Maine Hospital Association

MAINE'S LEADING
VOICE FOR HEALTHCARE

Comments of Maine Hospital Association on Proposed Rule amending MaineCare Benefits Manual Ch. I, Section 1, General Administrative Policies and Procedures
Proposed Rule Number 2021-P217

DATE: **December 23, 2021**

TO: Henry Eckerson, Maine Department of Health and Human Services

A. A Hearing Should Be Held on the Proposed Amendments

We believe a public rulemaking hearing will provide interested parties an important opportunity to comment on the proposed amendments. As noted in the Department's rulemaking notice, the changes in Section 1 are "various" and "complex." They include changes that may have a direct impact on reimbursement of various services, as well as on the rights of providers to appeal DHHS determinations and to seek flexibility with regard to the imposition of sanctions. Review of Key Amendments in Proposed Revision of MBM ch. I

B. 340B Provisions

The proposed rule adds a new § 1.03-14 (p.24[1]) governing the 340B program, allowing 340-B participants to "carve in" or "carve out" the use of 340B drugs for MaineCare covered patients but explicitly excludes retail pharmacies, in-house pharmacies "owned by and a legal part of a 340B covered entity," and contract pharmacies from opting into 340B for MaineCare patients.

The rulemaking notice also announces that the Department intends to repeal the 340B Program provisions currently set forth in MBM Ch. II, Sec. 80.09-1(D).

C. Offset or Recoupment from Affiliates

The Department proposes to expand § 1.12-2(C)(2), p. 50, which provides for withholding of payments when overpayments have not been repaid in 30 days of the date of an overpayment notice. The proposed new language adds that the Department may offset "and/or recoup" against a provider "related by ownership or control" to a provider that owes a "collectible debt." The proposed rule does not define collectible debt, but this term is defined by 22 M.R.S. § 1714-A(2) to mean a debt established by final agency action, with respect to which 31 days have passed after exhaustion of all appeal rights. The new language goes on to purport to define the ownership or control relationship, generally tracking § 1714-A(5) in doing so, except that the proposed rule incorrectly treats as an *example* of control a condition that is actually a *limitation* on what can be considered ownership and control for purposes of recouping against an affiliate. The statute states that "the department *may not* define any ownership or control relationship as subject to an offset *unless* the relationship allows the person whose relationship is the subject of the offset to control

[1] Page numbers herein refer to the PDF version of the proposed rule published by the Department.

at least the number of votes of the provider's governing body or management that is needed to govern the operations of the provider." The rule instead says that offsets can apply to a provider that can control the provider owing the debt "through, *for example,* controlling at least the number of votes of the provider's governing body or management needed to govern operations." The language is also confusing, because it starts with a cross-reference to requirements to *disclose* small percentages of ownership, which would typically be far less than what would be needed to have the votes to control another entities board or management, which is the statutory standard.

MHA proposes that these problems with the proposed change be addressed by revising it to read as follows:

> The Department may withhold payment on pending claims and on subsequently received claims for the amount of the overpayment when overpayments are not repaid as required in Section 1.12-2(C)(1) in accordance with state and federal rules and regulations. The Department may offset and/or recoup against MaineCare providers related by ownership and control to the provider that owes a collectible debt as defined in Title 22, section 1714-A(2). Providers are related by ownership and control ~~based on information provided in the Disclosure of Ownership and Control Interest Statement and requirements of Section 1.03-8(V) herein, if~~ only when the provider subject to the offset has the ability to control the operations of the provider that owes the debt ~~through, for example,~~ by controlling at least the number of votes of the provider's governing body or management needed to govern operations, as shown by the information required to be disclosed by Section 1.03-8(V).

D. Out-of-State Services (typo)

The words "State of Maine" appear to have been stricken inadvertently from the end of the second paragraph of § 1.14-2, at the bottom of p. 55

E. Termination from Participation

As the rulemaking notice states, "this rulemaking clarifies (Sec. 1.19-1(C)(2)) [p.63] that the Department may reimburse providers for covered services rendered during the period following a notice of termination *up to the effective date of termination, instead of for a period not to exceed thirty days* after the date of receipt of the notice of termination, *because providers may not be reimbursed after termination of a provider agreement.* The rulemaking also adds that providers must follow the provisions of their provider agreements and the MaineCare Benefits Manual to continue to receive reimbursement for services."

