OAH 71-9029-35836
Revisor R-4567

STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS

In the Matter of the Proposed Amendments to Rules Governing Use of Random Sample Extrapolation in Monetary Recovery;
Minnesota Rules 9505.2220

REPORT OF THE CHIEF ADMINISTRATIVE LAW JUDGE

This matter came before the Chief Administrative Law Judge pursuant to the provisions of Minn. Stat. § 14.15, subds. 3, 4 (2020) and Minn. R. 1400.2240, subp. 4 (2019). These authorities require that the Chief Administrative Law Judge review an Administrative Law Judge's findings that a proposed agency rule is defective and should not be approved.

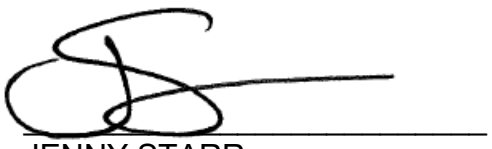
This rulemaking concerns the proposed rules of the Minnesota Department of Human Services (Department) governing the use of random sample extrapolation to identify and recover overpayments of Minnesota Health Care Program funds.

Based upon a review of the record in this proceeding, the Chief Administrative Law Judge **CONCURS** with the disapproval of the proposed rule amendments identified in the Administrative Law Judge's Report dated March 26, 2021. The Chief Judge concurs with the Administrative Law Judge's determination that the Department has not established that the proposed rules are needed and reasonable.

The changes or actions necessary for approval of the disapproved rules are identified in the Administrative Law Judge's Report.

If the Department elects not to correct the defects associated with the proposed rules, the Department must submit the rule to the Legislative Coordinating Commission and the House of Representatives and Senate policy committees with primary jurisdiction over state governmental operations for review under Minn. Stat. § 14.15, subd. 4.

Dated: April 1, 2021



JENNY STARR
Chief Administrative Law Judge

OAH 71-9029-35836
Revisor ID No. R-4567

STATE OF MINNESOTA
OFFICE OF ADMINISTRATIVE HEARINGS

In the Matter of the Proposed Amendments to Rules Governing Use of Random Sample Extrapolation In Monetary Recovery;
Minnesota Rules part 9505.2220

REPORT OF THE ADMINISTRATIVE LAW JUDGE

This matter came before Administrative Law Judge Jessica A. Palmer-Denig for a rulemaking hearing on January 28, 2021. To safeguard public health due to the ongoing COVID-19 pandemic, the public hearing was held remotely through an interactive video conference on the WebEx platform.

As explained below, the Department of Human Services (Department) proposes to amend its administrative rules governing the Department's use of random sample extrapolation to identify and recover overpayments of Minnesota Health Care Program (MHCP) funds.

The public hearing and this Report are part of a larger rulemaking process under the Minnesota Administrative Procedure Act.[1] The Minnesota Legislature designed this process to ensure that state agencies meet all of the requirements of law and rule in adopting and amending rules.

The public hearing was conducted to permit agency representatives and the Administrative Law Judge to hear public comments regarding the impact of the proposed rules, and any changes that might be appropriate. Further, the hearing process provides the public an opportunity to review, discuss, and critique the proposed rules, and to ensure a fully developed record.

As described more extensively below, the agency must establish that the proposed rules are necessary and reasonable; that the rules are within the agency's statutory authority; and that any modifications that the agency may have made after the proposed rules were initially published in the *State Register* are within the scope of the matter that was originally announced.

SUMMARY OF CONCLUSIONS

The Department has complied with all procedural requirements of rule and law. The Department also has the legal authority to adopt the proposed rules. The Department has not established that the proposed rules are needed and reasonable due to material defects in operative portions of the proposed amendments. Other portions of the proposed rules are not defective on their face, but do not stand alone and are not needed

[1] *See* Minn. Stat. §§ 14.05-.20 (2020).

and reasonable amendments of the current rule in isolation from the defective provisions. Accordingly, the Administrative Law Judge **DISAPPROVES** the Department's proposed rules amending Minn. R. 9505.2220.

Based upon all the record, including the Department's exhibits, and the oral and written comments received, the Administrative Law Judge makes the following:

FINDINGS OF FACT

I. Regulatory Background to the Proposed Rules

1. The Department proposes to amend Minnesota Rules, part 9505.2220 (2019), governing the Department's use of random sample extrapolation to identify and recover overpaid MHCP funds.

2. The Department is the state agency charged with administering the MHCP, which includes Minnesota's medical assistance program.[2] Vendors of medical and other health care services may enroll with the Department as MHCP providers to be eligible for payment for services provided to people who have health care coverage through the MHCP.[3]

3. Minn. Stat. § 256B.04, subd. 10 (2020) directs the Department to promulgate rules establishing criteria and procedures for the identification and prompt investigation of suspected fraud, theft, abuse, or false claims for MHCP funds by vendors of medical care, and for the imposition of sanctions against the vendors.

4. Minn. Stat. § 256B.04, subd. 15 (2020) requires the Department to establish a utilization review program to guard against the unnecessary and inappropriate use of medical assistance services and excess payments for services.

5. In 1981, the Department adopted Minn. R. 9505.2160 -.2245 to govern the administration of the Surveillance and Integrity Review Section (SIRS), which is tasked with monitoring MHCP providers' compliance with health services program requirements, as well as identifying and addressing fraud and abuse by providers and recipients participating in the MHCP.[4]

6. As currently written, Minn. R. 9505.2220, contains three subparts. Subpart 1, authorizes the Department to identify overpaid MHCP funds for recovery using random sample extrapolation methods.[5] This subpart also provides that the Department's random sample extrapolation constitutes a rebuttable presumption regarding the amount

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[2] *See* Minn. Stat. § 256B.04 (2020); Minn. R. 9505.2165, subp. 8 (2019). The medical assistance program in Minnesota is the joint federal-state program that implements the provisions of Title XIX of the Social Security Act by providing for the medical needs of persons with low income or with a disability and families of dependent children. 42 U.S.C. § 1396a (2020).

[3] *See* Minn. Stat. § 256B.04, subd. 21; Minn. R. 9505.0175, subp. 38 (2019) (definition of "provider"); Minn. Stat. § 256B.02, subd. 7 (2020) (definition of "vendor").

[4] Exhibit (Ex.) D at 2.

[5] S*ee also* Minn. R. 9505.2215 (2019) (providing for recovery of overpayments).

of the overpayment that may be recovered.[6] Subpart 2 establishes the circumstances under which the Department may use random sample extrapolation, limiting the use of statistical sampling to cases in which there are more than 1,000 claims to be reviewed, or when the claims reviewed represent services to 50 or more recipients.[7] The Department does not propose any changes to these subparts.

7. The Department proposes to add a new subpart 1a defining terms to be used in the revised rule.[8]

8. The Department also proposes to amend the existing text of subpart 3, which contains the methods the Department must use to conduct random sample extrapolations. As currently written, subpart 3(A) governs the sampling method selected and requires notice to a provider of the sampling method before the sample is drawn. Subpart 3(B) requires that samples of claims be drawn from the same period during which money was allegedly overpaid and for which the Department will seek recovery. Subpart 3(C) provides that the sampling method used for extrapolation must be performed according to statistical procedures explained in a textbook: W. Cochran, *Sampling Techniques*, John Wiley and Sons, New York 3rd Ed. (1977) (Cochran Textbook).[9] The rule incorporates the Cochran Textbook by reference.[10] Subpart 3(C) also establishes the minimum sample size to be used for simple and stratified sampling. Subpart 3(D) contains the method by which the Department must calculate the overpayment to be recovered from a vendor by multiplying the mean overpayment by the number of claims in the population. This subpart also provides the method for calculating the mean overpayment based upon the sampling method used.[11]

9. The Department contends that its proposed amendment is necessary to clarify its sampling procedures and eliminate reliance on the 1977 textbook. The Department maintains that the textbook's broad overview of statistical sampling theory does not provide meaningful guidance for sampling MHCP claims and recovering overpaid public funds.[12]

10. The Department states that its proposed modifications to the rule will allow SIRS to more efficiently recover MHCP funds paid as a result of fraud, abuse, or error. In addition, the Department maintains the proposed rule amendment will allow it to provide more detailed guidance to state and federal contractors who regularly use statistical sampling in their investigations to identify overpaid MHCP funds, and to better inform providers of what to expect when their audits include a statistical sample.[13]

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[6] Minn. R. 9505.2220, subp. 1.
[7] *See id.*, subp. 2.
[8] *See* Ex. C. Note that the SONAR uses different numbering in explaining the subparts, but this report uses the numbering scheme used in the draft of the proposed rules approved by the Revisor of Statutes.
[9] Minn. R. 9505.2220, subp. 3(C).
[10] *Id.*
[11] *Id.*, subp. 4(D).
[12] Ex. D at 5.
[13] *Id.* at 5, 8.

II. Rulemaking Authority

11. Minnesota participates in the Medicaid program,[14] which funds medical assistance[15] for eligible individuals who are unable to pay for their medical care.[16]

12. The Department is the state agency designated to supervise the administration of the state's medical assistance program.[17] Both state and federal law require the Commissioner to establish rules and regulations to ensure that the medical assistance program is carried out in an efficient, economic, and impartial manner.[18]

13. Federal and state regulations also require the Department to have a statewide surveillance and utilization review program.[19] In Minnesota, this function is performed by SIRS.[20]

14. Some commenters challenged the Department's legal authority to adopt the proposed rules.[21] ARRM is a non-profit association with over 200 members that provide home and community-based service programs supporting individuals with intellectual and developmental disabilities; many of ARRM's members are "vendors of medical care" under Minn. Stat. § 256B.02, subd. 7 (2020), and they provide services that are subject to post-payment reviews by SIRS.[22] ARRM contends that the Department lacks statutory authority to use random sample extrapolation methods to calculate monetary recoveries under Minn. Stat. § 256B.064, because the Department's enabling legislation does not specifically address authority for the use of these methods.[23] ARRM contends that the rule's long existence, since 1981, does not mean that it is a lawful exercise of authority today, and that the rule is still an operative provision only because an appeal challenging the Department's authority has not yet progressed to judicial review.[24]

15. The Department responds that rules governing the use of random sample extrapolation were first promulgated in 1981, and subsequently amended in 1991, 1995, and 2008, and that each legality review confirmed the Department's legal authority to adopt or amend Minn. R. 9505.2220.[25] The Department also noted the requirements of federal law it must meet as the state's designated agency for the supervision of the medical assistance program; and cited the specific authority afforded to it under Minn.

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[14] *See generally* 42 U.S.C. § 1396-1396v (2018); Minn. Stat. §§ 256B.01-.85 (2020).
[15] *See* Minn. Stat. § 256B.02, subd. 8.
[16] *See* 42 U.S.C. § 1396-1; 42 C.F.R. § 430.0 (2020).
[17] 42 C.F.R. § 431.10 (2020); Minn. Stat. § 256B.04, subd. 1.
[18] 42 C.F.R. § 431.10; Minn. Stat. § 256B.04, subd. 2.
[19] 42 U.S.C. § 1396a(a)(30) (2018); 42 C.F.R. §§ 455.12-455.23, 456.3 (2020).
[20] *See* Minn. R. 9505.2160 -.2245 (2019).
[21] This Report does not identify every commenter who took a particular position regarding the proposed rule. Instead, this Report references comments that are representative of others or that provided comprehensive analysis on a disputed portion of the proposed rule.
[22] ARRM's Rebuttal to DHS Statement of January 6, 2021 and Memorandum in Opposition to Proposed Amendments (ARRM Comments) at 2 (Jan. 28, 2021).
[23] *Id.* at 11-12.
[24] *Id.* at 13-14.
[25] Department's Comments at 1 (Feb. 17, 2021).

