



November 20, 2020

Legislative Reference Library
645 State Office Building
100 Rev. Dr. Martin Luther King Jr. Blvd.
St. Paul, MN 55155

Re: In the Matter of the Proposed Rules of the Department of Human Services Governing the Use of Random Sample Extrapolation in Monetary Recovery, *Minnesota Rules*, Parts 9505.2220; Revisor's ID Number 4567

Dear Librarian:

Enclosed is a copy of the Statement of Need and Reasonableness (SONAR) from the Minnesota Department of Human Services (Department) for the proposed amendments referenced above. DHS is publishing a Dual Notice of Intent to Adopt Rules Without a Public Hearing Unless 25 or More Persons Request a Hearing and Notice of Hearing If 25 or More Requests for Hearing are Received in the November 23, 2020 issue of the *State Register*.

As required by Minnesota Statutes, sections 14.131 and 14.23, the Department is sending an electronic copy of this SONAR to the Legislative Reference Library at the time the Department is sending the Dual Notice to the required parties.

If you have any questions, please contact me by email at vanessa.vogl@state.mn.us.

Yours very truly,

A handwritten signature in black ink that reads 'Vanessa Vogl'.

Vanessa Vogl
Rulemaking Attorney
Administrative Law Office | General Counsel's Office

Enclosure: Statement of Need and Reasonableness

Equal Opportunity Employer

Minnesota Department of Human Services

Office of Inspector General, Surveillance and Integrity Review Section

STATEMENT OF NEED AND REASONABLENESS

**Rules Governing Monetary Recovery through Random Sample Extrapolation;
Minnesota Rules, part 9505.2220; Revisor’s ID Number 4567**

INTRODUCTION

The Minnesota Department of Human Services (Department) is proposing an amendment to Minnesota Rules, part 9505.2220 (Rule 9505.2220), governing the Department’s use of random sample extrapolation to identify and recover overpaid Minnesota Health Care Program (MHCP) funds. This Statement of Need and Reasonableness is prepared pursuant to Minnesota Statutes, sections 14.131 and 14.23. It summarizes the rationale supporting the amendment.

ALTERNATIVE FORMAT

Upon request, this information can be made available in an alternative format, such as large print, braille, or audio. To make a request, contact Vanessa Vogl at the Minnesota Department of Human Services, PO Box 64254, Saint Paul, MN 55164-0254, or by phone at 651-431-3168, or by email at vanessa.vogl@state.mn.us.

BACKGROUND

The Department is the state agency charged with administering MHCP, including Minnesota’s medical assistance program.¹ Vendors of medical and other health care services can enroll with the Department as MHCP providers to be eligible for payment for services provided to people who have health care coverage through MHCP.² The Department oversees health care coverage and services to over one million people in Minnesota each month.

Minnesota Statutes, section 256B.04, subdivision 10 directs the Department to establish by rule criteria and procedures for the identification and prompt investigation of suspected fraud, theft, abuse, and other improper claims for MHCP, and for the imposition of sanctions against a vendor of medical care. Minnesota Statutes, section 256B.04, subdivision 15 requires the Department to establish a utilization review function to guard against the unnecessary and

¹ See Minn. Stat. § 256B.04; Minn. R. 9505.2165, subp. 8. 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.

² See Minn. Stat. § 256B.04, subd. 21; Minn. R. 9505.0175, subp. 38 (definition of “provider”); Minn. Stat. § 256B.02, subd. 7 (definition of “vendor”).

inappropriate use of medical assistance services and excess payments for services. In 1981, the Department promulgated Minnesota Rules, parts 9505.2160-9505.2245 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 in MHCP. Specifically, Minnesota Rules, part 9505.2220 sets out the procedure the Department must follow to identify and recover overpaid MHCP funds. The rule part authorizes the Department's use of random sample extrapolation when there are more than 1,000 claims to be reviewed, or when the services reviewed represent services to 50 or more recipients. Minnesota Rules, parts 9505.2160-9505.2245 were amended in 1991, 1995, and 2008, and only technical changes were made to part 9505.2220.

As it is currently written, part 9505.2220 relies on a forty year-old textbook, does not provide clear guidance about the Department's sampling procedures and requires the Department to issue a notice to a provider of its sampling method before drawing the sample. Collectively, these issues render the rule inefficient, unclear, and lacking in technical precision. The proposed amendment to Rule 9505.2220 will allow SIRS to efficiently recover MHCP funds paid as a result of fraud, abuse or error. The proposed amendment will also allow the Department to provide more detailed guidance to the state and federal contractors who regularly use statistical sampling to determine overpaid MHCP funds in their investigations. Finally, the language proposed by this rule will better inform providers of what to expect when their audits include a statistical sample.

STATUTORY AUTHORITY

Federal Medicaid regulations require a state to designate a single state agency to supervise the administration of a state's medical assistance program.³ The Department has been so designated by Minnesota Statutes, section 256B.04, subdivision 1. Both state and federal law require the Commissioner of Human Services to establish "uniform rules and regulations, not inconsistent with law" to ensure that the medical assistance program will be carried out in an efficient, economic, and impartial manner.⁴ Federal regulations also require the Department to have a statewide surveillance and utilization review program, which is known in Minnesota as the Surveillance and Integrity Review Section (SIRS).⁵

Under Minnesota Statutes, section 256B.04, subdivisions 2, 10 and 15, the Department must establish procedures through administrative rules for the investigation of fraud, theft, abuse and improper payment of MHCP claims. State statutes also require the Department to cooperate with the federal government "in any reasonable manner as may be necessary to

³ 42 C.F.R. § 431.10.

⁴ 42 C.F.R. § 431.10; Minn. Stat. § 256B.04, subd. 2.

⁵ 42 U.S.C. § 1396a(a)(30); 42 C.F.R. §§ 455.12-455.23, 456.3.

qualify for federal aid in connection with the medical assistance program.”⁶ Under these federal and state statutes, the Department has the necessary authority to adopt the proposed rules.

This rulemaking is an amendment to existing rules, so Minnesota Statutes, section 14.125 does not apply.

RULE ANALYSIS: NEED FOR AND REASONABLENESS OF THE RULE AMENDMENT

An amendment to Rule 9505.2220 is necessary and reasonable. As it is currently written, Rule 9505.2220 lacks clarity, relies on a textbook written in 1977, and requires SIRS to issue a notice to a provider of its sampling method before drawing the sample.⁷

The proposed language will resolve inconsistencies and clarify the terminology of the Department’s statistical sampling process. The proposed language reads as follows:

Subpart 1. Authorization.