The Department does not explain the basis for its conclusion that it cannot reimburse a provider after the termination date for services actually rendered. There may be circumstances where it is reasonable to do so, when new placements of members served is more difficult than expected, for example. If there are reasons to establish such a bright line regarding the effective date, the rule should also make it clear that the Department can extend a termination effective date retroactively, and the option of extending a date should be available for all providers, not limited to residential providers.

F. Sanction for Failure to Provide Information

The proposal inserts new § 1.20-1(BB) at p. 66, to add to the list of grounds for sanctions failure to provide information "or to otherwise respond to Departmental requests for information within a reasonable timeframe established by the Department." As proposed, the rule would authorize MaineCare to impose sanctions for failing to provide *any information whatsoever to the Department*, whether or not the Department is authorized to obtain that information. As written,

the provision also arguably allows the Department unfettered discretion to decide what timing is "reasonable" for an information request. Instead, the basis for sanctioning should be limited to information required to be maintained and available to the Department by this Chapter. MHA proposes the following revision:

> BB. Failure to provide information required to be available under §§ 1.03-8(M)(5) and (Z) to the Department upon reasonable request and within the time specified in the request, provided the time allowed in the request is reasonable or is extended upon reasonable request. ~~or to otherwise respond to Departmental requests for information within a reasonable timeframe established by the Department~~.

G. Revised Documentation Sanctions

This rulemaking proposes significant changes to subsection 1.20-2(H) at pp. 67-68, governing sanctions for "lack of adequate documentation." First, the rule substitutes "shall" for the words "in its discretion may" in establishing the penalties to result from proof that a provider "lacks mandated records for MaineCare covered goods or services." This proposed amendment needlessly limits the Department's own discretion to decide how and when to impose sanctions, arguably also limiting the Commissioner's discretion to consider all facts and circumstances on appeal, by rendering the imposition of the specified sanction mandatory. There is no reason to strip the sanction rule of flexibility in this manner, and none is offered in the rulemaking notice.

Proposed §1.20-2(H)(2) would mandate a new, 25% penalty for all missing member or guardian signatures. This is inserted in place of a previous provision now restated as (H)(3). No factual or policy basis is offered for this implicit determination that every missing member signature reduces the value of the service rendered by 25%. The resulting penalty could be extraordinarily large when, for example, the signature applies to a period of service delivery, or when the unit of service is a day rather than an hour or fraction thereof. Moreover, there are numerous situations in which services cannot await the obtaining of signatures, and when other circumstantial proof of the necessary member and guardian involvement in and consent to treatment is available. This provision should be stricken in its entirety. Missing signatures should be considered either in a licensing and quality assurance context or, if they amount to "lacking mandated records," under the existing documentation penalty provisions with a cap of 20%.

Third, the proposal narrows the current provision (renumbered H(3)) for a penalty "not to exceed" 20% where documentation is missing but the provider can prove the service was delivered, covered, and medically necessary. The proposed language *mandates* a 20% penalty unless a provider requests a reduction, in which event the rule indicates that the Department "may consider" a list of factors in deciding whether to reduce the percentage. This proposed change appears to mirror recent practice of the Program Integrity Unit, in which penalties below 20% are not considered in the audit process but only upon a request for informal review. Again, it is unclear why the Department would limit its own flexibility by requiring a 20% penalty. The "not to exceed" language should be retained, such that proposed paragraph 3 (or existing paragraph 2 if proposed paragraph 2 is stricken as it ought to be) would begin "A penalty not to exceed twenty percent (20%) recoupment . . . ."