Stat. § 256B.04, subds. 2, 10, 15, to establish administrative procedures to investigate and recover overpayments of MHCP funds.[26]

16. The Department does not propose to amend Minn. R. 9505.2220, subp. 1, which provides the Department with authority to use random sample extrapolation to calculate an amount for monetary recovery from a vendor. Therefore, the authorizing language of this subpart is not subject to review in this matter.[27] Further, a reassessment of the 1981 rulemaking matter in which this rule was initially adopted, or subsequent rulemakings considering the Department's statutory authority to amend the rule, are outside the scope of this proceeding. The question presented here is whether the Department has the legal authority to adopt the proposed rule amendments as they are written.

17. The Administrative Law Judge concludes that the Department has the statutory authority to adopt the proposed rules under 42 C.F.R. § 431.10 and Minn. Stat. § 256B.04, subds. 2, 10, 15.

III. Procedural Requirements of Minn. Stat. Ch. 14 and Minn. R. Ch. 1400

A. Request for Comments

18. Minn. Stat. § 14.101 requires that an agency, at least 60 days prior to the publication of a notice of intent to adopt rules or a notice of hearing, solicit comments from the public on the subject matter of a proposed rulemaking. Such notice must be published in the *State Register*.[28]

19. On December 26, 2018, the Department requested approval of its additional notice plan prior to publishing its Request for Comments.[29]

20. By Order dated January 2, 2019, Administrative Law Judge LauraSue Schlatter approved the Department's Additional Notice Plan for its Request for Comments contingent upon implementation of certain modifications to the plan.[30]

21. On April 29, 2019, the Department requested approval of its amended additional notice plan.[31] The amended notice plan incorporated the changes required by Judge Schlatter.[32]

22. By Order dated May 6, 2019, Administrative Law Judge Schlatter approved the Department's Amended Additional Notice Plan.[33]

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[26] *Id.* at 1-2.
[27] *See* Minn. R. 1400.2070 ("If an agency is amending existing rules, the agency need not demonstrate the need for and reasonableness of the existing rules not affected by the proposed amendments.").
[28] Minn. Stat. § 14.101.
[29] *See* Minn. R. 1400.2060, subp. 1.
[30] Order on Review of Additional Notice Plan (Jan. 2, 2019).
[31] Request to Review Amended Additional Notice Plan (Apr. 26, 2019).
[32] *Id.*
[33] Ex. K-1 (Order on Review of Amended Additional Notice Plan (May 6, 2019)).

23. On September 9, 2019, the Department published in the *State Register* its Request for Comments seeking comments on possible amendments to Minn. R. 9505.2250 governing random sample extrapolation in monetary recovery.[34] The Department explained that the proposed amendments were intended to eliminate the reference to the Cochran Textbook, clarify the sampling and extrapolation methodologies that are acceptable for it to use, and remove the requirement that the provider be notified of the sampling method before a sample is drawn.[35]

24. The Request for Comments was published at least 60 days prior to the publication of the Notice of Intent to Adopt Rules, as discussed below.

25. The Administrative Law Judge finds that the Department complied with the requirements established in Minn. Stat. § 14.101.

B. Publication of Notice of Intent to Adopt Rules

26. Minn. Stat. §§ 14.14, subd. 1a(a), 14.22 and Minn. R. 1400.2080, subp. 6 (2019), require that an agency publish in the *State Register* a notice of intent to adopt rules at least 30 days prior to the date of hearing and at least 30 days prior to the end of the comment period.

27. An agency may request approval of its notice of intent to adopt rules by an administrative law judge prior to service.[36]

28. The Department requested approval of its Notice of Intent to Adopt Rules Without a Public Hearing Unless 25 or More Persons Request a Hearing (Dual Notice) on November 4, 2020.

29. On November 12, 2020, Administrative Law Judge Jessica A. Palmer-Denig approved the Department's Dual Notice in form and substance.[37]

30. The Department published the Dual Notice in the *State Register* issued on November 23, 2020.[38] The Dual Notice set December 31, 2020, as the deadline for submitting comments and requesting a hearing.[39]

31. The Dual Notice stated that if more than 25 persons requested a hearing on the proposed rule amendments, the hearing would be held via interactive video conference on January 28, 2021. The Dual Notice provided information on how persons could connect to and join the hearing via the internet and telephone.[40]

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[34] Ex. A (Request for Comments).
[35] *Id*. The Department has withdrawn its proposal to eliminate the provider notice requirement, as discussed further below.
[36] Minn. R. 1400.2080; Minn. Stat. § 14.22.
[37] Order on Request for Review and Approval of Dual Notice (Nov. 12, 2020). By letter dated March 6, 2020, the Chief Administrative Law Judge reassigned this matter to Judge Palmer-Denig.
[38] Ex. F-2 (Dual Notice).
[39] Exs. F-1, F-2.
[40] Exs. F-1, F-2.

32. The Dual Notice contained all information required in Minn. R. 1400.2080.

C. Notice Requirements

1. Notice to Official Rulemaking List

33. Minn. Stat. § 14.14, subd. 1a, requires that each agency maintain a list of all persons who have registered with the agency for the purpose of receiving notice of rule proceedings.

34. On November 20, 2020, the Department mailed or emailed a copy of the Dual Notice to all persons and entities on its official rulemaking list.[41] The official rulemaking list was comprised of all persons and entities who requested to be placed on the Department's GovDelivery system for the purpose of receiving such notice, and all those who indicated a preference to receive notice by U.S. Mail.[42]

35. The Dual Notice advised that the comment period expired at 4:30 p.m. on December 31, 2020.[43] There are 40 days between November 20, 2020, and December 31, 2020.

36. Minn. Stat. § 14.14, subd. 1a, requires that agencies give notice of intent to adopt rules by U.S. mail or electronic mail to all persons on its official rulemaking list at least 30 days before the date of hearing.

37. Minn. R. 1400.2080, subp. 6 provides that a notice of hearing or notice of intent to adopt rules must be mailed at least 33 days before the end of the comment period or the state of the hearing.

38. The Administrative Law Judge concludes that the Department fulfilled the notice requirements set forth in Minn. Stat. § 14.14 and Minn. R. 1400.2080, subp. 6.

2. Additional Notice

39. Minn. Stat. § 14.14, subd. 1a(a) requires that an agency make reasonable efforts to notify persons or classes of persons who may be significantly affected by the rule being proposed by giving notice of its intent to adopt rules. Such notice may be made in newsletters, newspapers, or other publications, or through other means of communication.[44] This notice is referred to as "additional notice" and is detailed by an agency in its additional notice plan.

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[41] Ex. G-1 (Certificate of Delivery of Dual Notice).
[42] *Id.*
[43] Exs. F-1, F-2.
[44] Minn. Stat. § 14.14, subd. 1a(a).

40. Minn. Stat. §§ 14.131, .23 require that an agency include in its SONAR a description of its efforts to provide additional notice. Alternatively, the agency must detail why additional notification efforts were not made.[45]

41. An agency may request approval of its additional notice plan by an administrative law judge prior to service.[46]

42. The Department requested and was granted approval of its Amended Additional Notice Plan on May 6, 2019.[47]

43. On November 19 and 20, 2020, the Department provided notice according to its approved Amended Additional Notice Plan, as follows:[48]

(a) Sending notice to persons registered with the Department to receive notices of rulemakings;

(b) Notifying MHCP providers who have a signed provider agreement with the Department by sending notice of the proposed rule amendment and Request for Comments directly to their MN-ITS mailboxes;[49]

(c) Notifying MHCP providers by posting to the Provider news and updates webpage and providing a link to the posting through the providers' MN-ITS mailboxes;

(d) Sending notice to providers through the Department's email distribution lists to which providers may choose to subscribe to receive information related to specific topics; and

(e) Sending notice to the Department's list of provider associations.[50]

44. The Administrative Law Judge finds that the Department complied with its Amended Additional Notice Plan and fulfilled the additional notice requirements provided in Minn. Stat. §§ 14.14, subd. 1a(a), .131, .23.

3. Notice to Legislators

45. Minn. Stat. § 14.116 (2020) requires the agency to send a copy of the Notice of Intent to Adopt and the SONAR to certain legislators at the time it mails its Notice of Intent to Adopt to persons on its rulemaking list and pursuant to its additional notice plan.

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[45] Minn. Stat. §§ 14.131, .23.
[46] Minn. R. 1400.2060, subp. 3 (2019).
[47] Ex. K-1.
[48] Exs. G-1, H, K-5.
[49] MN-ITS is the free, web-based, HIPAA compliant system for providers to submit electronic claims.
[50] Ex. D a 10-13; Ex. H.

46. On November 20, 2020, the Department mailed or emailed a copy of the Dual Notice, SONAR, and proposed rules the chairs and ranking minority party members of the legislative policy and budget committees with jurisdiction over the proposed rules, and to the Legislative Coordinating Commission.[51]

47. The Administrative Law Judge concludes that the Department fulfilled its notification responsibilities under Minn. Stat. § 14.116.

4. Notice to the Legislative Reference Library

48. Minn. Stat. §§ 14.23, .131 and Minn. R. 1400.2070, subp. 3, require the agency to send a copy of the SONAR to the Legislative Reference Library when the Notice of Intent to Adopt is mailed.

49. On November 20, 2020, the Department mailed a copy of the SONAR to the Legislative Reference Library.[52]

50. The Administrative Law Judge concludes that the Department fulfilled its responsibilities under Minn. Stat. §§ 14.23, .131.

5. Notice to Commissioner of Agriculture

51. Minn. Stat. § 14.111 imposes additional notice requirements when the proposed rules affect farming operations. The statute requires that an agency provide a copy of any such changes to the Commissioner of Agriculture at least 30 days prior to publishing the proposed rules in the *State Register*.[53]

52. The Department's proposed rules do not impose restrictions or have an impact on farming operations. As a result, the Department was not required to notify the Commissioner of Agriculture.

6. Notice of Hearing to Those Who Requested a Hearing

53. In response to the Dual Notice, more than 25 persons requested a hearing in this matter.[54]

54. On November 20, 2020, the Department emailed a Confirmation of Hearing to all those who requested a hearing in compliance with Minn. Stat. § 14.25, subd. 1.[55]

[51] Ex. K-7 (Certificate of Sending Notice and SONAR to Legislators and Legislative Coordinating Commission).
[52] Ex. E.
[53] Minn. Stat. § 14.111.
[54] Ex. I-2, I-3 (Hearing Requests).
[55] Ex. K-8 (Certificate of Sending Confirmation of Hearing to those who Requested a Hearing).