For the purpose of part 9505.2215, the commissioner is authorized to calculate the amount of monetary recovery from a vendor based upon extrapolation from a random sample of claims submitted by the vendor and paid by the program or programs. The department's random sample extrapolation shall constitute a rebuttable presumption regarding the calculation of monetary recovery. If the presumption is not rebutted by the vendor in the appeal process, the department shall use the extrapolation as the monetary recovery figure specified in subpart 4.

Subp. 2. Definitions.

- A. Probe Sample. “Probe sample” is a limited initial random sample of at least 50 units, which can be used to provide guidance in selecting the sample size for a full random sample.
- B. Extrapolation. “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

⁶ Minn. Stat. § 256B.04, subd. 4.

⁷ These flaws were illustrated by *The Lazarus Project*, a case in which the provider challenged a statistically extrapolated overpayment. In that case, the Commissioner determined that Rule 9505.2220 required adherence to the textbook, but disallowed the use of a confidence interval. The confidence interval is an interval estimate of a population parameter that is discussed at length in the textbook as valuable in a variety of circumstances. Under the current rule language, the Department could never use a confidence interval, even though doing so is encouraged by the text.

extrapolation and its confidence interval depend on the method of random sampling.

- C. Ninety-Five Percent Confidence Interval. "Ninety-Five Percent Confidence Interval" is an interval estimate (estimate with margin of error) for a population parameter computed using a procedure that produces intervals that contain the true parameter for ninety-five percent of all random samples.
- D. Population or Population of Claims. "Population" or "Population of claims" means a defined set of paid claims for a specified time period that are in existence at the time of the audit or investigation.
- E. Random Sample of Claims. "Random Sample of Claims" means a subset of claims chosen from a population of claims using a random sampling method such as simple random sampling, stratified sampling, probability proportional to size sampling, or cluster sampling.
- F. RAT-STATS. "RAT-STATS" refers to the primary statistical software used by the Office of the Inspector General of the United States Department of Health & Human Services and the Centers for Medicare and Medicaid Services.
- G. Sampling Plan. "Sampling plan" means the combination of the identified population, the random sampling method(s), the sample size(s), and the technique(s) for implementing the random sampling method on the population.
- H. Statistical Analysis System. "Statistical Analysis System" or "SAS" is an analytics and statistics software system.

Subp. 3. Decision to use samples.

The department may use sampling and extrapolation to calculate a monetary recovery if:

- A. the claims to be reviewed represent services to 50 or more recipients; or
- B. there are more than 1,000 claims to be reviewed.

Subp. 4. Statistical method.

The department shall use the procedures in this subpart when calculating the amount of monetary recovery by extrapolation from the audit results of a random sample of claims.

- A. The sampling plan and extrapolation shall be chosen and performed according to generally accepted statistical standards and practices, which may include guidance from the Centers for Medicare and Medicaid Services.

- i. The sampling plan shall include a probe sample.
 - ii. The Department shall use tools which include but are not limited to RAT-STATS, SAS or any other generally accepted sampling software and methods.
- B. The vendor shall be required to pay an overpayment identified under this section only if the overpayment identified has a ninety-five percent confidence interval that does not contain \$0.

As discussed further in the Regulatory Analysis of this SONAR, the Department sought guidance from a statistician at the University of Minnesota to review its proposed language and provide an opinion on the clarity of the rule. The Department finds that it is reasonable and necessary to amend this rule to incorporate the appropriate terminology and to provide a clearer description of its statistical sampling process.

Rule 9505.2220 currently requires that, “[t]he sampling method, including drawing the sample, calculating values, and extrapolating from the results of the sample, shall be performed according to statistical procedures published in the following text: W. Cochran, *Sampling Techniques*, John Wiley and Sons, New York 3rd Ed. (1977).” This text, which was written over forty years ago for college-level statistics courses, offers a technical overview of the theory underlying statistical sampling. The Department does not find the book to be instructive or useful to its statistical sampling process. The text was not intended to guide government agencies in the recovery of overpaid public funds. While this text may have initially been referenced in the rule to provide context for statistical sampling, in practice, 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. In its place, the Department hopes to promulgate language that 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 adjust its methods to fit the variety of different sampling scenarios that will likely arise in its investigations. The proposed language will maintain the breadth of scope currently encompassed by the book and allow the Department to conduct statistical sampling in a manner that is responsive to the circumstances of each investigation. The proposed language will require the Department to follow an outline in its sampling procedures and ground its practices in generally accepted mathematical theory. In short, strict alignment to the inaccessible language of a textbook written four decades ago serves only to add confusion to the Department’s statistical sampling process. As such, it is necessary and reasonable to remove the citation to the text from Rule 9505.2220.

Sending a provider notice of the sampling method that the Department plans to use before drawing the sample is inefficient and does nothing to protect the provider’s due process rights. Procedural due process is intended to protect individuals from government deprivation of a liberty or property interest without some meaningful opportunity to challenge the

government's action.⁸ At the time the sample is drawn, nothing is being taken from the provider, and it is not even certain that the Department will seek to recover any overpayment from the provider. Therefore, due process does not require the Department to send the provider notice of the sampling method the Department plans to use.⁹ Once the investigation is complete and the Department has made a final overpayment determination, the provider then has the right to challenge the sampling method the Department used to reach its decision.¹⁰ The current notice requirement in part 9505.2220 serves only to add an unnecessary step to the Department's process without providing any procedural due process protections to providers. As a result, it is necessary and reasonable to remove from part 9505.2220 the requirement that the Department notify providers of the sampling method the Department intends to use.

REGULATORY ANALYSIS

Minnesota Statutes, section 14.131, sets out eight factors for a regulatory analysis that must be included in the SONAR. Paragraphs (1) through (8) below quote these factors and provide the Department's response.

“(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”

The rule amendment may affect any MHCP provider to whom the Department pays claims. Because the rule clarifies existing requirements and does not independently create new substantial costs, the Department expects that the rule amendment will not increase costs of compliance for providers.

“(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”

While the amended language clarifies the manner in which the Department may recover overpayments, it does not change the source or scope of recoverable payments. As such, the Department will not experience substantial cost increases resulting from this rule amendment and does not expect the rule amendment to generate any new revenue.

The implementation and enforcement of the rule will not affect any other state agency.

⁸ See *Mathews v. Eldridge*, 424 U.S. 319, 333, 96 S. Ct. 893, 902, 47 L. Ed. 2d 18 (1976) (“This Court consistently has held that some form of hearing is required before an individual is finally deprived of a property interest.”).

⁹ See *Mathews v. Eldridge*, 424 U.S. 319, 333, 96 S. Ct. 893, 902, 47 L. Ed. 2d 18 (1976) (“The fundamental requirement of due process is the opportunity to be heard *at a meaningful time* and in a meaningful manner.”) (emphasis added) (internal citations and quotation marks omitted).

¹⁰ Minn. R. 9505.2245; see also Minn. R. 9505.2230 (requiring the Department to give written notice to a provider of a monetary recovery, including how the dollar amount was computed).