Fourth, the list of factors provided for reducing the 20% penalty in proposed § 1.20-2(H)(3) differs from the general list of factors related to sanction decisions found in existing §1.20-3(A). This could lead to confusion due to the overlapping applicability of the two lists. More importantly, the newly proposed list in some instances only considers one side of what should be a two-sided balancing test. There are also important omissions from the new list that are found in the existing rule. A more balanced list would read as follows:

a. The nature and extent of the identified violations;

b. The impact or potential impact of the violation(s) on members;

c. The impact or potential impact of the violation on administration of the MaineCare program;

d. The financial impact of the violation on MaineCare;

e. The provider's ~~acceptance of responsibility~~ response to the findings of violation including its willingness and initiative in revising policies and practices, and training staff, to avoid recurrence of the errors identified, provided however that a provider's vigorous pursuit of its appeal rights shall not in itself be viewed as an inappropriate response;

f. Any history of prior violations;

g. Actions, findings, or recommendations taken by peer review groups, other payers, ~~or~~ licensing ~~boards~~ authorities, or quality assurance entities that reflect on the compliance climate or performance of the provider, either negatively, such as a citation or statement of deficiencies, or positively, such as a commendation or a review that finds only minor concerns or deficiencies; *[adapted from proposed §1.20-2(H)(3)(g) and existing § 1.20-3(A)(h)]*

h. Prior imposition of sanction(s); *[from existing §1.20-3(A)(d)]*

i. Prior provision of provider education; [*from existing §1.20-3(A)(e)]*

j. Provider willingness to obey MaineCare rules; *[from existing §1.20-3(A)(f)]*

k. Whether a lesser sanction will be sufficient to remedy the problem; *[from existing §1.20-3(A)(g)]*and

l. Any other factor the Department finds relevant to its consideration.

With respect to proposed paragraph (e), the notion of "acceptance of responsibility" seems to invite a subjective assessment of attitude toward the violation. A more objective and relevant test is the extent to which a provider exhibits a positive compliance climate by responding to violations with corrective action. The licensing provision found in different forms in the existing rule and the proposed new list seems to focus only on negative findings, when positive licensing reviews are equally pertinent to whether a severe sanction is appropriate or whether compliance can be readily expected following an audit without such sanctions. Explicit reference to the need for corrective incentives is found in the existing rule and should be carried forward in the new list.

There should be one list, rather than two, applicable to determining the full range of sanctions. Thus, the best result would be to *replace existing subsection 1.20-3(A)* with the revised and expanded list shown above, and to revise the new paragraph in proposed § 1.20-2(H)(3) to read:

> In determining on its own motion or ~~F~~following a request from a provider whether to impose a recoupment of a lower percentage than twenty percent (20%), the Department ~~may~~ shall review and consider the ~~following~~ factors set forth in § 1.20-3(A) as the basis for its decision~~:~~.

H. Decisions to Impose Sanctions

The Department proposes to revise the opening sentence of § 1.20-3(A) regarding imposition of sanctions, p. 69, to say that the decision is the responsibility of the Director of the Office of MaineCare Services instead of the Commissioner and that the OMS Director may delegate to an unnamed "designee," rather than allowing the Commissioner to delegate to the OMS Director and Division of Audit. While multiple layers of delegation may well occur in a large and busy agency, removing the ultimate responsibility from the Commissioner and vesting it in one of her office Directors is troubling to say the least. This change could be read to alter the standard of review on appeal, which, by statute, must be a *de novo* review following an evidentiary hearing with an ultimate decision by the Commissioner. 22 M.R.S. § 42(7)(D) and (E).[2] If the initial sanction decisions will be made by a different officer from the OMS Director, that delegation should be specific, but the ultimate responsibility should remain with the Commissioner, consistent with the appeal rights provided by statute. Thus, the opening sentence should read:

> The decision to impose a sanction shall be the responsibility of the Commissioner of the Department of Health and Human Services, who may delegate sanction responsibilities to the Division of Audit **[if still applicable]**, and the Director of MaineCare Services, who in turn may delegate these responsibilities to the _____, subject to informal review and ultimately review by the Commissioner through the appeal process, both as provided in §1.23-1.