D. Rule Hearing

55. The Administrative Law Judge conducted a public hearing on January 28, 2021. The Department's panel at the hearing, included: Vanessa Vogl, the Department's Rulemaking Attorney; and Elizabeth Oji, the Department's Federal Audit Supervisor.[56]

56. In support of its request for approval to adopt the proposed rules, the Department offered the following documents into the record as exhibits, as required by Minn. R. 1400.2220:

> Ex. A: Department's Request for Comments as published in the *State Register* on September 9, 2019;
>
> Ex. C: proposed rules dated November 4, 2020, including the Revisor's approval;
>
> Ex. D: Department's SONAR, dated September 10, 2020;
>
> Ex. E: Certificate of Mailing the SONAR to the Legislative Reference Library on November 20, 2020;
>
> Ex. F-1: Dual Notice as mailed and posted on the Department's website;
>
> Ex. F-2: Dual Notice as published in the *State Register* on November 23, 2020;
>
> Ex. G-1: Certificate of Mailing the Dual Notice to the rulemaking mailing list on November 20, 2020;
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> Ex. G-2: Certificate of Accuracy of the Mailing List;
>
> Ex. H: Certificate of Giving Additional Notice Pursuant to the Additional Notice Plan on November 19, 2020;
>
> Ex. I: written comments on the proposed rules that the Department received during the comment period that followed the Dual Notice, as well as the requests for hearing;
>
> Ex. K-1: Order of Administrative Law Judge LauraSue Schlatter approving the Department's Amended Additional Notice Plan dated May 6, 2019, with the Department's submission requesting approval;
>
> Ex. K-2: Request for Comments as mailed on September 9, 2019;

[56] Rulemaking Hearing Digital Recording (Jan. 28, 2021) (on file with the Minn. Office of Admin. Hearings).

Ex. K-3: Certificate of Accuracy of the Department's rulemaking lists dated September 1, 2019;

Ex. K-4: Certificate of Delivery of Department's Request for Comments to the Department's rulemaking lists on September 9, 2019;

Ex. K-5: Certificates of Delivery of Department's Request for Comments according to Amended Additional Notice Plan on September 27, and October 1, 2019;

Ex. K-6: Certificate of Delivery of Request for Comments to Certain State Legislators and the Legislative Coordinating Commission on September 9, 2019;

Ex. K-7: Certificate of Sending the Dual Notice and SONAR to Legislators and Legislative Coordinating Commission on November 20, 2020;

Ex. K-8: Certificate of Sending Confirmation of Hearing to those who requested a hearing on November 20, 2020;

Ex. K-9: Certificate of Consulting with the Commissioner of Management and Budget on September 15, 2020, and Memorandum from Minnesota Management and Budget dated October 14, 2020; and

Ex. L: written rulemaking hearing remarks of Vanessa Vogl, the Department's Rulemaking Attorney.

57. Ms. Vogl offered the Department's exhibits and addressed the procedural requirements for rulemaking.[57] Ms. Oji presented the Department's positions as to the need for and reasonableness of the rule.[58]

58. Approximately 70 people attended the hearing. The hearing continued until all interested persons, groups, or associations had an opportunity to be heard concerning the proposed rules. Six members of the public made statements during the hearing. Approximately 143 written comments were also received prior to the hearing.[59]

59. After the hearing, the Administrative Law Judge extended the time period for submission of public comments for another 20 calendar days – until February 17, 2021 – to permit interested persons and the Department to submit written comments.[60]

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[57] *Id.*
[58] *Id*.
[59] *See* Ex. I. Some of these comments contained identical language or were copies of a form letter that that the commenters adopted as their submission on the rule.
[60] *See* Minn. Stat. § 14.15, subd. 1.

During this period, four written comments were submitted by members of the public and the Department also submitted a post-hearing comment.

60. Following the initial comment period, the hearing record remained open an additional five business days to permit interested persons and the Department to reply to the earlier-submitted comments. One member of the public filed a rebuttal comment and the Department also submitted a comment in rebuttal. The rebuttal comment period closed on February 24, 2021, and the hearing record closed on that date.

IV. Statutory Requirements to be Addressed

A. Regulatory Factors

61. The Administrative Procedure Act requires an agency adopting rules to address eight factors in its Statement of Need and Reasonableness (SONAR).[61] Those factors are:

> (1) a description of the classes of persons who probably will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule;
>
> (2) the probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues;
>
> (3) a determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule;
>
> (4) a description of any alternative methods for achieving the purpose of the proposed rule that were seriously considered by the agency and the reasons why they were rejected in favor of the proposed rule;
>
> (5) the probable costs of complying with the proposed rule, including the portion of the total costs that will be borne by identifiable categories of affected parties, such as separate classes of governmental units, businesses, or individuals;
>
> (6) the probable costs or consequences of not adopting the proposed rule, including those costs or consequences borne by identifiable categories of affected parties, such as separate classes of government units, businesses, or individuals;

[61] Minn. Stat. § 14.131.

(7) an assessment of any differences between the proposed rule and existing federal regulations and a specific analysis of the need for and reasonableness of each difference; and

(8) an assessment of the cumulative effect of the rule with other federal and state regulations related to the specific purpose of the rule and reasonableness of each difference.[62]

1. Classes of Persons Affected, Benefitted, or Bearing Costs of the Proposed Rule

62. The Department states that the proposed rule amendments may affect any MHCP provider who submits claims to the Department for payment of MHCP funds. The Department contends, however, that because the proposed rule only clarifies existing requirements and does not independently create new substantial costs, the Department expects the proposed rule amendment will not increase costs of compliance for providers.[63]

2. Probable Costs to the Agency and Other Agencies for Implementation and Enforcement and Effect on State Revenues

63. The Department asserts that the proposed rule amendments clarify the method used by the Department to recover overpayments, but do not change the source or scope of recoverable payments. Consequently, the Department does not anticipate it will incur substantial additional costs in implementing or enforcing the rule. It also does not expect the amendment will generate new revenue for the state. Finally, the Department maintains that implementation and enforcement of the rule will not affect any other state agency.[64]

3. Less Costly or Less Intrusive Methods for Achieving the Purpose of the Proposed Rule

64. The Department maintains that the purpose of proposed rule amendments is to continue the Department's efforts to address fraud and abuse in the MHCP as required by federal regulations. According to the Department, the proposed rule amendments will clarify the current rule and eliminate unnecessary components.[65]

65. The Department expects that the changes to the sampling methods in the rule amendment will be cost neutral to the Department and to MHCP providers. Additionally, the Department maintains that, like the current rule, the proposed rule amendment is minimally intrusive and creates no impositions on providers.[66]

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[62] *Id.*
[63] Ex. D at 6.
[64] *Id.*
[65] *Id.* at 7.
[66] *Id.*

4. Description of Alternative Methods for Achieving the Purpose of the Proposed Rule Considered by the Agency and Why Alternatives Were Rejected

66. The Department sought guidance from a statistician from the University of Minnesota, Dr. Gary W. Oehlert, Ph.D., in preparing the proposed rule amendment. According to the Department, it sent Dr. Oehlert its initial draft of the proposed rule language and asked him to provide an opinion on the "coherence and mathematical integrity" of the proposed rule.[67] The Department asserts that Dr. Oehlert suggested several modifications to improve the rule.[68] For example, he provided advice on the correct use of terminology and clarified the wording of several definitions. In most instances, the Department modified the proposed rule language.[69]

67. The Department notes that Dr. Oehlert also advised it to place the following parameters around the sample size determination:

> The sampling plan and extrapolation method shall be chosen so that the anticipated margin of error for the population overpayment based on the full sample is no more that the larger of $ZZ or XX% of the total claims paid. The Department may, at its discretion, limit the full sample size to at most YYYY claims.[70]

68. Dr. Oehlert recommended that the Department choose set values for the figures represented by $ZZ, XX% and YYYY, and include those values in the proposed rule language. He explained that both $ZZ and XX% required set values because choosing just one value for $ZZ, or one value for XX%, could result in a margin of error that would either be too small for a large provider, or too large for a small provider. Choosing a value for both $ZZ and XX% would allow the Department to adjust its sample size according to the size of the provider under review, such that a small provider could be subject to a sample size with a margin of error of $ZZ, and a larger provider could be subject to a sample size with the margin of error determined by XX%. According to Dr. Oehlert, this language would balance the need for accuracy against the time and cost of sampling.[71]

69. The Department states it seriously considered Dr. Oehlert's recommendation, but it determined it could not designate static margins of error that would address the nuances of all possible audits with an adequate level of certainty. The Department asserts that given the ever-changing and increasing nature of health care costs, it is extremely hesitant to designate a dollar amount that could quickly become outdated. The Department was also concerned that employing a margin of error

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[67] *Id.*
[68] The opinions Dr. Oehlert provided to the Department are found in Appendix (App.) 1 to the SONAR.
[69] Ex. D at 7.
[70] *Id.*
[71] *Id.*

controlled only by the percentage of claims in the universe would potentially have a prejudicial effect on smaller providers.[72]

70. Ultimately, the Department rejected Dr. Oehlert's recommendation, deciding that a determination of the margin of error is best made on a case by case basis.[73]

71. Finally, the Department declined to incorporate the language allowing the Department to, "limit the full sample size to at most YYYY claims."[74] The Department asserts that it prefers to use sample sizes produced by RAT-STATS12[75] or similar tools. The Department has not found sample sizes calculated in this manner to be unduly burdensome.

72. The Department notes that providers who wish to challenge the Department's designation of the margin of error or the sample size may do so as part of the appeal process.[76]

5. Probable Costs of Complying with Proposed Rules, Including the Portion of the Total Costs Borne by Identifiable Categories of Affected Parties

73. The Department states that there are no probable costs of complying with the proposed rule for MHCP providers. The Department maintains that the overall substance and effect of the rule will remain unchanged, and that the proposed rule amendment only clarifies existing language and simplifies procedures.[77]

74. Several commenters contend that the proposed amendments do not provide clear standards because they use undefined terms, set standards based on methods that are "generally accepted," without setting parameters for what that means, and fail to adopt a margin of error, as the Department's own expert recommended, that would help to ensure the statistical validity of the Department's extrapolations.[78] These commenters assert that the Department's proposed rules will result in a greater number of contested case appeals and higher litigation costs because each case will become a "battle of the experts," related to the Department's statistical analysis.[79] The Department

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[72] *Id*. at 8.
[73] *Id.*
[74] *Id*.
[75] RAT-STATS is a software system maintained by the Office of the Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS) and Centers for Medicare and Medicaid Services (CMS) that can be used to determine sample size, generate random numbers, and calculate statistical estimates. *Id.* at 8-9; Comments of the Lovaas Institute for Early Intervention-Midwest, Inc. (Lovaas Institute) (Feb. 17, 2021) at Ex. A at 2. The acronym, RAT-STATS, stands for the Regional Advanced Technique Staff Statistics Program. Department's Comments at 5, n.13.
[76] Ex. D at 8.
[77] *Id*.
[78] *See, generally,* AARM Comments.
[79] *Id.* at 2.

has not addressed whether increased litigation costs for parties are likely as a result of the proposed rules or whether the Department's own costs could increase.