“(3) a determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule”

The proposed rule amendments continue the Department’s efforts to address fraud and abuse in MHCP as directed by federal regulations. The rule amendment serves to clarify the present rule and eliminate its unnecessary components. The Department expects that the changes to the methods in the rule amendment will be cost neutral to the Department and to MHCP providers. Additionally, like the current rule, the proposed rule amendment is minimally intrusive and creates no impositions on providers.

“(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”

The Department sought guidance from a statistician at the University of Minnesota in its preparation of the proposed rule amendment. The Department sent the statistician its draft of the proposed language and asked that the statistician provide an opinion on the coherence and mathematical integrity of the Department’s proposed rule.

The statistician provided several suggestions¹¹ for improvement of the rule. First, the statistician provided advice on the correct use of terminology and clarified the wording of several definitions. The Department modified its language accordingly.

Second, the statistician advised the Department 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 than 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.

The statistician suggested that including this language would provide further guidance on the Department’s sampling procedures. The statistician recommended that the Department choose set values for \$ZZ, XX% and YYYY, and include those values in the proposed rule language. The statistician 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%. This language would balance the need for accuracy against the time and cost of sampling.

¹¹ The statistician’s final report is included as Appendix 1.

After serious consideration, the Department determined that it could not designate static margins of error that would address the nuances of all possible audits with an adequate level of certainty. Additionally, given the ever-changing nature of health care costs, the Department is extremely hesitant to designate a dollar amount which could quickly become outdated, and, as mentioned above, employing a margin of error controlled only by the percentage of claims in the universe may have a prejudicial effect on smaller providers. The Department believes that the determination of the margin of error is a decision that is best made on a case by case basis.

Finally, the Department declined to incorporate the language allowing the Department to, “limit the full sample size to at most YYYY claims.” The Department prefers to use sample sizes produced by RAT-STATS¹² or similar tools. The Department has not found sample sizes calculated in this manner to be unduly burdensome.

Furthermore, 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.

“(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”

There are no probable costs of complying with the proposed rule for MHCP providers. The overall substance and effect of the rule will remain unchanged, as the proposed amendment seeks only to clarify existing language and simplify procedures.

“(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”

The consequences of not adopting the proposed amendment would be detrimental to the Department and providers.

If the methodology language proposed by this rule is not adopted, providers will continue to have very little knowledge of what to expect when their audits include a statistical sample.

Additionally, 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.

The proposed language will also allow the Department to provide more detailed guidance to the state and federal contractors who regularly use statistical sampling to determine overpaid funds in their investigations. Without clearer language, the Department’s ability to provide this guidance will be limited.

¹² RAT-STATS refers to the primary statistical sampling software used by the Office of the Inspector General of the United States Department of Health & Human Services and the Centers for Medicare and Medicaid Services.

“(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”

The proposed rule amendment does not contain any differences from existing federal regulations. Indeed, the rule incorporates the software and methodology used by the federal government in its statistical sampling of potentially overpaid Medicare claims.¹³ Moreover, the Department finds that the proposed rule aligns well with the Office of the Inspector General of the United States Department of Health & Human Services’ approval of statistical sampling in program integrity operations.¹⁴

“(8) an assessment of the cumulative effect of the rule with other federal and state regulations related to the specific purpose of the rule. . . . ‘[C]umulative effect’ means the impact that results from incremental impact of the proposed rule in addition to other rules, regardless of what state or federal agency has adopted the other rules. Cumulative effects can result from individually minor but collectively significant rules adopted over a period of time.”

Other state and federal regulations related to the specific purposes of this proposed amendment are:

1. 42 U.S.C. § 1396a(a)(30), which requires state plans for Medicaid to provide methods for monitoring payments.
2. 42 U.S.C. § 1396b(a), which sets out payment limitations in Medicaid.
3. 42 U.S.C. 1320a-7k, which are Medicare and Medicaid Program Integrity Provisions.
4. 42 C.F.R. § 455.1, which requires states to establish a fraud and abuse detection and investigation program in Medicaid.
5. Minn. Stat. § 256B.04, subd. 10, which requires the Department to establish criteria for identification and investigation of fraud, theft and abuse in MA.
6. Minnesota Rule 9505.2160, which sets out the scope of SIRS’ authority and identifying relevant state and federal statutes.
7. Minnesota Rules, part 9505.2215, which sets out the standards for the recovery of overpaid MHCP funds.

The cumulative effect of the proposed amendment with these state and federal regulations will be to ensure that the Department is able to carry out its program integrity responsibilities in a manner that is as efficient and clear as possible. As explored in the Rule Analysis of this SONAR, the purpose of the proposed amendment is to clarify the language of the rule and eliminate unnecessary provisions. MHCP providers are already expected to comply with this rule provision

¹³ Centers for Medicare & Medicaid Services, *Medicare Program Integrity Manual*, Pub. No. 100-08 (2018), available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c08.pdf>.

¹⁴ See, e.g. Department of Health and Human Services, Office of Inspector General, *Statistical Sampling: A Toolkit for MFCUs* (2018), available at <https://oig.hhs.gov/fraud/medicaid-fraud-control-units-mfcu/files/MFCU%20Sampling%20Guidance%20Final.pdf>.

as well as the other federal and state regulations that pertain to monetary recovery. Therefore, the cumulative effect will be small and manageable.

PERFORMANCE-BASED RULES

Minnesota Statutes, sections 14.002 and 14.131, require that the SONAR describe how the agency, in developing the rules, considered and implemented performance-based standards. Performance-based standards emphasize superior achievement in meeting the Department's regulatory objectives and maximum flexibility for the regulated parties and the Department in meeting those goals.

As noted previously, the Department has identified three objectives of the rule amendment: 1) to clarify existing language governing the Department's sampling procedures, 2) to eliminate reliance on a textbook published in 1977, and 3) to remove an unnecessary requirement that the Department provide advance notice of its sampling procedures to providers. The Department endeavored to meet all of these objectives in a manner that is concise and straightforward. The 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.

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.

ADDITIONAL NOTICE

Minnesota Statutes, sections 14.131 and 14.23, require that the SONAR contain a description of the Department's efforts to provide additional notice to persons who might be affected by the proposed rules or explain why these efforts were not made.

This Additional Notice Plan was reviewed by the Office of Administrative Hearings and approved as amended in a May 6, 2019 Order by Administrative Law Judge Laura Sue Schlatter.

