

BEFORE THE COMMISSIONER OF SECURITIES AND INSURANCE  
MONTANA STATE AUDITOR

In the matter of the adoption of NEW ) NOTICE OF ADOPTION  
RULE I pertaining to Patient- )  
Centered Medical Homes )

TO: All Concerned Persons

1. On August 21, 2014, the Commissioner of Securities and Insurance, Montana State Auditor, published MAR Notice No. 6-211 pertaining to the public hearing on the proposed adoption of the above-stated rule at page 1863 of the 2014 Montana Administrative Register, Issue Number 16.

2. On September 11, 2014, a public hearing was held on the proposed adoption of the above-stated rule in Helena. Comments were received by the September 19, 2014, deadline.

3. The department has adopted New Rule I (ARM 6.6.4907) exactly as proposed.

4. The department has thoroughly considered the comments and testimony received. A summary of the comments received and the department's responses are as follows:

COMMENT NO. 1: The first commenter stated that the rule should specifically reference data privacy and security requirements for quality measure data reported to the PCMH program.

RESPONSE NO. 1: The Office of the Commissioner of Securities and Insurance (CSI), the Department of Public Health and Human Services (DPHHS) and all of the participants in the Montana Patient Centered Medical Home Program are bound by various state and federal privacy protection laws that require them to safeguard all protected personal health and financial information. These laws include, but are not limited to, the Health Insurance Portability and Accountability Act (HIPAA), various privacy and security regulations related to the Gramm-Leach-Bliley Act (GLBA), the Montana Insurance Information and Privacy Protection Act, and the Montana Constitution. It is not necessary to restate those laws here. All applicable state and federal privacy laws will be followed in the administration of this program. No change was made to the rule in response to this comment.

COMMENT NO. 2: The same commenter also stated that the rule should clarify how the data requested would be de-identified and then went on to state that de-identified data would need to be protected from re-identification. On this same issue, the commenter raised other issues related to data use restrictions.

RESPONSE NO. 2: This rule was adopted in response to a legislative requirement placed in the statute, requiring the CSI to establish "a uniform set of health care quality and performance measures that include prevention services" and to provide for reporting to the commissioner and the Department of Public Health and Human Services to ensure compliance. Outside of reporting to those two state agencies, the statute and the rules reference only a report of aggregate data results to the public and to the legislature, to be prepared by the commissioner and the stakeholder council. In addition to the rule, the commissioner is adopting data reporting guidelines, which were drafted by the stakeholder council. The guidelines will provide more detail about the level of de-identification. In addition, a confidentiality and data use agreement will be drafted by the Office of the Commissioner of Securities and Insurance, in consultation with the stakeholders and then executed for each program participant. If the uses or level of de-identification changes, a new agreement will be executed, and additional changes will be made to the guidelines and rules, if necessary. The concerns about privacy and the scope of the data use expressed by this commenter will be addressed in the data use agreement that can be updated as needed. No change was made to the rule in response to this comment.

COMMENT NO. 3: The second commenter stated that the quality measures identified in the rules should also include cancer screenings.

RESPONSE NO. 3: The commissioner and the PCMH stakeholder council limited the initial number of quality measures to four because these measures also require data reporting. Some health care providers expressed a need to limit the amount of data reporting required. These particular measures were chosen because the data collected from these four measures may also be used to promote previously identified public health improvement goals. Many PCMH payors require reporting on numerous additional quality measures by PCMH health care providers, including measures relating to cancer screening. In the future, the stakeholder council and the commissioner may recommend the adoption of additional quality measures. No change was made to the rule in response to this comment.

COMMENT NO. 4: The second commenter also expressed concern that the public reports will contain only aggregate data on PCMH quality measure reporting, which they believe would limit transparency and make the report less meaningful.

RESPONSE NO. 4: The aggregate data restriction was requested by the health care providers who were concerned about public reporting of data from identified PCMH practices. The CSI and many stakeholders believe that meaningful data on quality measures can be reported to the public using aggregated data from all of the PCMH practices, rather than practice-specific data. No change was made to the rule in response to this comment.