In addition, as noted above in connection with § 1.20-2, the list of criteria to consider in determining sanctions under §1.20-3(A) should be revised and expanded as shown in part G of these comments.

I. Additional Sanctions – Plans of Correction

The proposal at p. 68 introduces plans of correction as an additional category of possible sanction for violations of MaineCare rules. This is a potentially constructive addition, as there may be many instances where major recoupment penalties are ill-suited to record-keeping quality issues, especially where subjective judgments as to recordkeeping are being made, and/or where a payment penalty may unfairly understate the value of the services actually delivered and thus fail unfairly to cover the costs of those services. The pitfalls in this new approach are (1) that it should be used as a substitute, rather than a cumulative sanction, absent truly egregious violations; and (2) that it should not duplicate the existing licensing survey plans of correction where they apply.

Program Integrity has from time to time relied on licensing violations as a basis for payment recoupment and has refused to consider prior or parallel licensing reviews of similar records in imposing these sanctions. Providers should not be subject to two differing sets of interpretations of the same licensing rules. Further, certain portions of the proposed POC

[2] D. The hearing officer shall conduct a hearing de novo on issues raised in the notice of appeal filed by the provider and shall in a timely manner render a written recommendation based on the record and in accordance with applicable state and federal law, rule and regulation. The hearing officer shall provide a copy of the recommendation to the department and to the provider along with notice of the opportunity to submit written comments to the commissioner. E. The recommendation of the hearing officer must be forwarded to the commissioner for a final decision, based on the record, which must include any written comment submitted in a timely manner by the provider and the department. The commissioner may adopt, adopt with modification or reject the recommendation of the hearing officer. The commissioner shall issue a final decision in writing, which must include the reasons for any departure from the recommendation of the hearing officer and notice of the process for appeal pursuant to Title 5, chapter 375, subchapter 7. If the commissioner deviates from a prior decision cited in the course of a proceeding, the final decision must include an explanation of the reason that the prior decision was not followed. [PL 2003, c. 419, §2 (AMD).]

requirement are unclear and perhaps are derived from specific fact patterns that PI has addressed in the past. These provisions should be eliminated (as shown below) or clarified so that they are generally understandable by providers. Finally, some detailed provisions should be stricken to reserve flexibility for the Department to accept plans of varying levels of specificity depending on the nature of the violations being addressed and the generally applicable factors for determining sanctions. Accordingly, MHA proposes the following adjustments to proposed § 1.20-2(I):

I. Require the provider to submit a plan of correction to the Department for review and approval, responding to findings specifically designated for such a plan by the Department in its Notice of Violation. A required plan of correction must neither duplicate nor conflict with a statement of deficiencies issued by the applicable licensing or certification authority. Failure to provide a plan of correction satisfactory to the Department within the time specified may result in the Department choosing to impose different and/or additional sanction(s) on the provider. The plan of correction must be a specific plan which describes how the provider will correct or address the identified deficiency (event, incident, or risk), including the actions the provider will undertake to bring about correction. The plan of correction must:

a. Address correction of the specific deficiencies described by the Department in the Notice of Violation;

b. ~~Address all identified areas where the correction of all related deficient circumstances will be implemented;~~

c. Identify specific actions/steps the provider will complete to prevent the identified deficiency from recurring. ~~The specific events cited may not represent all instances within the site/services where the practice is deficient~~;

d. Specify the date or frequency when each element of the plan will occur. ~~Terms such as "frequently," "periodically," "as needed," and "ongoing" lack the necessary specificity;~~

e. Identify, by title ~~and name~~, the ~~individual~~ position(s) responsible for implementing and monitoring the plan;

f. Provide dates by which all components of the plan will be implemented and when the corrections will be completed. ~~The length of time to correct the deficiency must be as soon as possible~~; and

g. Not duplicate or closely parallel a previously submitted and failed plan of correction

J. Other New Sanctions

Noting that "providers who grow rapidly may not have adequate infrastructure to maintain quality of service provision," the proposed rule at p. 70 adds the following sanctions to the list in § 1.20-3:

- Impose a suspension of referrals to a provider;
- Deny or pend any enrollment applications submitted by a provider;
- Limit the number of service locations a provider may enroll; and
- Limit the number of MaineCare members the provider may serve.