The Department followed its Additional Notice Plan when it published the Request for Comments, and will follow the same Additional Notice Plan when it publishes the proposed rules and Notice of Intent to Adopt Rules. For this rule amendment, the Department's Additional Notice Plan consists of:

- Sending notice to persons registered with the Department to receive notices of rulemaking;
- 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 providers through their MN-ITS mailboxes (MN-ITS is the free, web-based, HIPAA-compliant system for providers to submit electronic claims. See more information about MN-ITS later in this letter.); and
- Further notifying MHCP providers as follows:

- Posting to the [Provider news and updates](#) webpage for which the Department provides a link to providers through their MN–ITS mailboxes;
- Sending notice to providers through the Department’s email distribution lists to which providers can choose to subscribe to receive information related to specific topics; and
- Sending notice to provider associations for which the Department maintains contact lists.

The Department’s Additional Notice Plan complies with the statute because it reaches the group of people that is most significantly affected by the rule amendment: MHCP providers.

All MHCP providers sign a provider agreement with the Department when they apply for enrollment, and the MN–ITS mailbox is the primary way in which the Department communicates with MHCP providers. In the “welcome letter” the Department sends to providers to notify them of their enrollment, and in the MHCP Provider Manual, providers are informed that they must register for MN–ITS in order to submit claims and other transactions and receive communication relevant to their enrollment. The Department rarely communicates to providers via email or U.S. mail, relying instead on the provider’s MN–ITS mailbox. Sending notice of this rulemaking directly to the MN–ITS mailbox of each individual provider provides notice directly to each individual MHCP provider.

The providers directly affected by this rule change are the pay-to providers to whom the Department pays claims. These providers are required to have a MN–ITS mailbox. The Department would not use the random sample extrapolation rule to assess overpayments against individual support providers (Consumer-Directed Community Supports workers, Consumer Support Grant workers, and Personal Care Assistants) who do not directly submit claims to the Department. For example, the Department would not use the random sample extrapolation rule to assess an overpayment against an individual PCA who provides services, but who does not submit claims for payment. The Personal Care Provider Organization (PCPO) is ultimately responsible for submitting claims for payment to the Department and is also responsible for the accuracy of those claims. As a result, the Department could use the statistical extrapolation rule to assess an overpayment against a PCPO as the pay-to provider, even though the direct care services were provided by the individual PCA, who is employed by that PCPO.¹⁵ All MHCP providers who are directly affected by this rule have a MN–ITS mailbox and will receive notice of the rulemaking through that channel under this proposed Additional Notice Plan.

In addition to a direct message through their MN–ITS mailboxes, the Department will also advise MHCP providers about the rule change through the following three channels:

¹⁵ In its administrative actions, SIRS typically initiates recoveries of overpayments from the pay-to providers. There are some scenarios, like criminal restitution, in which a provider who did not directly submit claims to DHS would be required to personally repay overpaid funds, but that would not involve this statistical extrapolation rule.

- 1) Posting the notice to the [Provider news and updates](#) webpage. The news announcements advise providers about events and policy or program changes that are of interest to providers. The Department provides a link to the news webpage to providers every other week through their MN–ITS mailboxes. The public may also see the news by going to the Department’s public website at <https://mn.gov/dhs/partners-and-providers/news-initiatives-reports-workgroups/minnesota-health-care-programs/provider-news/>.
- 2) Emailing the notice to all of the distribution lists to which providers can choose to subscribe to receive information related to specific topics. The Department maintains email distribution lists for providers pertaining to the following topics:
 - Audiologists and Hearing Aid Dispensers
 - Child and Teen Checkups
 - Chiropractors
 - Clearinghouses
 - County and Tribal Human Services
 - Day training and habilitation (DT&H) services
 - Dental care providers
 - Family planning providers
 - Health Care Delivery System
 - Home care providers and personal care assistance
 - Hospice
 - Hospitals
 - Housing Support Supplemental Services
 - Immunizations and vaccinations
 - Managed care organizations
 - Medical supplies and equipment
 - Mental health providers
 - Nursing facilities and ICF-DD
 - Pharmacies
 - Physicians and clinic services
 - Rehabilitation services
 - School district and Individualized Education Program
 - Substance Use Disorder
 - Transportation services
 - Vision providers
 - Waivers
- 3) Emailing the notice to provider associations for which the Department maintains contact lists. The Department often sends information to these contacts for posting in their newsletters or distributing through their email lists to their members. We are including a copy of this contact list for your reference.

The Department’s Additional Notice Plan also addresses statutory notice requirements. The Department initially published a Request for Comments in the State Register on September 9, 2019 as an Official Notice. The comment period remained open until December 4, 2019. The

Department also sent the Request for Comments to everyone who registered for the Department's rulemaking notification list under Minnesota Statutes, section 14.14, subdivision 1a. The list mainly consists of MHCP providers, advocates and organizations who work with current and potential MHCP recipients, and employees of the Department. The Department also gave notice to the Legislature as required by Minnesota Statutes, section 14.116.

As a result of following our additional notice plan, DHS received comments from providers. Commenters were concerned that eliminating the requirement that the Department notify providers before drawing a sample would reduce protections for providers. Commenters also voiced a concern that the removal of the reference to the textbook would create uncertainty in the sampling process. The comments primarily concerned potential consequences of the rule amendment, and questions for clarification. Some providers (though not all) commented that they do not support the rule amendment. DHS considered each comment and in some cases engaged in clarifying conversations with commenters.

Our Notice Plan did not include notifying the Commissioner of Agriculture because the rules do not affect farming operations per Minnesota Statutes, section 14.111.

CONSULTATION WITH MMB ON LOCAL GOVERNMENT IMPACT

As required by Minnesota Statutes, section 14.131, the Department will consult with Minnesota Management and Budget (MMB). Before publishing the Notice of Intent to Adopt, the Department will send MMB the following documents: the Governor's Office Proposed Rule and SONAR Form; the proposed rules; and the SONAR. The Department will submit a copy of the cover correspondence and any response received from MMB to OAH at the hearing or with the documents it submits for ALJ review.

The Department does not anticipate any fiscal impact or benefit of the proposed rule amendment on local governments. The rule does not involve local governments directly or indirectly.

DETERMINATION ABOUT RULES REQUIRING LOCAL IMPLEMENTATION

As required by Minnesota Statutes, section 14.128, subdivision 1, the Department has considered whether the proposed rule amendment will require a local government to adopt or amend any ordinance or other regulation in order to comply with these rules. The Department has determined that it does not, because the rule amendment only applies to the Department's determination of MHCP overpayments. No local governments are required to adopt ordinances or regulations for implementation of this rule amendment.

COST OF COMPLYING FOR SMALL BUSINESS OR CITY

As required by Minnesota Statutes, section 14.127, the Department has considered whether the cost of complying with the proposed rules in the first year after the rules take effect

will exceed \$25,000 for any small business or small city. The Department has determined that the cost of complying with the proposed rules in the first year after the rules take effect will not exceed \$25,000 for any small business or small city.

