

CONCISE EXPLANATORY STATEMENT

SUBJECT: Concise Explanatory Statement as required by RCW 34.05.325
WAC: Chapter 82-75 WAC, All-Payer Health Care Claims Database, (WAC 82-75-600 thru WAC 82-75-665) Penalties for Inappropriate Disclosures or Uses

Pursuant to RCW 34.05.325(6)(a):

(6)(a) Before it files an adopted rule with the code reviser, an agency shall prepare a concise explanatory statement of the rule:

- (i) Identifying the agency's reasons for adopting the rule;
- (ii) Describing differences between the text of the proposed rule as published in the register and the text of the rule as adopted, other than editing changes, stating the reasons for differences; and
- (iii) Summarizing all comments received regarding the proposed rule, and responding to the comments by category or subject matter, indicating how the final rule reflects agency consideration of the comments, or why it fails to do so.

In accordance with this requirement, the Office of Financial Management (OFM) prepared this concise explanatory statement for the rules related to the penalties for the inappropriate disclosure or use of direct patient identifiers, indirect patient identifiers, or proprietary financial information, also known as protected information. The rules set out the potential penalties, the factors taken into consideration when determining the penalty, the procedures for filing a complaint, investigating and finding a violation along with how to appeal the determination of a violation and assessed penalty.

Reasons for adopting the rule.

Chapter 43.371 RCW directs the Office of Financial Management (OFM) to establish a statewide all-payer health care claims database to support transparent public reporting of health care information. To accomplish this requirement, OFM is further directed to select a lead organization to coordinate and manage the database. RCW 43.371.070(1)(h) provides that the OFM director shall rules necessary to implement this chapter, including the penalties associated with the inappropriate disclosure or use protected information.

Differences between the text of the proposed rule as published and the text of the rule as adopted.

Based on the comments received, the following changes were made to the text of the proposed rules that were published.

- WAC 82-75-600(1). Language was added to make clear that penalties may be imposed for inappropriate disclosure or use of the information not only received from, but also provided to or contained in the WA-APCD.
- WAC 82-75-610(6)(b). Language was added to make clear that notice that a complaint has been closed without action will include the basis for that determination.
- WAC 82-75-630(1). To make it clear that the OFM director would not direct the lead organization, when it is the alleged violator, to do a review of its own contract to determine whether it breached that contract, language was added that the lead would not be directed to do the review if it is the violator and that the WA-APCD program director would do the review.
- WAC 82-75-630(2). Language was added to clarify that demand for the destruction of data includes all WA-APCD data, “whether stand alone or combined with other data, all data products, and derivatives produced from WA-APCD data,…”
- WAC 82-75-635. Language was changed to reflect that the OFM director will look at culpability levels in determining the penalty.

The adopted rules reflect these changes, which is more in the way of clarification to ensure these rules are properly interpreted consistent with the intent of the rules as has been expressed in each and every stakeholder meeting. Since the adopted rules are not substantially different from the proposed rules, further comment is not needed.

Summary of comments, OFM response and reflection in the final rule.

OFM worked with stakeholders, including members of effected state agencies and the private sector, as well as the selected Lead Organization and the Data Vendor. In addition, OFM received input from stakeholders prior to drafting these rules, as well as comments on the prior version of the rules as they were being developed. Also, OFM held a stakeholder meeting on the draft rules. Many comments requested and received were incorporated into the final version of the rules that were the subject of this hearing.

Once published, OFM received written comments from Regence Blue Shield, Premera Blue Cross, Northwest Health Law Advocates, and Community Health Plan of Washington. Attached is a summary of the comments received and OFM's response to these comments. A copy of the comments is also attached for your reference.

Finally, OFM held a hearing on May 8, 2018. Adrianna Simonelli, from Regence, attended the hearing and provided verbal comment similar to that which was submitted in writing. The one requested change referenced above was accepted and the change made to the final rules.