Like the plan of correction, these sanctions may improve the Department's ability to match a sanction to the conduct of concern. Like the POC, however, it is critically important to avoid simply accumulating sanctions rather than matching them to the circumstances presented.

Accordingly, addition of these new sanctions should be paired with insertion of the following at the beginning of § 1.20-2:

> The Department may impose the following sanctions ~~may be invoked~~ against providers, individuals or entities based on the grounds specified in Section 1.20-1, in accordance with applicable state and federal rules and regulations. In selecting sanctions to impose, the Department must consider the cumulative impact on the provider and the effectiveness of sanctions, alone or in combination, to ensure program integrity and access to services for members.

K. Appeal Procedure

The proposal modifies § 1.23-1 governing the timing of appeals, p. 82, by providing that a request for informal review is due 60 calendar days from the date of "written notification of the action," whereas the existing rule provides 60 days from the date of *receipt* of the decision. The intent of this change is unclear, as it seems to create rather than resolve uncertainty as to the date from which the time period runs. It also raises questions about whether the MBM contemplates that every appealable action will be accompanied by a written statement of findings and reasons for that action. If not, then the waiver provisions regarding issues to be raised in an informal review are particularly inapposite. If the Department is proposing to begin the appeal period before a written decision is received by the provider, this change would be an unlawful restriction of the statutory 60-day period. 22 M.R.S. § 42(7)(A) explicitly refers to the date of receipt.

If the change from "decision" to "notification of action" is intended to relieve the Department of the obligation to provide its reasons in writing before an informal review deadline arises, then this change must be accompanied by removing the current, severe limitation on appeal rights that arises from limiting issues at the formal, adjudicatory appeal stage to those raised in a request for informal review. Any revision of the appeal process should carefully consider the value of revising these limitations. By doing so, both the Department and providers could focus at the informal review stage on refining the action and the rationale for it as appropriate, and only after a written final review decision is rendered should the appellant be required to declare or waive issues for purposes of an appeal hearing.

A welcome clarification is provided in the proposed revisions to § 1.23-1. A sentence is added to clarify that if the deadline falls on a weekend or holiday, the date is extended to the next business day.

In summary, the proposed revisions of this section on pp. 82-83 should be modified to read as follows (with portions that remain unchanged elided):

> The request for an informal review must be in writing (handwritten or email) and addressed to the Director of Compliance, Office of MaineCare Services. This review will be conducted by a designated Department representative who was not involved in the decision under review. The informal review will consist solely of a review of documents in the Department's possession including submitted materials/documentation and, if deemed necessary by the Department, it may include a personal meeting with the provider or provider applicant to obtain clarification of the materials. ~~Issues that are not raised by the provider, provider applicant, individual, or entity through the written request for an informal review or the submission of additional materials for consideration prior to the informal review are waived in subsequent appeal proceedings.~~
>
> ~~The request for informal review may not be amended to add further issues.~~
>
> . . . .

A. Administrative Hearing

. . . .. If the provider or provider applicant is dissatisfied with the informal review decision, ~~he or she~~ that person may write the Director of Compliance, Office of MaineCare Services, ~~Commissioner of the Department of Health and Human Services~~to request a hearing and a decision on the appeal by the Commissioner, provided ~~he/she~~ that the person requesting the hearing does so within sixty (60) calendar days ~~of~~from the date of receipt[3] of the informal review report on the Department's action. If the deadline falls on a weekend or holiday, the deadline will be extended to the next business day. ~~Subsequent appeal proceedings will be limited only to those issues raised during the informal review process.~~

L. Conclusion

Thank you for considering the above comments. MHA reserves the right to offer further comments when a hearing is held on this proposed rule.

David Winslow
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[3] These two words appear in the current rule but are not shown at all in the proposed rule. It is therefore unclear whether the Department proposed to omit them or deleted them from the proposal accidentally. As explained above, these words are consistent with the applicable statute and should be retained.