This rule amendment does not affect small cities. And while the rule amendment does affect small businesses engaged as MHCP providers, the Department does not anticipate that any provider will experience costs exceeding \$25,000 to comply with this rule in the first year. The cost to comply with this rule is minimal, as the rule amendment does not require providers to make any changes to their billing systems or structures.

LIST OF WITNESSES

If this proposed rule amendment goes to a public hearing, the Department anticipates the possibility of having Dr. Gary W. Oehlert testify at the hearing.

LIST OF EXHIBITS

In support of the need for and reasonableness of the proposed rules, the Department anticipates that it will enter the following exhibits into the hearing record:

Exhibit 1 – Final Report Regarding Review of Proposed Revised Language for: 9505.2220

Monetary Recovery; Random Sample Extrapolation. Gary W. Oehlert, Ph. D., School of Statistics, University of Minnesota.

This exhibit is also included as Appendix 1 of this document.

CONCLUSION

Based on the foregoing, the proposed rules are both needed and reasonable.

9/10/2020



Amy Akbay
Chief General Counsel
Minnesota Department of Human Services

APPENDIX 1

Dr. Oehlert's report is copied here. Highlights are retained from original report.

Review of Proposed Revised Language for: 9505.220 Monetary Recovery; Random Sample Extrapolation

Gary W. Oehlert, Ph. D.
School of Statistics
University of Minnesota

June 21, 2018

The requested review focuses on two issues provided by the department:

First, please provide us with an assessment of our use of statistical terms in the proposed rule language. We would like to know whether we are using these terms correctly and appropriately.

Second, please compare the proposed rule language with the current rule language, and identify any instances in which the proposed changes render the rule less statistically sound than the current language.

I have expanded this charge somewhat to make suggestions on the language where I believe that the language can be made more precise and/or understandable without changing its meaning.

In comparing the current and proposed language, subparts 1, 2, and 3 have become subparts 1, 3, and 4, and a new subpart 2 (definitions) has been inserted. Thus the first question is primarily about new subpart 2, and the second question is primarily about new subpart 4; new subparts 1 and 3 appear to be identical to old subparts 1 and 2.

Let me begin by presenting "clean copy" suggested text for subparts 2 and 4. Then I will go back through each with detailed comments and highlighted changes.

Clean copy:

Subp. 2. Definitions.

- A. Population or Population of Claims. "Population" means a set of items about which we wish to learn. "Population of claims" means a defined set of paid claims for a specified time period that are in existence at the time of the audit or investigation.
- B. Random Sample or Random Sample of Claims. "Random sample" means a subset of items chosen from a population using a random sampling method such as simple random sampling, stratified sampling, probability proportional to size (PPS) sampling, or cluster sampling. "Random sample of claims" means a random sample from the population of claims.
- C. Discovery Sample. "Discovery sample" as used here is a limited, initial random sample of at least 50 units, typically used to provide guidance in selecting the sample size for a full random sample.

- D. Sampling Plan. "Sampling plan" as used here is the combination of the identified population, the random sampling method(s), the sample size(s), and the technique(s) for implementing the random sampling method on the population.
- E. Ninety-five percent confidence interval. A "ninety-five percent confidence interval" is an interval estimate (estimate with margin of error) for a population parameter computed using a procedure that produces intervals that contain the true parameter for ninety-five percent of all random samples.
- F. Extrapolation. "Extrapolation" as used here 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.
- G. RAT-STATS. "RAT-STATS" refers to the primary statistical software used by the Office of the Inspector General of the United States Department of Health & Human Services and the Centers for Medicare and Medicaid Services.
- H. Statistical Analysis System. "Statistical Analysis System" or "SAS™" is an analytics and statistics software system from the SAS Institute.

Subp. 4. Statistical method

The department shall use the procedures in this subpart when calculating the amount of monetary recovery by extrapolation from the audit results of a random sample of claims.

- A. The sampling plan and extrapolation shall be chosen and performed according to generally accepted statistical standards and practices, which may include guidance from the Centers for Medicare and Medicaid Services or generally accepted texts on statistical sampling. In particular,
 - a. The sampling plan shall represent a compromise between the goals of high precision, low cost, and wide acceptability.
 - b. The sampling plan shall include a discovery sample.
 - c. The Department shall use tools that include but are not limited to RAT-STATS, SAS or any other generally accepted sampling software and methods.
- B. 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 than 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.
- C. The Department may, with agreement of the vendor, terminate sampling after the discovery sample and extrapolate the total overpayment from the discovery sample.
- D. The vendor shall be required to pay an overpayment identified under this section only if the overpayment identified has a ninety-five percent confidence interval that does not contain \$0.

OK, this isn't really clean copy, because the Department still needs to specify XX, ZZ, and YYYY in Subp 4. B on sample size. Selection of the precision goal for the sample and the upper limit of the sample size have both political and budgetary implications that go beyond the statistics of the issue.

Detailed comments on Subpart 2. This subpart lists the definitions of several terms and concepts. The definitions are presented in alphabetical order, which is certainly traditional and perhaps required, but MN DHS might consider presenting the definitions in conceptual order for ease of understanding. I

present my comments and suggestions below in conceptual order. Changes from the proposed language are highlighted in yellow.

Several of the definitions in the proposed language include aspects of the current problem in the definition of terms/concepts that are much more general. In my suggestions, I have generally tried to make the definitions more general, or at least to include both a general and a specific.

“Universe”. I prefer “population” to “universe”, although both are technically correct. I have used population in my suggestions, but it is easy to go back to universe if you wish. Perhaps something like:

Universe Population or Population of Claims. “Universe Population” means a set of items about which we wish to learn. “Population of claims” means a defined set population of paid claims in for a specified time period that are in existence at the time of the audit or investigation.

“Sample”. The sample is the units selected, regardless of the number or how it is selected. Let’s be sure we emphasize random samples. Also, I have tried not to limit the form of sampling; the current language favors simple random samples (which is reasonable), and the proposed language is silent on type of sample. If you want to be more restrictive, we can certainly change the wording to reflect that. How about:

Random Sample or Random Sample of Claims. “Random sample” means a subset of items chosen from a population using a random sampling method such as simple random sampling, stratified sampling, probability proportional to size (PPS) sampling, or cluster sampling. “Random sample of claims” means a random sample from the population of claims. statistically valid number of sampling units obtained for review from the universe of claims.

“Discovery Sample”. I suggest we define this term and then use it in the methods section. This is sometimes called a probe sample or initial sample; the terminology is not consistent across fields.

Discovery Sample. “Discovery sample” as used here is a limited, initial random sample of at least 50 units, typically used to provide guidance in selecting the sample size for a full random sample.

“Sampling Plan”. I would suggest adding a specific definition of sampling plan separate from those of the sample and the population. I think this could ease some of the later text.