6. Probable Costs or Consequences of not Adopting the Proposed Rules, Including Costs Borne by Individual Categories of Affected Parties

75. The Department contends that not adopting the proposed rule amendments will have detrimental consequences for the Department and for providers. The Department asserts that if the new methodology language is not adopted, providers will continue to have very little knowledge of what to expect when their audits include a statistical sample.[80] Additionally, the Department states that failure to adopt the amendments will leave the Department with an inefficient and confusing standard that it must use to attempt to recover MHCP funds paid as a result of fraud, abuse, or error.[81]

76. The Department maintains that the proposed language will also allow it to provide more detailed guidance to the state and federal contractors who regularly use statistical sampling to determine overpaid funds in their investigations. The Department contends its ability to provide this guidance will be limited without clearer language.[82]

7. Assessment of Differences Between Proposed Rules and Existing Federal Regulations

77. The Department states that the proposed rule amendment does not contain any differences from existing federal regulations. In fact, the Department asserts that the rule incorporates the software and methodology used by the federal government in its statistical sampling of potentially overpaid Medicare claims.[83] Moreover, the Department maintains that the proposed rule aligns well with the HHS-OIG's approval of statistical sampling in program integrity operations.[84]

8. Cumulative Effect of the Rule with Other Federal and State Regulations

78. While noting the various state and federal regulations governing monitoring and detecting fraud and recovering overpayments in Medicare and Medicaid programs, the Department contends the cumulative effect of the proposed rule amendment will be positive and manageable. The Department maintains the proposed amendment will ensure it is able to carry out its program integrity responsibilities more efficiently because the amendment clarifies rule language and eliminates unnecessary provisions.[85]

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[80] Ex. D at 8.
[81] *Id.*
[82] *Id.*
[83] *Id.* at 9. (The Department cites the CMS Medicare Program Integrity Manual (PIM), Pub. No. 100-08 (2018), found online at the following website: https://www.cms.gov/Regulations-andGuidance/Guidance/Manuals/Downloads/pim83c08.pdf.)
[84] Ex. D at 9.
[85] *Id.*

79. Moreover, the Department points out that MHCP providers are already governed by this rule provision as well as the other federal and state regulations that pertain to monetary recovery. Therefore, the Department contends that ultimately the cumulative effect will be small and manageable.[86]

B. Performance-Based Regulation

80. An agency is required to describe in its SONAR the manner in which the agency has considered and implemented the legislative policy supporting performance-based regulatory systems.[87] A performance-based rule is one that emphasizes superior achievement in meeting the agency's regulatory objectives and maximum flexibility for the regulated party and the agency in meeting those goals.[88]

81. The Department identifies two objectives for its proposed amendments: 1) to clarify existing language governing the Department's sampling procedures, and 2) to eliminate reliance on a textbook published in 1977.[89] The Department asserts that it endeavored to meet these objectives in a concise and straightforward manner. The Department contends that the proposed rule amendment provides definitions, incorporates plain language to the extent possible, and remains consistent with the larger state and federal regulatory framework of the medical assistance program. In addition, the Department maintains that the rule amendment provides parameters around statistical sampling that are generally understood while giving the Department the most flexibility to conduct statistical sampling that is tailored to the circumstances of each investigation.[90]

82. The Administrative Law Judge finds that the Department has met the requirement to address how it considered the legislative policy related to performance-based regulatory systems under Minn. Stat. § 14.131.[91] However, due to defects identified in the analysis below, the Department has not established that the proposed rule amendments comply with the legislative policy articulated in Minn. Stat. § 14.002.

C. Consultation with the Commissioner of Minnesota Management and Budget

83. Minn. Stat. § 14.131 requires that agencies consult with the Commissioner of Minnesota Management and Budget (MMB) to help evaluate the fiscal impact and fiscal benefits of the proposed rule on local units of government.

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[86] *Id.*
[87] Minn. Stat. §§ 14.002 and 14.131.
[88] Minn. Stat. § 14.002.
[89] Ex. D at 10. The Department originally also identified eliminating the requirement that it notify providers of its sampling plan, but it has withdrawn that proposed rule change.
[90] *Id.*
[91] Minn. Stat. § 14.131.

84. On September 15, 2020, the Department sent a letter to MMB's Commissioner, along with the proposed rules and SONAR, seeking the required consultation.[92]

85. On October 14, 2020, MMB issued a Memorandum analyzing the fiscal impacts and benefits of the proposed rule amendment on local units of government.[93] After noting that the proposed rule amendment will alter the procedure and notification process regarding statistical sampling in MHCP claims, MMB concluded that that the proposed rule amendment will not impose any costs on local units of government.[94]

D. Summary of Requirements Set Forth in Minn. Stat. § 14.131

86. The Administrative Law Judge finds that the Agency has met the requirements set forth in Minn. Stat. § 14.131 for assessing the impact of the proposed rules, including consideration and implementation of the legislative policy supporting performance-based regulatory systems, and the fiscal impact on units of local government.

E. Cost to Small Businesses and Cities under Minn. Stat. § 14.127

87. Minn. Stat. § 14.127, requires the Agency to "determine if the cost of complying with a proposed rule in the first year after the rule takes effect will exceed $25,000 for: (1) any one business that has less than 50 full-time employees; or (2) any one statutory or home rule charter city that has less than ten full-time employees." The Agency must make this determination before the close of the hearing record, and the Administrative Law Judge must review the determination and approve or disapprove it.[95]

88. Because the proposed rule amendment applies only to MHCP overpayment claims, the Department determined the cost of complying with the proposed rule amendment will not exceed $25,000 for any business or any statutory or home rule charter city in the first year after the rule takes effect.[96]

89. The Administrative Law Judge finds that the Department has made the determinations required by Minn. Stat. § 14.127 and approves those determinations.

F. Adoption or Amendment of Local Ordinances

90. Under Minn. Stat. § 14.128, the agency must determine if a local government will be required to adopt or amend an ordinance or other regulation to comply with a proposed agency rule. The agency must make this determination before the close

[92] Ex. K-9 (Certificate of Consulting with Comm'r of MMB).
[93] *Id.*
[94] *Id.*
[95] Minn. Stat. § 14.127, subds. 1 and 2.
[96] Ex. D at 13-14.

of the hearing record, and the Administrative Law Judge must review the determination and approve or disapprove it.[97]

91. The Department concluded that no local government will be required to adopt or amend an ordinance or other regulation to comply with the proposed rules.[98]

92. The Administrative Law Judge finds that the Department has made the determination required by Minn. Stat. § 14.128 and approves that determination.

V. Rulemaking Legal Standards

93. A rulemaking proceeding under the APA must include the following inquiries: whether the agency has statutory authority to adopt the rule; whether the rule is unconstitutional or otherwise illegal; whether the agency has complied with the rule adoption procedures; whether the proposed rule grants undue discretion to government officials; whether the rule constitutes an undue delegation of authority to another entity; and whether the proposed language meets the definition of a rule.[99]

94. Under Minn. Stat. § 14.14, subd. 2, and Minn. R. 1400.2100, the agency must establish the need for, and reasonableness of, a proposed rule through an affirmative presentation of facts. In support of a rule, the agency may rely upon materials developed for the hearing record,[100] "legislative facts" (namely, general and well-established principles that are not related to the specifics of a particular case, but which guide the development of law and policy),[101] and the agency's interpretation of related statutes.[102]

95. A proposed rule is reasonable if the agency can "explain on what evidence it is relying and how the evidence connects rationally with the agency's choice of action to be taken."[103]

96. By contrast, a proposed rule will be deemed arbitrary and capricious where the agency's choice is based upon whim or devoid of articulated reasons, or if it "represents its will and not its judgment."[104]

97. An important corollary to these standards is that, when proposing new rules, an agency is entitled to make choices between different possible regulatory approaches, so long as the alternative selected by the agency is a rational one. Thus, while reasonable minds might differ as to whether one or another particular approach represents "the best

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[97] Minn. Stat. § 14.128, subd. 1.
[98] Ex. D at 13.
[99] *See* Minn. R. 1400.2100 (2019).
[100] *See Manufactured Hous. Inst. v. Pettersen*, 347 N.W.2d 238, 240 (Minn. 1984); *Minnesota Chamber of Commerce v. Minnesota Pollution Control Agency*, 469 N.W.2d 100, 103 (Minn. Ct. App. 1991).
[101] *Compare generally United States* v. *Gould,* 536 F.2d 216, 220 (8th Cir. 1976).
[102] *See Mammenga v. Agency of Human Servs.*, 442 N.W.2d 786, 789-92 (Minn. 1989); *Manufactured Hous. Inst.*, 347 N.W.2d at 244.
[103] *Manufactured Hous. Inst.*, 347 N.W.2d at 244.
[104] *See Mammenga*, 442 N.W.2d at 789; *St. Paul Area Chamber of Commerce v. Minn. Pub. Serv. Comm'n,* 251 N.W.2d 350, 357-58 (Minn. 1977).

alternative," the agency's selection will be approved if it is one that a rational person could have made.[105]

98. Based upon comments received in this matter, the Department agreed to make a few grammatical changes to the proposed rule language after the date it was originally published in the *State Register*, and as a result, it is also necessary to address whether this new language is substantially different from the language as originally proposed.[106]

99. Minn. Stat. § 14.05, subd. 2(b), details the standards used to determine whether any changes to proposed rules create a substantially different rule. A modification does not make a proposed rule substantially different if:

> (1) "the differences are within the scope of the matter announced . . . in the notice of hearing and are in character with the issues raised in that notice;"
>
> (2) the differences "are a logical outgrowth of the contents of the . . . notice of hearing, and the comments submitted in response to the notice;" and
>
> (3) the notice of hearing "provided fair warning that the outcome of that rulemaking proceeding could be the rule in question."[107]

100. When determining whether modifications result in a rule that is substantially different, the Administrative Law Judge must consider whether:

> (1) "persons who will be affected by the rule should have understood that the rulemaking proceeding . . . could affect their interests;"
>
> (2) the "subject matter of the rule or issues determined by the rule are different from the subject matter or issues contained in the . . . notice of hearing;" and
>
> (3) "the effects of the rule differ from the effects of the proposed rule contained in the . . . notice of hearing."[108]

101. The proposed grammatical changes include substituting the word "must" for the word "shall," eliminating the word "time" from a reference to a "time period," changing "which" to "that," and substituting "among" for "amongst."[109] The Administrative Law

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[105] *Minnesota Chamber of Commerce*, 469 N.W.2d at 103; *Peterson v. Minn. Dep't of Labor & Indus.*, 591 N.W.2d 76, 78 (Minn. Ct. App. 1999).
[106] *See* Department's Rebuttal Comments (Feb. 24, 2021).
[107] Minn. Stat. § 14.05, subd. 2(b).
[108] *See* Minn. Stat. § 14.05, subd. 2(c).
[109] Department's Rebuttal Comments at 2.

Judge finds that the modifications to the proposed rule are minor grammatical revisions that do not result in a substantially different rule.[110]

VI. General Analysis of Rule

102. The role of the Administrative Law Judge during a legal review of rules is to determine whether the agency has made a reasonable selection among the regulatory options that it has available. A judge does not fashion requirements that the judge regards as best suited for the regulatory purpose. The delegation of rulemaking authority is drawn from the Minnesota Legislature and is conferred upon the agency. The legal review under the APA begins with this important premise.[111]

103. The majority of comments received in this proceeding fell into the following general groupings: (1) comments objecting to the Department's removal of the reference to the Cochran Textbook; (2) comments objecting to the proposed rule as containing impermissibly vague language; and (3) comments concerning the Department's decision to reject certain recommendations made by its statistical consulting expert. The Administrative Law Judge has read and considered all comments submitted. This report does not discuss every comment received, but instead includes discussion of representative comments in each of these categories.

A. Comments on the Department's Removal of the Cochran Textbook from the Methodology for Conducting Random Sample Extrapolation

104. Minn. R. 9505.2220, subp. 3 contains four subsections identifying the methods the Department must use to calculate an overpayment amount through random sample extrapolation. The Department proposes to restructure the rule in a manner that eliminates these specific requirements. In particular, the Department proposes to eliminate the reference to the Cochran Textbook in Minn. R. 9505.2220, subp. 3(C).

105. In support of this rule change, the Department notes that the Cochran Textbook was published in 1977 and contains a "technical overview of the theory underlying statistical sampling," but that it was "not intended to guide government agencies in the recovery of overpaid public funds."[112] The Department asserts that the broad language of the text is "not sufficiently tailored to the work of the Department to provide any meaningful assistance in the statistical sampling of MHCP claims."[113] The Department also contends that the language of the Cochran Textbook is "inaccessible."[114]

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[110] *Id*.