COMMENT NO. 5: The second commenter also expressed support for patient-level data reporting on quality measures, with an "opt-out" option for PCMH practices that do not currently have a payor contract and therefore are not already reporting this

and other data to a payor. This commenter believes that research indicates that patient-level data reporting is necessary for an effective evaluation of the program.

RESPONSE NO. 5: Because the stakeholder council and other interested parties were split on the issue of reporting on patient-level data, as opposed to reporting on aggregate data accompanied by an attestation from the health care provider, a compromise was reached and is expressed in the data reporting guidelines that are referenced in these rules. The proposed guidelines allow the practices to choose to report using aggregate or patient-level data in the first year. The requirement for all patient-level data reporting will be phased in over a two-year period. No change was made to the rule in response to this comment.

COMMENT NO. 6: A third commenter objects to the fact that the instructions for data reporting are contained in guidance published by the commissioner instead of in the rule itself. The commenter goes on to complain that the draft guidance for reporting data is not yet complete and places too great a burden on primary care practices because it proposes reporting of patient-level data. In addition, the commenter states that the Office of the Commissioner of Securities and Insurance (CSI) has not fully considered the needs of primary care practices.

RESPONSE NO. 6: The commissioner is committed to working with the interested parties on all aspects of the administration of the Montana PCMH program and the commissioner has created a stakeholder council for that purpose. In addition, there has been constant outreach to other interested parties. There are 157 entities on the interested parties list, including all qualified PCMH health care practices. Many interested parties, in addition to appointed stakeholder council members regularly participate in the monthly stakeholder council meetings and subcommittee meetings. On average, the CSI holds at least three meetings a month with all stakeholders. The guidelines for data reporting and the draft of the rules were discussed at nearly all of those meetings. The state-specific measures, including patient-level reporting guidelines were initially introduced to the stakeholder council and interested parties at the December 2013 meeting where the proposal received positive response, including the concern for measures that show PCMH specific practice improvement. These rules and the accompanying guidelines have been discussed with the interested parties for at least 12 months and many adjustments and changes were made in the rule and the guidelines for data reporting in order to respond to concerns expressed by the interested parties.

The stakeholder council agreed that keeping the instructions for data reporting outside of the rule was the best approach in order to allow for necessary flexibility in data reporting instructions. Those instructions are issued by the commissioner, but in fact were written by members of the quality measure subcommittee and approved by the stakeholder council as a whole. After many months of discussions and changes to the rules and the guidelines, additional concerns were expressed about the need to for patient-level data rather than aggregate data attested to by the health care provider. In response to those concerns, the CSI worked with stakeholders to get agreement about the content of the guidelines for data reporting. Additional

research was done and information was provided to the council about the value of patient-level data for evaluating the success and performance of PCMH health care delivery methods.

The issue of requiring patient-level data versus aggregate data was put to a vote of the stakeholder council. That vote was essentially tied. Therefore, a longer meeting was scheduled with the council in order to discuss next steps for finalizing the reporting guidelines in October 2014. Great care was taken to balance the burden that data reporting places on health care providers against the importance of collecting valid data that would inform the Montana PCMH program concerning the long term effectiveness and cost savings generated by certain healthcare delivery reforms implemented under PCMH.

At the October 2014 meeting, the council developed a consensus to recommend to the commissioner a stepwise approach, including a voluntary pilot group for patient-level reporting, allowing for inclusivity and time to develop better systems/infrastructures for future data reporting, as well as data-sharing agreements. The council made the following recommendation to the commissioner: All practices will submit aggregate clinical quality data in March of 2015 for the quality measures identified in ARM 6.6.4907. Practices can volunteer to submit patient-level data as a pilot in March of 2015. The ultimate goal is for all practices participating in the Montana PCMH Program to submit patient-level data starting March of 2017. A work group will convene to oversee the development of required systems to collect, analyze, and report on patient-level data by March 2017. The work group will also recommend privacy and security infrastructure and data governance.

