, 223 (Dr. Wachs).

Dr. Keller argues, however, that it is not feasible to use the formula when selecting the sample size for this type of audit because the skewness measure that is used in the formula comes from the results of the audit.²⁷⁷ Therefore, Dr. Keller maintains the formula cannot be used when the sample size is initially selected.

While Dr. Keller is correct that the formula cannot be used at the planning stage for this type of audit, the formula can be used after the initial audit results are obtained to determine if the sample size is sufficiently large. If the formula shows that the sample size is too small, the auditor can draw additional samples before finalizing the audit. Health Integrity has provided no reason for not using the formula in this manner.

In fact, in its comments on the Draft Audit Report, the Department specifically requested that Health Integrity compare Health Integrity's sampling and extrapolation methodology to the requirements in Minn. R. 9505.2220.²⁷⁸ This rule specifically incorporates the Cochran Treatise by reference. If Health Integrity had used the formula on page 42 of the Cochran Treatise after reviewing the 150 claims, Health Integrity would have known that its sample size was too small.

In this case, it would have been easy for Health Integrity to increase its sample size to the size derived from the formula ($n>203$) because RAT-STATS recommended a sample size of 206 and Health Integrity had pulled 206 claims for review.²⁷⁹ Instead of sampling the full 206 claims as recommended by RAT-STATS, Health Integrity decided to stop at 150 claims.

Health Integrity has provided no statistically valid reason for not sampling all 206 claims as recommended by RAT-STATS, or for not using the formula on page 42 of the Cochran Treatise to determine if its sample size of 150 was sufficiently large.²⁸⁰ Instead, Health Integrity wanted to save time and expense, but in doing so failed to use a sampling methodology that is consistent with the sampling produces in the Cochran Treatise.

Likewise, Dr. Keller's claim the sample size of 150 should be deemed sufficient because CMS and OIG do not have a minimum sample size is not persuasive.²⁸¹ This argument ignores that the Department's audit must comply with the sampling procedures set forth in the Cochran Treatise.²⁸² As noted above, the sample size in this case must exceed 203 to comply with the statistical procedures set forth in the Cochran Treatise.

Similarly, Dr. Keller's reliance on the general statement in the *Dictionary of Statistics & Methodology* that a sample size of 30 or more will "usually" be sufficient is misplaced.²⁸³ This statement is general in nature. It also acknowledges that a sample size of 30 is not sufficient in all cases. This general assertion provides no evidence as to

²⁷⁷ Tr. *Id.* at 278-79 (Dr. Keller).

²⁷⁸ Ex. 27 (Letter from Department to Health Integrity dated March 25, 2014).

²⁷⁹ Ex. 2 at 2 (Sampling Plan Summary; noting that Health Integrity initially drew 206 random sample units).

²⁸⁰ See Tr. at 317-319 (Dr. Wachs).

²⁸¹ *Id.* at 280 (Dr. Keller).

²⁸² See Minn. R. 9505.2220, subp. 3C.

²⁸³ Tr. at 281 (emphasis added) (Dr. Keller).

whether the sample size in this case is sufficient to produce a statistically valid extrapolation.

Also, Dr. Keller's focus on the slipknot clause included in RAT-STATS and the null hypothesis results also lack persuasive value.²⁸⁴ Dr. Keller fails to explain how either the inclusion of the slip-knot clause or the null hypothesis results are consistent with the sampling procedures in the Cochran Treatise. As such, neither the existence of the slip-knot clause in RAT-STATS nor the null hypothesis results demonstrate that the sampling method used by Health Integrity was performed according to the statistical procedures included in the Cochran Treatise as required by Minn. R. 9505.2220.

Finally, the Department erroneously maintains that even if the sample size was not sufficient to satisfy the Central Limit Theorem and produce a normal distribution of means, its extrapolation still complies with Minn. R. 9505.2220.²⁸⁵ This argument fails to recognize that by incorporating the Cochran Treatise, Minn. R. 9505.2220 requires a sample size that satisfies the Central Limit Theorem. Having a normal distribution of sample means is necessary not only to calculate the confidence intervals but also to have a valid point estimate. Simply put, because the sample size is not large enough to satisfy the Central Limit Theorem, there is no basis on which to determine whether the average overpayment of \$44.14 for the sample is in anyway representative of the average overpayment in the universe of 13,531 claims. Therefore, even if the confidence intervals are not used to determine the estimated overpayment amount, any extrapolation based on the sample mean of \$44.14 to the universe of 13,531 claims is not statistically valid.²⁸⁶

For the reasons set forth above and those in the Order on Cross Motions for Partial Summary Disposition, the Administrative Law Judge respectfully recommends that the Commissioner limit the recovery from Lazarus to \$6,620.85 rather than the \$369,979 set forth in the Notice of Agency Action.

J. M. C.

²⁸⁴ *Id.* at 81, 72-74, 291.

²⁸⁵ Department Br. at 18.

²⁸⁶ Because the record shows that the sample size is not sufficient to satisfy the Central Limit Theorem and is not consistent with formula on page 42 of the Cochran Treatise, it is not necessary to address the other sampling and extrapolation concerns raised by Dr. Wachs and Lazarus.