[111] *See Manufactured Housing Institute, supra,* 347 N.W.2d at 244 (The Court instructs that the state courts are to restrict the review of agency rulemaking to a "narrow area of responsibility, lest [the court] substitute its judgment for that of the agency"); *see also, In the Matter of the Proposed Rules of the Minnesota Pollution Control Agency Governing Permits for Greenhouse Gas Emissions*, Minnesota Rules Chapters 7005, 7007 and 7011, Docket No. 8-2200-22910-1 at 20, REPORT OF THE ADMINISTRATIVE LAW JUDGE (Minn. Office Admin. Hearings Nov. 9, 2012).

[112] Ex. D. at 5.

[113] *Id.*

[114] *Id.* The Department did not offer examples of any particular language it found to be inaccessible.

106. The Department points to a recent contested case that it contends illustrates the flaws in the current rule, *In the Matter of the SIRS Appeal by the Lazarus Project*.[115] The Department asserts that the Commissioner's final order in that matter required adherence to the Cochran Textbook, but disallowed the use of a confidence interval, which it asserts is a "an interval estimate of a population parameter that is discussed at length" in the Cochran Textbook "as valuable in a variety of circumstances."[116] The Department contends that, under the current rule language, it "could never use a confidence interval, even though doing so is encouraged by the text."[117]

107. The Lovaas Institute takes issue with the Department's contention that the Cochran Textbook is an outdated resource, noting that federal guidance issued in 2018, upon which the Department relies in the SONAR, specifically identifies the Cochran Textbook as a useful resource covering the basics of statistical sampling.[118] The federal guidance document, entitled "Statistical Sampling: A Toolkit for MFCU's" (Sampling Toolkit) outlines statistical analysis methods to support recovery of improperly paid medical assistance claims, and states regarding the Cochran Textbook that: "*Sampling Techniques* is one of the seminal textbooks on survey sampling. While additional methods have been developed since the publication of Cochran's classic textbook, the proofs outlined in *Sampling Techniques* are just as valid today as when they were initially written."[119]

108. The Lovaas Institute also contends that the Department's determination that the Cochran Textbook's language is "inaccessible" does not support excision of the resource from the rule.[120] It argues that "random sample extrapolation by its nature involves the use to complex principles of statistical[] sampling and methodology," and that a challenge to the statistical validity of a random sample extrapolation used by the Department will inevitably involve a complex discussion of statistical methodology."[121]

109. The Lovaas Institute and ARRM both disagree with the Department's assessment of the decision in the *Lazarus Project*, and they maintain that the outcome of that case does not establish the need for or reasonableness of the proposed rule amendments.[122]

110. ARRM identifies several issues related to the *Lazarus Project* matter. ARRM notes that the Department is unable to credibly assert that the Cochran Textbook is out-of-print or cannot be found; notwithstanding its age, the entire Cochran Textbook

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[115] *See In re the SIRS Appeal by the Lazarus Project*, Docket No. 68-1800-33278, FINDINGS OF FACT, CONCLUSIONS OF LAW, AND RECOMMENDATION (Minn. Office of Admin. Hearings July 24, 2017); *In re the SIRS Appeal by the Lazarus Project*, COMMISSIONER'S FINAL ORDER (Nov. 28, 2017). ARRM submitted copies of both of these orders in support of its comments in this matter. *See* ARRM Comments at Ex. B.
[116] Ex. D. at 3, n.7.
[117] *Id.*
[118] Lovaas Institute Comments at 3-4, Exhibit A at 25.
[119] *Id*. at Ex. A at 2, 25.
[120] *Id.* at 4.
[121] *Id.*
[122] *Id*. at 6-7; ARRM Comments at 7, 16, 18.

was made a part of the record in the *Lazarus Project* case.[123] ARRM further asserts that the administrative law judge's recommendation and the Commissioner's final order in that matter demonstrate that the principles articulated in the Cochran Textbook could be understood and applied to analyze the extrapolation methodology used by the Department.[124]

111. ARRM also contends that the Department was unsuccessful in recovering the extrapolated claim amount in the *Lazarus Project* because the Department's contractor examined only 150 claims, failing to follow either the Cochran Textbook's methodology (which would have required analysis of 203 claims), or the RAT-STATS' program (which would have required analysis of 206 claims).[125] As a result, the Department's random sample extrapolation was based on an inadequate sample size and was not statistically valid.[126]

112. The Lovaas Institute identifies the same fault with the underlying analysis in the *Lazarus Project*; it argues this outcome does not demonstrate flaws in the current rule, but instead shows the importance of the rule's procedural safeguards in random sample extrapolation matters.[127]

113. Numerous commenters expressed concerns about methodological safeguards and characterized the Department's proposed amendments as an effort to loosen the standards for the performance of random sample extrapolation to the commenters' detriment. For example, ARRM identifies four instances, including the *Lazarus Project*, in which it contends that the Department used random sample extrapolation to seek recovery from providers of over $300,000, $600,000, $1,600,000, and $2,700,000, and it maintains that the Department was not able to recover the extrapolated amounts in any of these instances.[128] ARRM notes that the recovery in the *Lazarus* Project was reduced from over $330,000, to a little over $6,600 after a contested case hearing.[129] ARRM identifies another overpayment claim that was reduced from $602,000, to $35,000, in a settlement without a contested case hearing.[130] ARRM contends that "[i]t is neither reasonable nor necessary for SIRS to simplify or dumb-down a statistical technique in the hopes of making it easier for auditors to issue extrapolated recoveries."[131]

114. The Lazarus Project itself submitted a comment in opposition to the proposed rule. It noted that it "already fought to keep a non-statistically sound judgement against our agency from putting us out of business." It expressed concern that small, non-fraudulent errors may be extrapolated into high-dollar monetary recovery claims, and

[123] ARRM Comments at 7.
[124] *Id.* at 16.
[125] *Id.* at 18, Ex. B (Commissioner's Final Order at 3, 7).
[126] *Id.* at 18, Ex. B (Commissioner's Final Order at 3, 7).
[127] Lovaas Institute Comments at 7.
[128] ARRM Comments at 7-8.
[129] *Id.* at 8, n. 13, Ex. B (Commissioner's Final Order at 4).
[130] ARRM Comments at 7, Ex. A.
[131] *Id.* at 21.

stated that "[w]hen you go after small providers with small staff and few resources, you make the job we do caring for and improving the lives of children nearly impossible."[132]

115. Care Providers of Minnesota (Care Providers) articulated concerns about the impact on providers of using less statistically rigorous methods. Care Providers noted that claim extrapolations may result in six to seven figure overpayment amounts, based on only a small subset of reviewed claims, and that such overpayment calculations "have the capability of financially sinking and ending the missions of many well-intentioned providers."[133]

116. Minnesota First Provider Alliance, a trade association of personal care assistance (PCA) agencies and waiver services providers, also contended that the amended rule could put well-intentioned providers, acting in good faith, out of business.[134] Rainbow Health Kare, Inc., a PCA provider agency, had the same concerns, and also expressed that recovery of funds based on less rigorous statistical methodologies could disproportionately impact women- and minority-owned businesses.[135] Many other PCA service providers noted the low reimbursement rate for PCA services and the importance of ensuring that Minnesotans with disabilities and older adults can remain in their homes; according to these agencies the Department's proposed rules could do "further financial harm to already struggling agencies."[136]

117. Behavioral Dimensions, Inc. noted that extrapolated recoveries under the proposed amended rules could negatively impact the availability of services for Minnesotans with disabilities.[137] The Rochester Center for Autism shared that same concern.[138]

118. The Department disagrees with concerns about the Cochran Textbook's removal from the rule, noting that the book "was written over forty years ago, using terminology that is outdated and difficult for a modern audience to understand."[139] The Department responded to praise for the Cochran Textbook by noting that the text may be a good resource regarding basic theories of statistics, but that it was written to teach statistics to college students, and the text does not contain a step-by-step guide for conducting statistical sampling of healthcare claims.[140] The Department contends that it is "ineffective and unnecessary" for the rule to reference a "generalized textbook that is difficult for the general public to comprehend and that does not provide specific methodological guidance to the Department."[141]

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[132] Ex. I-2 at OAH Page 118 (Comments of The Lazarus Project).
[133] Ex. I-2 at OAH Page 216 (Comments of Care Providers of Minnesota).
[134] Ex. I-2 at OAH Page 167 (Comments of Minnesota First Provider Alliance).
[135] Ex. I-2 at OAH Page 109 (Comments of Rainbow Health Kare. Inc.).
[136] *See, e.g.*, Ex. I-2 at OAH Page 173 (Comments of North Country Home Care, Inc.).
[137] Ex. I-2 at OAH Page 137 (Comments of Behavioral Dimensions, Inc.).
[138] Ex. I-2 at OAH Page 140 (Comments of Rochester Center for Autism).
[139] Department's Comments at 4.
[140] *Id.*
[141] *Id.*

B. Comments Asserting the Proposed Rule is Impermissibly Vague

119. Many commenters expressed concerns that the proposed rule amendments use vague and ambiguous language and undefined terms.

120. Commenter Ian Lewenstein submitted an initial comment prior to the hearing noting that the Department has not defined certain technical terms in the rule: population value, interval estimate, population parameter, and random sampling method.[142] He asserts that this makes the rule impermissibly vague. He also notes the rule's references to "generally accepted amongst statisticians" and "generally accepted statistical standards and practices."[143] Mr. Lewenstein contends that these terms are too vague and fail to provide adequate notice to a regulated party of the standard that applies to it.[144] Finally, Mr. Lewenstein objects to the Department's reference to federal guidance issued by CMS, contending that the Department must incorporate such guidance by reference.[145] Mr. Lewenstein's subsequent rebuttal comment highlighted these issues again, and contended that the Department's failure to define the meaning of the term "generally accepted statistical standards and practices" affords the Department unfettered discretion to decide what these terms mean and runs the risk that the proposed rule will be arbitrarily applied.[146]

121. Many commenters contended the proposed rule's references to "generally accepted statistical standards and practices" and "generally accepted sampling software and methods" lacked clarity and would allow recoveries based upon the Department's "whimsy," rather than in reliance on sound and well-defined statistical methodologies.[147]

122. The Lovaas Institute contends that using the term "generally accepted statistical standards and practices" makes the proposed rule less technically precise than the current rule.[148] It asserts that, by using this term, the Department's proposed rules accomplish the opposite of the Department's objective to provide clear guidance about the Department's sampling process.[149]

123. The Department disagrees with these assessments, asserting that its proposed rule language is "detailed and informative."[150] The Department notes that the rule requires adherence to "generally accepted standards," defines certain terms, provides examples of the software systems it may use, and references CMS as a source of guidance.[151] The Department states that it is "wary of establishing more rigid

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[142] Ex. I-1 at OAH Page 106 (Comments of Ian Lewenstein).
[143] *Id.*
[144] *Id.*
[145] *Id.*
[146] Rebuttal Comments of Ian Lewenstein (Feb. 22, 2021).
[147] Ex. I-2 at OAH Page 156 (Comments of the Good Samaritan Society-St. James), OAH Page 158 (Comments of The Estates at Delano/Monarch Healthcare Management), OAH Page 163 (Comments of Villa Healthcare), OAH Page 165 (Comments of Oaklawn Rehabilitation Center).
[148] Lovaas Institute Comments at 5.
[149] *Id.*
[150] Department's Comments at 5.
[151] *Id.*

parameters regarding its statistical methodologies, as doing so may render it unable to effectively tailor its methods to the demands of each particular investigation."[152]