Sampling Plan. “Sampling plan” as used here is the combination of the identified population, the random sampling method(s), the sample size(s), and the technique(s) for implementing the random sampling method on the population.

“Confidence level”. I am afraid that your explanation is one of the most common misconceptions about confidence intervals; it’s what we all wish a confidence interval meant, but it is not what it actually means. Please consider the following:

Ninety-five percent confidence interval. A “ninety-five percent confidence interval” is an interval estimate (estimate with margin of error) for a population value computed using a procedure

that produces intervals that contain the true parameter for ninety-five percent of all random samples.

“Extrapolation”. As a statistician, I would simply call this estimation. However, given that extrapolation was used in the current language, it is probably best to maintain the usage. I found the proposed wording a little awkward and suggest the following wording be considered:

Extrapolation. “Extrapolation” as used here means the methodology of estimating an unknown population value by projecting, with a calculated precision of margin of error, the results of the review of a from a random sample to the universe population from which the random sample was drawn using a statistically valid sampling methodology. The form and computations for the extrapolation and confidence interval depend on the method of random sampling.

“Statistical Analysis System”. SAS is so much more than sampling. It might be better to say something like:

Statistical Analysis System. “Statistical Analysis System” or “SAS” is an analytics and statistics software system from the SAS Institute. used in statistical sampling

As a general comment, SAS is almost certainly a registered trademark of the SAS Institute; I don’t know the parentage of RAT-STATS. Do you need to indicate trademarks in the rule?

Detailed comments on Subpart 4. Your proposed language is generally less prescriptive than the current language. I think that is good from the department’s perspective as it allows you the opportunity to obtain more precise extrapolations at lower cost.

Your proposed language is silent regarding sample size; this is a substantial shortcoming in the proposed language. Sample size is usually chosen by compromise between trying to estimate as accurately as possible (which leads to a large sample size), trying to reduce sampling costs (which leads to a small sample size), and trying to use as simple a sampling scheme as possible (which could constrain the sampling and extrapolation methods). The current language says “at least 50 claims,” which is incomplete and arbitrary in its own way, but at least not silent on the topic. In my suggestions, I include a suggestion that is still incomplete and needs three values to be filled in by you. Again, my suggested changes from the proposed language are highlighted in yellow.

The introductory sentence of subpart 4 is acceptable, but I think it can be made somewhat more understandable with a minor edit:

The department shall use the methods procedures in this subpart in when calculating the amount of monetary recovery by extrapolation from the audit results of a random sample extrapolation of claims.

For section A, I suggest you make use of “sampling plan” to simplify the text. I also suggest you include the option of taking guidance from standard text(s) on sampling as in the current language; if you want to include specific sample texts, these could include *Sampling: Design and Analysis 2nd Edition* (2010) by Sharon Lohr (which is the book I would consult first).

I have also added a sentence describing the goals of the sampling plan. To some extent, this is covered in “generally accepted standards and practices,” but given the fact that the proposed language is generally less prescriptive than the current language, I thought that a bit of explicit guidance might be useful. Left unstated is the fact that “generally accepted standards and practices” admits the use of ratio estimates, regression estimates, and other more complex estimation techniques that appear to be disallowed (or at least discouraged) by the current language.

The sampling plan and extrapolation method, including drawing the sample, stratifying the sample (if necessary), calculating values, and extrapolating from the results of the sample, shall be chosen and performed according to generally accepted statistical standards and procedures practices, which may include guidance from the Centers for Medicare and Medicaid Services or generally accepted texts on statistical sampling. In particular,

- i. The sampling plan shall represent a compromise between the goals of high precision, low cost, and wide acceptability.
- ii. The sampling plan shall include a discovery sample.
- iii. The Department shall use tools that which include but are not limited to RAT-STATS, SAS or any other generally accepted sampling software and methods.

I suggest that you insert a section B on sample size. There are many ways to do that. In my suggestion, I have said that the sample size is chosen so that the margin of error on the extrapolation of overpayment should be no more than a percentage (to be defined by you) of the total payments already made, but in no case must the margin of error be made less than an absolute number you can specify (this absolute limit might not really be necessary, but I included it as another way to limit costs). Doing this requires the results of the discovery sample as well as the professional knowledge and skills of MN DHS staff. I also suggest that the department be allowed to cap the sample size (in order to control costs). You would need to determine both the precision goal and a reasonable cap on the sample size.

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 than 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.

We need to allow for the possibility of stopping after the discovery sample. This is also to control costs, especially in situations where the discovery sample indicates there may be little to recover.

The Department may, with agreement of the vendor, terminate sampling after the discovery sample and extrapolate the total overpayment from the discovery sample.

Finally, I have reworded part D (part B in your proposed language) to conform more closely to statistical language.

The vendor shall be required to pay an overpayment identified under this section only if the overpayment identified has a ninety-five percent confidence interval that does not contain \$0 level or greater.

Minnesota Department of Human Services

Office of Inspector General, Surveillance and Integrity Review Section

DUAL NOTICE: Notice of Intent to Adopt Rules Without a Public Hearing Unless 25 or More Persons Request a Hearing, and Notice of Hearing if 25 or More Requests for Hearing Are Received; Revisor's ID Number 4567

Proposed Amendment to Rules Governing Use of Random Sample Extrapolation in Monetary Recovery, Minnesota Rules, part 9505.2220

Introduction. The Minnesota Department of Human Services intends to adopt rules without a public hearing following the procedures in the rules of the Office of Administrative Hearings, Minnesota Rules, parts 1400.2300 to 1400.2310, and the Administrative Procedure Act, Minnesota Statutes, sections 14.22 to 14.28. If, however, 25 or more persons submit a written request for a hearing on the rules by 4:30 p.m. on December 31, 2020, the Department will hold a virtual public hearing on the proposed rule changes. **An Administrative Law Judge will conduct the hearing** starting at 9:30 a.m. on Thursday, January 28, 2021. To find out whether the Department will adopt the rules without a hearing or if it will hold the hearing, you should contact the agency contact person after December 31, 2020 and before January 28, 2021.

For video and audio connection to the virtual hearing, join through an internet connection, such as with a computer or tablet:

Enter <https://minnesota.webex.com>

Meeting number: 146 976 9291

Meeting password: TsYYgtyA232

For audio connection only, join the hearing by phone:

Call: 1-415-655-0003 (US Toll)

Access code: 146 976 9291

Agency Contact Person. Submit any comments or questions on the rules or written requests for a public hearing to the agency contact person. The agency contact person is:

Vanessa Vogl

Minnesota Department of Human Services

Administrative Law Office

PO Box 64254

Saint Paul, MN 55164-0254

Email: Vanessa.Vogl@state.mn.us

Phone: 651-431-3168

Fax: 651-431-7714

TTY users may call the Department at (800) 627-3529. You may also review the proposed rule and submit written comments via the [Office of Administrative Hearings Rulemaking eComments website https://minnesotaoah.granicusideas.com/discussions](https://minnesotaoah.granicusideas.com/discussions).]