The rule requires all payors to adapt their reporting requirements to the reporting requirements of the state program. In addition, the rule requires that the reporting of quality measures must line up with PQRS reporting requirements.

At this point the instructions for data reporting are complete on all substantive details and the stakeholders have agreed on the reporting methods for 2014 to 2016. The commissioner is committed and legally required to consult with stakeholders and the minutes of the numerous stakeholder meetings and calls are evidence of that commitment.

COMMENT NO. 7: Commenter number three also disagrees that supporting public health goals is a benefit and that the only purpose of these rules should be to support the improvement of clinical care of patients and patient populations from the perspective of primary care practices.

RESPONSE NO. 7: In the Act that implements the PCMH program, the legislature states certain goals, which include but are not limited to:

1. The development of "a single definition and common set of quality measures, as well as a uniform payment methodology, [in order to] provide the best chance of

success for the patient-centered medical homes model by increasing consistency in reporting across health plans and primary care practices."

2. "Help slow the continuing escalation of health care costs as well as improve health outcomes for Montana citizens."

3. Develop "an ongoing process (...) to evaluate the effectiveness of patient-centered medical homes."

The law and the administrative rule require the commissioner to consult with interested parties at all times. Section 33-40-104, MCA, specifically includes the public health agencies as a required "interested party."

In one of the first stakeholder council meetings, at the beginning of the rulemaking process, the Department of Public Health and Human Services (DPHHS) presented its suggestions for quality measures to the other stakeholders. The director of the public health department is a member of the stakeholder council, per legislative direction. She and her colleagues presented four measures that would advance the goals of promoting and supporting primary care, preventive health care, the Montana PCMH program and state public health improvement goals. These are not obscure measures, but rather are measures that achieve multiple goals. In addition, all payors who are requiring reporting of measures are including these four measures, which are also PQRS measures.

These measures were discussed at numerous meetings and at no time was there any disagreement on the measures. This commenter does not appear to disagree with measures, but with the statement that the measures also support public health goals. The quality measures chosen for the program are limited in number and clearly support all the goals of the PCMH program.

COMMENT NO. 8: Commenter number three also states that aggregate data is sufficient to support the goal of enhancing primary care.

RESPONSE NO. 8: As stated in response number six, this matter has been resolved by changes in the data reporting instructions to allow the requirement of patient-level data to be phased in over a two year period. Evidence concerning the need for patient-level data was presented to the stakeholder council. This evidence was supported by the long-term experience of other PCMH programs that started out with aggregate data, found it to be ineffective to support the goals of the program and had to switch to patient-level data. Because of the information presented, many primary care provider stakeholders are opting to provide patient-level data in the first year. At no time did the CSI or the majority of other stakeholders state or believe that patient-level data was for the benefit of the public health department only.

This commenter goes on to state the entire stakeholder council should agree before additional data elements are added. Additional data elements would be classified as additional quality measures, which would require additional rulemaking. The law

already requires the commissioner to consult with stakeholders before adopting new rules.

This commenter also states that "primary care providers" must be in agreement before changes to the rule or the instructions for data reporting are made. Although primary care practices are extremely important to the program, they are not the only stakeholders. Health care providers, payors, and patients must work together—and the legislature lists all three of those groups as equal stakeholders in this process. The vote of the stakeholder council was extremely divided on this issue and the later debate on the changes to the instructions included many primary care physician groups who are not members of the stakeholder council.

COMMENT NO. 9: Commenter number three goes on to state that the commissioner is not doing enough to require that all payors reimburse all qualified PCMH practices.

RESPONSE NO. 9: This comment is not relevant to the rules on quality measures. The commissioner is also adopting rules on payor standards. The commissioner does not have the authority to force payors to reimburse providers.

/s/Nick Mazanec  
Nick Mazanec  
Rule Reviewer

/s/Christina L. Goe  
Christina L. Goe  
General Counsel

Certified to the Secretary of State December 15, 2014.