124. As to the request for additional definitions, the Department contends that it has sufficiently defined necessary terms and that the meaning of other terms can be gleaned from their use in context in other parts of the rule.[153]

C. Comments Contending that the Department Ignored Its Own Expert's Opinions

125. The Department consulted with a statistical expert at the University of Minnesota, Dr. Oehlert, by submitting its first draft of the rule for comment. The Department requested that Dr. Ohelert offer comments as to whether the Department's planned language was "less statistically sound" than the current rule.[154]

126. Dr. Oehlert recommended that the Department revise its initial proposal by identifying a margin of error based upon a specified dollar value or number of claims.[155] Dr. Oehlert also recommended that the Department adopt language allowing it to limit the sample size to a specific upper limit of claims to be examined.[156]

127. The Department declined to incorporate Dr. Oehlert's recommendations regarding the selection of a margin of error based upon its concerns about rapidly changing healthcare costs, and its belief that choosing a set percentage of claims could result in a margin of error that was either too large or too small for a particular provider.[157] The Department determined that it preferred to determine the margin of error on a case by case basis.[158] The Department declined to adopt a maximum sample size, noting that it preferred to use sample sizes calculated by statistical software programs.[159]

128. Many commenters asserted that the Department's decision to deviate from its expert's recommendation rendered its proposed rule language unreasonable. For example, Holland Autism Center & Clinic and the Minnesota Autism Center commented that it was arbitrary and capricious for the Department to consult a statistician to ensure the mathematical integrity of the proposed amendments, and then reject his recommendations regarding the margin of error and sample size.[160]

129. ARRM contends that the Department's decision to reject its expert's opinion shows that the proposed amendments "build too much latitude and flexibility into an audit

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[152] *Id.*
[153] Department's Rebuttal Comments at 1.
[154] Ex. D at App. 1 at 15.
[155] *Id*. at App. 1 at 19.
[156] *Id.*
[157] Ex. D at 7.
[158] *Id*. at 8.
[159] *Id*.
[160] Ex. I-2 at OAH Page 117 (Holland Center Comments), OAH Page 145 (Minnesota Autism Center Comments); *see also* Lovaas Institute Comments at 8.

procedure that can literally end a provider's mission by amplifying a monetary recovery."[161] ARRM notes that setting the margin of error on a case by case basis allows auditors too much authority and that future contested case proceedings on extrapolations will become battles of competing expert opinion, increasing the cost of contested case proceedings.[162]

130. Bethesda Lutheran Communities noted that "[w]hile providers would have the ability to appeal any judgements, it is always much more difficult to challenge unfair or problematic findings after the fact rather than before the process begins."[163] It also stated that the proposed rules create "a likely scenario in which the number and size of provider appeals is increased. This is a waste of taxpayer revenues …"[164]

131. The Department stands by its decision not to include a specific margin of error and identify a specific limit on the size of claim samples.[165] The Department reiterates that the margin of error to be used is a decision best made on a case by case basis.[166]

VII. Rule by Rule Analysis

132. The Department proposes to add a new subpart 1a to Minn. R. 9505.2220, containing defined terms. The Department also proposes to amend the rule language of subpart 3.

133. This Report focuses on the portions of the proposed rules as to which there is a genuine dispute as to the reasonableness of the Department's regulatory choice or that otherwise require closer examination.

A. Minn. R. 9505.2200, Subp. 1a (Definitions)

134. The Department proposes to add definitions for the terms "extrapolation," "95 percent confidence interval," "population" or "population of claims," "probe sample," "random sample of claims," "RAT-STATS," "Sampling Plan," and "Statistical analysis system" or "SAS."[167]

135. One commenter noted that technical terms contained within these definitions are themselves undefined and the absence of definitions for these additional terms makes certain proposed definitions impermissibly vague.[168] The specific terms identified by the commenter are "population value," "interval estimate," "population

[161] ARRM Comments at 20.
[162] *Id.* at 2, 20.
[163] Comments of Bethesda Lutheran Communities (Feb. 8, 2021).
[164] *Id.*
[165] Department's Comments at 5.
[166] *Id.*
[167] Ex. C at 1-2.
[168] Ex. I-1 at OAH Page 106 (Comments of Ian Lewenstein).

parameter," and "random sampling method."[169] The Department asserts that the meaning of these terms can be derived from the context in which they are used in the definitions.[170]

136. With regard to the terms "population value," "interval estimate," and "population parameter," the Administrative Law Judge concludes that definitions are required and, in the absence of definitions for these terms, the proposed amendments that use these terms are impermissibly vague. The parties that will be subject to regulation by the proposed rules are providers of MHCP-reimbursed services, not statistical experts, and these terms could be interpreted in a variety of ways. The use of these terms for the purposes of statistical analysis is not well-understood or discernable through context. Each of these terms is addressed specifically below.

137. In item A, the Department proposes to define the term "extrapolation." The proposed definition is as follows:

> A. "Extrapolation" means estimating an unknown population value by projecting, with a calculated margin of error, the results from a random sample to the population from which the random sample was drawn. The form and computations for the extrapolation and its confidence interval depend on the method of random sampling."

138. The Administrative Law Judge determines that the proposed definition for "extrapolation" is vague because the term "population value" is undefined. The Department proposes a definition of "population" or "population of claims" in Item C to mean "a defined set of paid claims for a specified period that exist at the time of the audit or investigation."[171] But the meaning of "population value" cannot be determined from the context of Item A, even looking to Item C, and this term does not appear elsewhere in the rule. The word "value" could mean different things. The rule is designed to calculate an overpayment of funds, so "value" could mean the monetary worth of a population of claims.[172] It seems more likely that the Department intends the word "value" to mean "a numerical quantity that is assigned or determined by calculation or measurement,"[173] but the Department has not said so. The Department must define this term to correct this defect at Minn. R. 9505.2200, Subp. 1a(A) as proposed.

139. In Item B, the Department proposes to adopt a definition for "95 percent confidence interval," as follows:

> B. "95 percent confidence interval" means an interval estimate, or estimate with a margin of error, for a population parameter computed using a procedure that produces intervals that

[169] *Id.*
[170] Department's Rebuttal Comments at 1.
[171] Ex. C at 1.
[172] *Value*, MERRIAM-WEBSTER.COM, https://www.merriam-webster.com/dictionary/value (last visited Mar. 18, 2021).
[173] *Id.*

> contain the true parameter for 95 percent of all random samples.

140. This definition contains two problematic terms. First, the term "interval estimate" is undefined. This is a technical term. The HHS-OIG guidance document, the Sampling Toolkit referenced above, provides some information about the selection of confidence levels and resulting confidence intervals.[174] The Toolkit provides a step-by-step method for conducting a random sample extrapolation. At Step 7 of 13, the Toolkit states:

> Choose the confidence level for the calculation of the estimate. The confidence level is usually determined by agency policy and is decided on before pulling the sample. The confidence level represents how often the upper and lower limits of an estimate should contain the population quantity of interest (e.g., the overall improper payment amount). The upper and lower limits together are known as the confidence interval.
>
> Most agencies, as a matter of policy, use either a 90- or 95-percent confidence level. A 90-percent confidence level is common in the Medicare administrative appeals process. A 95-percent confidence level is more common in academic settings. As the confidence level of an estimate increases, the associated confidence interval gets wider.[175]

141. The Department could use information from this explanation, or other statistical source material, to craft a definition further clarifying this term.[176] Without additional information, the definition is impermissibly vague. The Department must define "interval estimate" to correct the defect in this definition.

142. In order to adopt this definition, the Department must also provide a definition for "population parameter." Again, the Department has defined the term "population" in Item C, but the meaning of the term parameter in this context is unclear. The term parameter may mean "an arbitrary constant whose value characterizes a member of a system," "a quantity (such as a mean or variance) that describes a statistical

[174] Lovaas Institute Comment at Ex. A at 5.

[175] *Id.*

[176] The Administrative Law Judge looked to the record to ascertain whether a definition could be gleaned from the Department's exhibits. Dr. Oehlert's opinion contains this term, but looking to Dr. Oehlert's opinion to derive a meaning adds another level of uncertainty. Dr. Oehlert's recommendation phrased the definition differently to include the wording: "interval estimate (estimate with a margin of error)." *See* Ex. D at App. 1 at 17. It is unclear whether Dr. Oehlert was suggesting the wording in the parenthetical to further define the term "interval estimate" through a limitation, or to provide an example of an interval estimate. The Department used commas to set off the phrase "or estimate with a margin of error" from the term "interval estimate," Ex. C at 1, a change that does not add clarity as to the Department's intent. Because the record on this point is ambiguous, the Administrative Law Judge is unable to suggest clarifying language to resolve this defect.

system," or simply a "limit [or] boundary."[177] Given the highly technical nature of statistical analysis, it is possible that this term should be defined in another way. The Administrative Law Judge looked to the record to find language to remedy this defect but encountered an ambiguity. Dr. Oehlert's report uses different terms in defining "95 percent confidence interval," in one instance using "population parameter," and in the other using the term "population value."[178] The record does not show whether population parameter and population value mean the same thing or can be used interchangeably, and as noted above, population value is also undefined. As a result, the definition of "95 percent confidence interval" suffers from an additional defect that must be resolved through clarification or through further definitions.

143. As to the other term identified by the commenter, "random sampling method," it is possible to understand the meaning of this term by looking to the definitions proposed by the Department. Proposed Items G and E are definitions containing this term, stating:

> E. "Random sample of claims" means a subset of claims chosen from a population of claims using a random sampling method including simple random sampling, stratified sampling, probability proportional to size sampling, cluster sampling, or any other sampling methods that are generally accepted among statisticians.[179]
>
> G. "Sampling plan" means the combination of the identified population, the random sampling method, the sample size, and the technique for implementing the random sampling method on the population.

144. The definition proposed in Item E includes a list of sampling methods that explain the Department's meaning of this term, for example, simple random sampling, stratified sampling, probability proportional to size sampling, and cluster sampling. However, these too are technical terms that would benefit from being further defined.[180] The Administrative Law Judge notes that the current version of Minn. R. 9505.2220, subp. 3(A) provides an explanation of simple random sampling, stating: "Samples of a given size shall be selected in such a way that every sample of that size shall be equally likely to be selected, these samples are called simple random samples." This subpart currently references stratified random sampling without defining that term. While the

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[177] *Parameter*, MERRIAM-WEBSTER.COM, https://www.merriam-webster.com/dictionary/parameter (last visited Mar. 18, 2021).

[178] Ex. D at App. A at 16-17.

[179] Note that this recitation incorporates one of the grammatical changes that the Department agreed to make.

[180] The factual findings in the *Lazarus Project* provide possible plain-language definitions for some of these terms. The administrative law judge's recommendation stated simple random sampling means "every sampling unit in the sample frame has an equal chance of being selected for the sample." *See* ARRM Comment at Ex. B (Recommendation at 6). Stratified sampling is a grouping technique "dividing the claims into groups, and then taking a sample from each of the groups." *Id.* The Commissioner's Final Order adopted these factual findings. *See id.* at Ex. B (Commissioner's Final Order at 1).

Administrative Law Judge does not find a defect that prevents adoption of Item E in connection with the term "random sampling method," defining additional terms would provide greater clarity to regulated parties and would assist administrative and judicial decision-makers who will be called upon to interpret these terms at a later date.