Subject of Rules and Statutory Authority. The proposed rules are about the Department's use of random sample extrapolation in monetary recovery for fraud, theft, abuse, and other improper claims related to the Minnesota Health Care Programs (MHCP). As it is currently written, Minnesota Rules, part 9505.2220 does not provide clear guidance about the Department's sampling procedures, references a textbook published in 1977 that was not intended to guide government agencies in the recovery of overpaid public funds, and requires the Department to issue a notice to a provider of its sampling method before drawing the sample. The proposed amendment to part 9505.2220 will allow the Department to efficiently recover MHCP funds paid as a result of fraud, abuse, or error. The proposed amendment will enable the Department to provide more detailed guidance to the state and federal contractors who regularly use statistical sampling to determine overpaid MHCP funds in their investigations, while still allowing the Department flexibility to adjust its methods to fit the variety of different sampling scenarios that arise in its investigations. The proposed amendment will also better inform providers of what to expect when their audits include a statistical sample.

The current rule language uses technical terms without defining them. The proposed amendment creates a subpart that contains definitions related to statistical sampling. Providing definitions helps to clarify the random sample extrapolation process. The proposed amendment also identifies certain sampling software used for reviewing claims, but gives the Department flexibility to use other generally accepted software and methods to maximize its responsiveness to the circumstances of each investigation. And, like the current language, the proposed amendment sets certain parameters around when the Department may use sampling and extrapolation to calculate monetary recovery, as well as when a provider will be required to pay an overpayment determined through this method.

The statutory authority to adopt the rules is Minnesota Statutes, section 256B.04, subdivision 10. A copy of the proposed rules is published in the State Register and available on the Department's website at <https://mn.gov/dhs/partners-and-providers/policies-procedures/rulemaking/>. A free copy of the rules is also available upon request from the agency contact person listed above.

Comments. You have until 4:30 p.m. on Thursday, December 31, 2020, to submit written comments in support of or in opposition to the proposed rules or any part or subpart of the rules. Your comments must be in writing and received by the agency contact person by the due date. Comments are encouraged. Your comments should identify the portion of the proposed rules addressed, the reason for the comment, and any change proposed. You are encouraged to propose any change that you desire. Any comments that you have about the legality of the proposed rules must also be made during this comment period.

Request for a Hearing. In addition to submitting comments, you may also request that the Department hold a hearing on the rules. You must make your request for a public hearing in writing, which the agency contact person must receive by 4:30 p.m. on Thursday, December 31, 2020. You must include your name and address in your written request. In addition, you must identify the portion of the proposed rules that you object to or state that you oppose the entire set of rules. Any request that does not comply with these requirements is not valid and the agency cannot count it when determining whether it must hold a public hearing. You are also encouraged to state the reason for the request and any changes you want made to the proposed rules.

Withdrawal of Requests. If 25 or more persons submit a valid written request for a hearing, the Department will hold a public hearing unless a sufficient number of persons withdraw their requests in writing. If enough requests for hearing are withdrawn to reduce the number below 25, the agency must give written notice of this to all persons who requested a hearing, explain the actions the agency took to effect the withdrawal, and ask for written comments on this action. If a public hearing is required, the agency will follow the procedures in Minnesota Statutes, sections 14.131 to 14.20.

Alternative Format/Accommodation. Upon request, this information can be made available in an alternative format, such as large print, braille, or audio. To make such a request or if you need an accommodation to make this hearing accessible, please contact the agency contact person at the address or telephone number listed above.

Modifications. The Department might modify the proposed rules, either as a result of public comment or as a result of the rule hearing process. It must support modifications by data and views submitted to the agency or presented at the hearing. The adopted rules may not be substantially different than these proposed rules unless the Department follows the procedure under Minnesota Rules, part 1400.2110. If the proposed rules affect you in any way, the Department encourages you to participate in the rulemaking process.

Cancellation of Hearing. The Department will cancel the hearing scheduled for January 28, 2021, if the agency does not receive requests for a hearing from 25 or more persons. If you requested a public hearing, the agency will notify you before the scheduled hearing whether the hearing will be held. You may also contact Vanessa Vogl after December 31, 2020 to find out whether the hearing will be held.

Notice of Hearing. If 25 or more persons submit valid written requests for a public hearing on the rules, the Department will hold a hearing following the procedures in Minnesota Statutes, sections 14.131 to 14.20. The Department will hold the hearing on the date and at the time and place listed above. The hearing will continue until all interested persons have been heard. Administrative Law Judge Jessica A. Palmer-Denig is assigned to conduct the hearing. Judge Palmer-Denig can be reached at the Office of Administrative Hearings, 600 North Robert

Street, P.O. Box 64620, Saint Paul, Minnesota 55164-0620, telephone (651) 361-7875, and fax (651) 539-0310.

Hearing Procedure. If the Department holds a hearing, you and all interested or affected persons, including representatives of associations or other interested groups, will have an opportunity to participate. You may present your views either orally at the hearing or in writing at any time before the hearing record closes. All evidence presented should relate to the proposed rules. You may also submit written material to the Administrative Law Judge to be recorded in the hearing record for five working days after the public hearing ends. At the hearing the Administrative Law Judge may order that this five-day comment period is extended for a longer period but not more than 20 calendar days. Following the comment period, there is a five-working-day rebuttal period when the agency and any interested person may respond in writing to any new information submitted. No one may submit new evidence during the five-day rebuttal period.

All post-hearing comments and responses must be submitted to the Administrative Law Judge no later than 4:30 p.m. on the due date. The Office of Administrative Hearings strongly encourages all persons submitting comments and responses to do so using the [Administrative Hearings' Rulemaking eComments website](https://minnesotaoah.granicusideas.com/discussions) <https://minnesotaoah.granicusideas.com/discussions>. If using the eComments website is not possible, you may submit post-hearing comments in person, via United States mail, or by fax addressed to Judge Palmer-Denig at the address or fax number listed in the Notice of Hearing section above.

All comments or responses received will be available for review at the Department of Human Services or on the agency's website at <https://mn.gov/dhs/partners-and-providers/policies-procedures/rulemaking/>. This rule hearing procedure is governed by Minnesota Rules, parts 1400.2000 to 1400.2240, and Minnesota Statutes, sections 14.131 to 14.20. You may direct questions about the procedure to the Administrative Law Judge.

Statement of Need and Reasonableness. The statement of need and reasonableness summarizes the justification for the proposed rules, including a description of who will be affected by the proposed rules and an estimate of the probable cost of the proposed rules. It is now available from the agency contact person. You may review or obtain copies for the cost of reproduction by contacting the agency contact person. The SONAR is also available on the Department of Human Service's website at <https://mn.gov/dhs/partners-and-providers/policies-procedures/rulemaking/>.

Lobbyist Registration. Minnesota Statutes, chapter 10A, requires each lobbyist to register with the State Campaign Finance and Public Disclosure Board. Ask any questions about this requirement of the Campaign Finance and Public Disclosure Board at: Suite #190, Centennial Building, 658 Cedar Street, St. Paul, Minnesota 55155, telephone (651) 539-1180 or 1-800-657-3889.

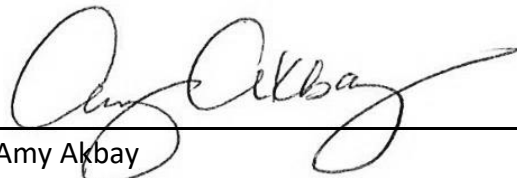
Adoption Procedure if No Hearing. If no hearing is required, the agency may adopt the rules after the end of the comment period. The Department will submit the rules and supporting documents to the Office of Administrative Hearings for a legal review. You may ask to be notified of the date the rules are submitted to the office. If you want to receive notice of this, to receive a copy of the adopted rules, or to register with the agency to receive notice of future rule proceedings, submit your request to the agency contact person listed above.

Adoption Procedure after a Hearing. If a hearing is held, after the close of the hearing record, the Administrative Law Judge will issue a report on the proposed rules. You may ask to be notified of the date that the Administrative Law Judge's report will become available, and can make this request at the hearing or in writing to the Administrative Law Judge. You may also ask to be notified of the date that the agency adopts the rules and the rules are filed with the Secretary of State by requesting this at the hearing or by writing to the agency contact person stated above.

Order. I order that the rulemaking hearing be held at the date, time, and location listed above.

9/10/2020

Date



Amy Akbay

Chief General Counsel

Minnesota Department of Human Services

1.1 **Department of Human Services**

1.2 **Proposed Permanent Rules for Surveillance and Integrity and Review: Monetary**
1.3 **Recovery; Random Sample Extrapolation**

1.4 **9505.2220 MONETARY RECOVERY; RANDOM SAMPLE EXTRAPOLATION.**

1.5 *[For text of subpart 1, see Minnesota Rules]*

1.6 Subp. 1a. **Definitions.** For purposes of this part, the following terms have the meanings
1.7 given them.

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

1.12 B. "95 percent confidence interval" means an interval estimate, or estimate with
1.13 a margin of error, for a population parameter computed using a procedure that produces
1.14 intervals that contain the true parameter for 95 percent of all random samples.

1.15 C. "Population" or "population of claims" means a defined set of paid claims for
1.16 a specified time period that exist at the time of the audit or investigation.

1.17 D. "Probe sample" means a limited initial random sample of at least 50 units which
1.18 can be used to provide guidance in selecting the sample size for a full random sample.

1.19 E. "Random sample of claims" means a subset of claims chosen from a population
1.20 of claims using a random sampling method including simple random sampling, stratified
1.21 sampling, probability proportional to size sampling, cluster sampling, or any other sampling
1.22 methods that are generally accepted amongst statisticians.

1.23 F. "RAT-STATS" refers to the primary statistical software used by the Office of
1.24 the Inspector General of the United States Department of Health and Human Services and
1.25 the Centers for Medicare and Medicaid Services.

2.1 G. "Sampling plan" means the combination of the identified population, the random
2.2 sampling method, the sample size, and the technique for implementing the random sampling
2.3 method on the population.

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

2.6 *[For text of subpart 2, see Minnesota Rules]*

2.7 Subp. 3. **Statistical method.** The department shall use the ~~methods in items A to D~~
2.8 ~~in~~ procedures in this subpart when calculating the amount of monetary recovery by random
2.9 sample extrapolation from the audit results of a random sample of claims. ~~The federal share~~
2.10 ~~of overpayment determined by the federal government under a federal random sample~~
2.11 ~~extrapolation method shall be recovered by the department from a medical assistance vendor~~
2.12 ~~according to Minnesota Statutes, section 256B.0641, subdivision 1, clause (1).~~

2.13 A. ~~Samples of a given size shall be selected in such a way that every sample of~~
2.14 ~~that size shall be equally likely to be selected, these samples are called simple random~~
2.15 ~~samples. The department may choose to employ other sampling designs, such as the stratified~~
2.16 ~~random sampling, if it determines that those designs are more likely to lead to greater~~
2.17 ~~precision, or a closer approximation to the population mean. The department shall tell the~~
2.18 ~~provider the sampling method the department is using prior to drawing the sample. The~~
2.19 sampling plan and extrapolation shall be chosen and performed according to generally
2.20 accepted statistical standards and practices, which includes guidance from the Centers for
2.21 Medicare and Medicaid Services.

2.22 (1) The sampling plan shall include a probe sample.

2.23 (2) The department shall use tools that include RAT-STATS, SAS, or any
2.24 other generally accepted sampling software and methods.

3.1 B. ~~Samples shall only be selected from claims for health services provided within~~
3.2 ~~the interval of time that coincides with the interval during which money allegedly was~~
3.3 ~~overpaid and for which recovery will be made.~~ The vendor shall be required to pay an
3.4 overpayment identified under this part only if the overpayment identified has a 95 percent
3.5 confidence interval that does not contain zero dollars.

3.6 C. ~~The sampling method, including drawing the sample, calculating values, and~~
3.7 ~~extrapolating from the results of the sample, shall be performed according to statistical~~
3.8 ~~procedures published in the following text: W. Cochran, Sampling Techniques, John Wiley~~
3.9 ~~and Sons, New York 3rd Ed. (1977). Sampling Techniques is incorporated by reference~~
3.10 ~~and is available through the Minitex interlibrary loan system. Samples must consist of at~~
3.11 ~~least 50 claims. Each stratum in a stratified sample must contain at least 30 claims or, if a~~
3.12 ~~population stratum contains less than 30 claims, all of the claims in that population stratum.~~

3.13 D. ~~The vendor shall be required to pay the department the estimated overpayment~~
3.14 ~~only if the null hypothesis that the mean overpayment is less than or equal to zero can be~~
3.15 ~~rejected with probability less than 0.05. The amount owed to the department shall be the~~
3.16 ~~mean overpayment multiplied by the number of claims in the population. With simple~~
3.17 ~~random samples, the mean overpayment is the sum of all differences between correct and~~
3.18 ~~actual charges in the sample, divided by the number of claims in the sample. With stratified~~
3.19 ~~samples, the mean overpayment is the sum of the products of the mean differences within~~
3.20 ~~strata and the proportion of all claims in the population that are in the strata.~~