145. This reasoning does not mean that Item E passes muster, however. Item E follows the list of specific random sampling methods with the phrase "or any other sampling methods that are generally accepted among statisticians." This phrase is impermissibly vague. There are very limited instances in which general acceptance is understood in a particular industry or discipline in a way that would permit this language to be used in rulemaking. For example, generally accepted accounting principles or "GAAP" are a common set of principles and standards adopted by the Financial Accounting Standards Board (FASB).[181]

146. The Department does not identify a governing body that adopts statistical sampling methods, making this situation unlike GAAP. The Department does not address the process by which a sampling method becomes generally accepted, or identify the decision-makers who would determine that a sampling method is generally accepted, or state the number of statisticians who would be required to agree that a sampling method is generally accepted. It is possible that sampling methods other than those listed are "generally accepted by statisticians," but the Department does not specifically identify what any of those other sampling methods might be. Though federal guidance materials could contain further information that would be helpful in this regard, the Department has not pointed to any particular source that could offer an explanation of other potential sampling methods or incorporated any such guidance. This leaves the interpretation of this term open to the Department's unfettered discretion or to case-by-case litigation as to whether a sampling method is "generally accepted by statisticians." Item E contains a defect making it impermissibly vague and granting the Department undue discretion, and it cannot be adopted in its current form.

147. To remedy the defect in this definition, the Department could excise the phrase regarding other methods with "general acceptance by statisticians from the definition," leaving Item E to say:

> E. "Random sample of claims" means a subset of claims chosen from a population of claims using a random sampling method including simple random sampling, stratified sampling, probability proportional to size sampling, **or** cluster sampling.

148. Alternatively, the Department could use language from the current rule to provide a limitation on the Department's exercise of discretion in selecting a sampling method. Subpart 3(A) of Minn. R. 9505.2220 as it is currently worded allows the Department to use simple random sampling, "or other sampling designs, such as the

[181] See Rebuttal Comments of Ian Lewenstein at 1 (Feb. 22, 2021); *see also* https://www.fasb.org/jsp/FASB/Page/LandingPage&cid=1175805317350 (last viewed Mar. 18, 2021) (explaining the FASB Accounting Standards Codification).

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*."[182] This language checks the agency's exercise of discretion by specifying the reasons that the Department may use a different random sampling method than those listed. This language is also designed to promote greater statistical validity in the Department's ultimate extrapolation. If the Department wished to adopt this alternative, Item E would read:

> E. "Random sample of claims" means a subset of claims chosen from a population of claims using a random sampling method including simple random sampling, stratified sampling, probability proportional to size sampling, cluster sampling, or **another sampling method that it determines is more likely to lead to greater precision, or a closer approximation to the population mean**.

149. If the Department adopts either of these revisions to cure the defect in Item E, the revision will not make the rule substantially different under Minn. Stat. § 14.05, subd. 2.

150. Based upon the record produced by the Department, further clarification is also necessary to resolve an ambiguity in Item H, in which the Department proposes to define the term "Statistical analysis system" or "SAS." As proposed, the definition reads as follows:

> H. "Statistical analysis system" or "SAS" means an analytics and statistics software system.

151. According to Dr. Oehlert, "SAS" refers to a particular software system developed by the SAS Institute. Dr. Oehlert recommended defining this term to include the reference to the company that created SAS. The Department definition, however, refers to SAS in general terms as "an analytics and statistics software system." Later in the proposed rule, in subpart 3(A)(2), the Department references SAS, along with RAT-STATS, in a manner that suggests it does intend to refer to the specific SAS Institute analytical system, and not generally to any system that performs the same functions. In contrast to SAS, the Department has defined RAT-STATS with specific reference to HHS-OIG and CMS. The Department's SONAR does not address this issue and the Administrative Law Judge is unable to determine the Department's intent regarding this term with certainty. As a result of this ambiguity, Item H contains a defect. The Department may resolve this defect by providing further explanation or a revised definition of this term.

152. The Administrative Law Judge concludes that proposed subpart 1a, Items A, B, E, and H contain defects and cannot be adopted as written.

[182] Emphasis added.

153. Items C, D, F, and G do not contain defects, though the Department should consider whether the rule would benefit from additional definitions.[183] Even so, Items C, D, F, and G could be approved as written. These terms, however, are part of a larger restructuring and revision the Department proposed for Minn. R. 9505.2220. These definitions do not closely relate to the language of the current rule. As discussed below, there are material defects that prevent adoption of the Department's proposed subpart 3, and if subpart 3 cannot be adopted, these definitions are not needed and reasonable amendments of Minn. R. 9505.2220 as it currently stands.

B. Minn. R. 9505.2200, Subp. 3. Statistical method

154. The Department initially proposed to revise this subpart to read as follows:

> Subp. 3. **Statistical method**. The department shall use the ~~methods in items A to D in~~ procedures in this subpart when calculating the amount of monetary recovery by random sample extrapolation from the audit results of a random sample of claims. ~~The federal share of overpayment determined by the federal government under a federal random sample extrapolation method shall be recovered by the department from a medical assistance vendor according to Minnesota Statutes, section 256B.0641, subdivision 1, clause (1).~~
>
> A. ~~Samples of a given size shall be selected in such a way that every sample of that size shall be equally likely to be selected, these samples are called simple random samples. The department 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. The department shall tell the provider the sampling method the department is using prior to drawing the sample.~~ The sampling plan and extrapolation shall be chosen and performed according to generally accepted statistical standards and practices, which includes guidance from the Centers for Medicare and Medicaid Services.
>
> (1) The sampling plan shall include a probe sample.
>
> (2) The department shall use tools that include RAT-STATS, SAS, or any other generally accepted sampling software and methods.

[183] Some commenters objected to the Department's limitation in Item D of the size of the probe sample to at least 50 units. A probe sample is defined as the "limited initial random sample . . . that can be used to provide guidance in selecting the sample size for a full random sample." Ex. C at 1. The Department has made a policy choice regarding the size of the initial probe sample. There is no basis upon which to conclude that this definition contains a defect.

B. ~~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~~. The vendor shall be required to pay an overpayment identified under this part only if the overpayment identified has a 95 percent confidence interval that does not contain zero dollars.

~~C. 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 following text: W. Cochran, Sampling Techniques, John Wiley and Sons, New York 3rd Ed. (1977). Sampling Techniques is incorporated by reference and is available through the Minitex interlibrary loan system. Samples must consist of at least 50 claims. Each stratum in a stratified sample must contain at least 30 claims or, if a population stratum contains less than 30 claims, all of the claims in that population stratum~~.

~~D. The vendor shall be required to pay the department 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. The amount owed to the department shall be the mean overpayment multiplied by the number of claims in the population. With simple random samples, the mean overpayment is the sum of all differences between correct and actual charges in the sample, divided by the number of claims in the sample. With stratified samples, the mean overpayment is the sum of the products of the mean differences within strata and the proportion of all claims in the population that are in the strata~~.

155. In its initial proposal, the Department sought to remove the requirement that it provide notice of its sampling procedures to providers before drawing the sample.[184] In response to objections to this rule change, the Department has withdrawn that proposed amendment.[185] As that portion of the rule is no longer at issue, this Report will not address the factual submissions or reasoning the Department initially offered in support of that proposed rule change or the comments in opposition.

156. As revised by the Department, and for simplification of this analysis, the Administrative Law Judge produces proposed subpart 3 as the Department intends for it to read, including the grammatical changes the Department agreed to implement and the

[184] Ex. D at 2.
[185] Department's Comments at 3.

withdrawal of its proposal to remove the provider notice requirement. With new text underlined, the Department proposes for subpart 3 to read as follows:

> Subp. 3. **Statistical method.** The department must use the procedures in this subpart when calculating the amount of monetary recovery by random sample extrapolation from the audit results of a random sample of claims.
>
> A. The department must tell the provider the sampling method the department is using prior to drawing the sample. The sampling plan and extrapolation must be chosen and performed according to generally accepted statistical standards and practices, which includes guidance from the Centers for Medicare and Medicaid Services.
>
> (1) The sampling plan must include a probe sample.
>
> (2) The department must use tools that include RAT-STATS, SAS, or any other generally accepted sampling software and methods.
>
> B. The vendor must be required to pay an overpayment identified under this part only if the overpayment identified has a 95 percent confidence interval that does not contain zero dollars.

157. The Department's proposed rule change eliminates the reference to the Cochran Textbook, as discussed further above. Though commenters challenged the need for and reasonableness of this decision, it is within the Department's authority as a matter of policy to update the references on which its rules rely or to designate more specific resources or practices, so long as it does so in a manner that complies with the legal standards for promulgating rules.

158. It should be noted that the Department's reasoning as to the need to remove the Cochran Textbook's reference from the rule relies on an erroneous reading of the final decision in the *Lazarus Project*. The Department contends that the Commissioner's Final Order in that matter prohibits it from using a confidence interval in conducting a random sample extrapolation, stating "[u]nder the current rule language, the Department could never use a confidence interval . . ." even though the Cochran Textbook considers the confidence interval to be valuable in a variety of circumstances.[186] The Commissioner's Final Order does not conclude that a confidence interval is inherently unreliable or that the Department is barred from using a confidence interval as part of the process for conducting a random sample extrapolation. On the contrary, the Administrative Law

[186] Ex. D at 3, n.7.

Judge recommends that the Department determine a confidence level and interval in order to ensure greater statistical validity of its sampling process.[187]

159. The flaw found in the *Lazarus Project* is that the contractor conducting the statistical extrapolation calculated the confidence interval and resulting dollar figure range and then selected the lower limit of the range produced as the overpayment amount.[188] The Commissioner's Final Order notes that the contractor made this determination based upon CMS's Medicare PIM.[189] This method of selecting the overpayment to be recovered is not permitted by the current rule language, which requires an additional step to reach the final overpayment calculation. Minn. R. 9505.2220, subp. 3(D), provides that:

> The amount owed to the department *shall be the mean overpayment multiplied by the number of claims in the population*. With simple random samples, the mean overpayment is the sum of all differences between correct and actual charges in the sample, divided by the number of claims in the sample. With stratified samples, the mean overpayment is the sum of the products of the mean differences within strata and the proportion of all claims in the population that are in the strata.[190]

160. The Department's claims in the *Lazarus Project* failed not because a confidence interval was used, but because the contractor improperly used the lower limit of the dollar-figure range to select the overpayment amount, rather than using the confidence interval as a preliminary step to support the accuracy of its calculation.[191]

161. Notwithstanding the apparent misreading of the *Lazarus Project* decision, it is possible for the Department to establish the need for and reasonableness of a rule that substitutes a different method or source for the Cochran Textbook. The language chosen by the Department to fulfill this purpose, however, contains serious defects that prevent adoption of the proposed process.

162. The Department's proposed subpart 3(A) requires the Department to choose a sampling plan and extrapolation "according to generally accepted statistical standards and practices, which includes guidance from the Centers for Medicare and Medicaid Services." This language is defective because the meaning of "generally accepted statistical standards and practices" is impermissibly vague.

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[187] *See* Lovaas Institute Comments at Ex. A at 5 (referencing the confidence level and interval as a mid-stream step of the statistical extrapolation process).

[188] ARRM Comments at Ex. B (Commissioner's Final Order at 8.) The contractor also used an inadequate sample size, as discussed above.

[189] *Id.* at Ex. B (Commissioner's Final Order 2, 8).

[190] Emphasis added.

[191] *See* Lovaas Institute Comments at Ex. A at 17 (explaining that the "confidence level represents how often the confidence interval is expected to contain the population quantity. For example, suppose a sample is re-pulled many times. Roughly 90 percent of the 90-percent confidence intervals that were calculated across these samples would contain the actual recoverable dollars in the sampling population."), 23 (noting that the "higher the confidence level, the larger the sample size needed.").

163. "A rule, like a statute, is void for vagueness, if it fails to give a person of ordinary intelligence a reasonable opportunity to know what is prohibited or fails to provide sufficient standards for enforcement."[192] The proposed rule does not articulate any particular standard or practice that the Department might use, meaning that regulated parties are afforded no understanding of the methods the Department could choose. The Department's decision not to identify a margin of error, and instead to leave this issue to determination on a case-by-case basis, takes on additional significance in this context because a margin of error would operate as a limitation intended to ensure statistical validity of the standards and practices used in each case. Referencing CMS guidance does not save this rule. While CMS may promulgate guidance regarding statistical sampling methods, the rule does not clearly limit the Department to CMS's methods, identify any particular methods CMS uses, or incorporate specific CMS guidance. This rule grants the Department unfettered discretion and cannot be approved. To correct this defect, the Department must specify which statistical sampling methods the Commissioner will use to calculate overpayments.

164. Additionally, the underlying record does not contain information or examples regarding any specific standards and practices the Department might use to conduct a statistical extrapolation under subpart 3(A). The rulemaking record required to support amendment of a rule varies with the nature of the rule.[193] In some cases a "substantial evidentiary record may be needed . . . while in other cases, 'common knowledge' or 'common sense' will suffice."[194] The subject matter of this rule is not grounded in common knowledge or common sense, but instead involves the use of complex statistical analysis and methods. The Department has not provided an affirmative presentation of facts regarding the standards and practices it intends to use sufficient to support the proposed amendment of subpart 3(A). As a result, the Department has not provided a record establishing the reasonableness of this provision under Minn. R. 1400.2100(B).[195]

165. Proposed subpart 3(A)(2) contains a similar defect. This provision requires the Department to use "tools that include RAT-STATS, SAS, or any other generally accepted sampling software or methods."[196] The reference to SAS, as noted above, requires clarification, but the more significant problem is the Department's reference to other "generally accepted" software or methods. This too is impermissibly vague. To cure this defect, the Administrative Law Judge recommends the Department delete its reference to "generally accepted" software or methods, as well as define more specifically what it refers to by SAS, as discussed above.

166. Regarding the terms of proposed subpart 3, the Department maintains that its proposed language is "specific enough to give providers an outline of the Department's statistical sampling process, but general enough to allow the Department the flexibility to

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[192] *In re N.P.*, 361 N.W. 2d 386, 394 (Minn. 1985), *citing Grayned v. City of Rockford*, 408 U.S. 104, 108-09, 92 S. Ct. 2294, 2298-99 (1972).
[193] *Mammenga*, 442 N.W.2d at 791.
[194] *Id.*
[195] Minn. Stat. § 14.14, subd. 2; Minn. R. 1400.2100.
[196] Ex. C at 2.

adjust its methods to fit the variety of different sampling scenarios that will likely arise in its investigations."[197] This assertion is belied by a review of the cumulative impact of the Department's decision not to use greater specificity. Under the entire rule as proposed, the Department could calculate an overpayment using a sampling plan and extrapolation "performed according to generally accepted statistical standards and practices," using a sampling method that is "generally accepted among statisticians," and through unspecified "generally accepted sampling software and methods."[198] The vagueness in these standards goes to the heart of the process the Department will use to arrive at an extrapolated overpayment, and a calculation performed according to these terms, which may run to hundreds of thousands or millions of dollars, would obtain a presumption of correctness in a contested case.[199]

167. The Department reasoned that the Cochran Textbook should be removed from the rule, in part, because it did "not provide specific methodological guidance to the Department."[200] The Department's rule, as written, provides no specific methodological guidance. Instead, it contains broad language granting the Department discretion without any meaningful limitation. In seeking the greatest flexibility to alter its methods to address any possible circumstances that might occur in an investigation, the Department has failed to comply with the state's requirements for promulgation of rules.

168. This is not to say that an agency may not reserve discretion for itself in the promulgation and enforcement of administrative rules. As noted by the Court of Appeals:

> "The government cannot operate without agencies that exercise discretionary power. . . . Nonetheless, conferring too much discretion on an individual or an institution creates the potential for harm attributable to the abuse of discretion. The challenge is to balance the need for discretion with the need for checks on discretion at each level of decisionmaking. Rules are an effective limit both on agency discretion and on the discretion of agency personnel, and the most powerful form of a rule is the legislative rule, which is adopted though a formal rulemaking process such as chapter 14; when valid, it can bind courts, members of the public, and the agency itself."[201]

169. Therefore, the issue is not that the Department recognized the need for flexibility to adapt its investigative techniques, but that it has afforded itself undue discretion by proposing rules that set no clearly defined limits on the exercise of discretion and that do not apprise regulated parties of the standards that may apply to them. The Department contends that a regulated provider will receive notice of the sampling plan to be used in its particular case, and that this will "sufficiently address the vagueness concern."[202] An agency cannot remediate a vague rule down the road on a case-by-case

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[197] Department's Rebuttal Comments at 1.
[198] Ex. C at 1-2.
[199] Minn. R. 9505.2220, subp. 1.
[200] *Id.*
[201] *Coalition of Greater Minnesota Cities*, 765 N.W.2d at 165-66 (internal citations and quotations omitted).
[202] Department's Rebuttal Comments at 1.

basis, as a rule must be disapproved when it grants the agency discretion beyond that allowed by law.[203]

170. The defects in proposed subparts 3(A) and 3(A)(2) are material. It is possible that the Department could salvage proposed subpart 3(A)(2) by removing the reference to generally accepted sampling software and methods, but that does not address the more critical defect in subpart 3(A). As written, proposed subparts 3(A) and 3(A)(2) cannot be approved.

171. In many instances, administrative law judges suggest language that may be used to cure a defect. The Department proposed to eliminate the four current rule subsections in Minn. R. 9505.2220, subp. 3, containing instructions for conducting random sample calculations and offered no specific protocols in their place. The defect in proposed subpart 3(A) goes to the essential purpose of this rulemaking and it cannot be remedied by wordsmithing an alternative proposal.

172. Proposed subpart 3's preamble text, subpart 3(A)(1), which requires the Department to draw a probe sample, and subpart 3(B), which limits the circumstances in which the Department recovers an overpayment depending on whether the 95 percent confidence interval includes zero dollars, do not have defects on their face. But these proposed rule parts do not stand on their own or create a process for the calculation of an overpayment. The Department has not established that these terms are needed or reasonable in isolation from the defective provisions it is proposed rule.

173. Therefore, the Administrative Law Judge determines that proposed subpart 3 must be disapproved in its entirety.

Based upon the Findings of Fact and the contents of the rulemaking record, the Administrative Law Judge makes the following:

CONCLUSIONS

1. The Administrative Law Judge has authority and jurisdiction to review these rules under Minn. Stat. § 14.14, .15, .50, and Minn. R. 1400.2100 (2019).

2. The Department gave notice to interested persons in this matter and fulfilled its additional notice requirements.

3. The Department fulfilled the procedural requirements of Minn. Stat. § 14.14 and all other procedural requirements of law or rule.

4. The Department demonstrated it has statutory authority to adopt the proposed rules, and it fulfilled all other substantive requirements of law or rule within the meaning of Minn. Stat. §§ 14.05, subd. 1-2, 14.50(i), (ii).

[203] Minn. R. 1400.2100(D).

5. The Department has not demonstrated the need for and reasonableness of portions of its proposed rules, as required by Minn. Stat. §§ 14.14 and 14.50(iii), which portions are defective and disapproved as noted in the following Findings:

Finding 152 relating to proposed Subpart 1a, Items A, B, E, and H; and

Finding 170 relating to proposed Subpart 3(A) and 3(A)(2).

6. In Findings 138, 141-142, 147-148, 151, 163, and 165 the Administrative Law Judge has suggested actions to correct some of the defects noted in Conclusion 5.

7. As noted in Findings 153 and 172, proposed Subparts 1a, Items C, D, F, and G, subpart 3's preamble text, and subparts 3(A)(1) and 3(B), do not contain defects. Notwithstanding that the language of these rule parts could be approved, the proposed amendments in these subparts do not stand on their own or relate to provisions in the existing rule. The Department has not shown the need for and reasonableness of proposed subparts 1a, Items C, D, F, and G, subpart 3's preamble text, and subparts 3(A)(1) and 3(B), in isolation from its other proposed changes or as amendments or substitutions of the terms in the existing Minn. R. 9505.2220.

8. Due to Conclusion 5, this Report has been submitted to the Chief Administrative Law Judge for her approval pursuant to Minn. Stat. § 14.15, subd. 3.

9. As part of the public comment process, a number of stakeholders urged the Department to adopt other revisions to the proposed rules. Unless otherwise stated, in each instance, the Department's rationale in declining to make the requested revisions to its rules was grounded in this record and reasonable.

10. The modifications to the proposed rules suggested by the Department after publication of the proposed rules in the *State Register* are not substantially different from the proposed rules as published in the *State Register* within the meaning of Minn. Stat. §§ 14.05, subd. 2, .15, subd. 3.

Based upon the foregoing Conclusions, the Administrative Law Judge makes the following:

RECOMMENDATION

IT IS HEREBY RECOMMENDED that the proposed rules, as modified, be **DISAPPROVED**.

Dated: March 26, 2021

JESSICA A. PALMER-DENIG
Administrative Law Judge

NOTICE

The Department must make this Report available for review by anyone who wishes to review it for at least five working days before it may take any further action to adopt final rules or to modify or withdraw the proposed rules. If the Department makes changes in the rules, it must submit the rules, along with the complete hearing record, to the Chief Administrative Law Judge for a review of those changes before it may adopt the rules in final form.

Because the Administrative Law Judge has determined that the proposed rules are defective in certain respects, state law requires that this Report be submitted to the Chief Administrative Law Judge for her approval. If the Chief Administrative Law Judge approves the adverse findings contained in this Report, she will advise the Department of actions that will correct the defects, and the Department may not adopt the rules until the Chief Administrative Law Judge determines that the defects have been corrected.

However, if the Chief Administrative Law Judge identifies defects that relate to the issues of need or reasonableness, the Department may either adopt the actions suggested by the Chief Administrative Law Judge to cure the defects or, in the alternative, submit the proposed rules to the Legislative Coordinating Commission for the Commission's advice and comment. If the Department makes a submission to the Commission, it may not adopt the rules until it has received and considered the advice of the Commission. However, the Department is not required to wait for the Commission's advice for more than 60 days after the Commission has received the Board's submission.

If the Department elects to adopt the actions suggested by the Chief Administrative Law Judge and make no other changes and the Chief Administrative Law Judge determines that the defects have been corrected, it may proceed to adopt the rules. If the Department makes changes in the rules other than those suggested by the Administrative Law Judge and the Chief Administrative Law Judge, it must submit copies of the rules showing its changes, the rules as initially proposed, and the proposed order adopting the rules to the Chief Administrative Law Judge for a review of those changes before it may adopt the rules in final form.

After adopting the final version of the rules, the Department must submit them to the Revisor of Statutes for a review of their form. If the Revisor of Statutes approves the form of the rules, the Revisor will submit certified copies to the Administrative Law Judge, who will then review them and file them with the Secretary of State. When they are filed with the Secretary of State, the Administrative Law Judge will notify the Department, and the Department will notify those persons who requested to be informed of their filing.