Penalties for Inappropriate Disclosures or Uses Rules
Summary of Stakeholder comments and OFM response to comments

Stakeholder Comments	OFM Response to Comments
Regence Blue Shield (Regence)	
<p>1. WAC 82-75-630(1)(b). This section if a violation is found, OFM director may direct the lead organization to determine if there was a breach of contract and take appropriate action. Request a sentence is added to clarify that the lead organization cannot be directed to conduct this review if the lead organization is the violator.</p>	<p>1. OFM agrees that the lead organization would not be directed to do this review if the lead organization is the violator. OFM will add the clarifying phrase to subsection (1)(b) as follows: unless the lead organization is the violator, in which 1(a) of this section shall apply.</p>
Premera Blue Cross (Premera)	
<p>1. Premera submitted comments, a copy of which is attached. In addition to general comments about not having enough time or access to various drafts released during this process, Premera referenced prior comments but did not state what those comments were.</p> <p>2. WAC 82-75-610. The rule requires that complaints be submitted in writing. Request that it be authorized for complaints to be submitted verbally.</p> <p>3. WAC 82-75-60 and 615. Concerned that the role of the lead organization is overly broad and involvement of lead is inappropriate.</p>	<p>1. OFM made numerous changes to the final rules based on the comments previously submitted by Premera.</p> <p>2. OFM does not believe that requiring a complaint to be submitted in writing in an onerous burden. The amount of information is minimal, and the form may be either paper or electronic. Since a complaint may trigger an investigation and cause OFM, the lead organization, the data vendor, the subject of the complaint and numerous others to have to take actions, OFM does not believe it is inappropriate to ask that the complaint be in writing. In addition, having the complainant provide a written submittal will reduce the risk that the complaint is misinterpreted. Finally, OFM reviewed numerous state statutes that provide the ability to file a complaint, and these statutes not only require a written submission, some require the submission be "signed." So this requirement is consistent with similar requirements in other state agencies. Therefore, based on these reasons, OFM does not agree with the comment and no change has been made.</p> <p>3. These comments were previously submitted and addressed in this final version. The lead organization's role has been minimized, consistent with these comments. The issue no longer exists.</p>

Northwest Health Law Advocates (NoHLA)

They commented on earlier drafts and are pleased that their recommendations were incorporated. Submitted three remaining concerns:

1. WAC 82-75-605. The rule provides that OFM will conduct an investigation unless it determines that it is without merit or frivolous. All complaints should be investigated, and it should be made clear that all complaints must be given to OFM to make the determination.
2. WAC 82-75-610. It does not appear that OFM must include a reason for closing a complaint without action. Requests additional language that notice that a complaint is closed without action should include a basis for that decision.
3. WAC 82-75-630(2). NoHLA does not believe the rule addresses misuse of derivative data produced using APCD, but only addresses the raw data received from the APCD. The rule should address derivative data.
4. WAC 82-75-655. This rules allows a hearing before the OFM director or designee, or an administrative law judge. Hearings should only be held before an independent ALJ to avoid conflict or potential bias.

1. As written, all complaints must go to OFM, which entity will be making the final decision. If a complaint is without merit or frivolous, there is nothing to investigate. It would not be a good use of limited state resources to investigate such a complaint.
2. OFM intends to provide the basis for closing a complaint without action. OFM agrees to add a sentence that memorializes this action. However, NoLHa appears to have used an earlier version, as the sentence will be added to subsection (6).
3. OFM agrees that the rule should apply to derivative data as well as the raw data. To ensure clarity in its application, OFM will add a language to this subsection.
4. OFM does not agree that a hearing should only be held before an administrative law judge. OFM believes that it should have the flexibility to determine who will preside over a hearing. If the director or designee presides over a hearing, barriers will be put in place to ensure there is no conflict or bias, and that hearing is properly conducted.

Community Health Plan of Washington (CHP)

1. WAC 82-75-030. CHP believes that the definition of "malicious intent" should not include the phrase "without legal justification" as this allows a defense.
2. WAC 82-75-030. CHP believes the definition of WA-APCD program director should be changed from an individual designated by the office to an employee of the office designated by the director.
3. WAC 82-75-600. Subsection (1) should be amended to ensure application to both data vendor and the lead organization by adding "provided to, or contained in" the WA-APCD. Subsection (2) should be amended to tie it more closely to "malicious intent."

1. This definition has been crafted with the assistance of OFM's assigned counsel. OFM agrees that it allows a defense, but it is an appropriate defense.
2. OFM does not agree that the WA-APCD program director must be an employee of OFM. OFM has the authority to determine its own staffing, and to decide whether to hire an employee or contract with an individual to fulfill this role.
3. It appears that CHP does not understand this section. It applies equally to all persons that make an inappropriate disclosure or use of the specified data. In addition, the suggested language for subsection (1) is redundant. However, since it does

4. WAC 82-75-605. CHP would like the lead organization to be taken out of the process of receiving and reviewing complaints in subsection (1). It also requests a new subsection be added that requires OFM to provide notice to data suppliers with a detailed explanation in writing to the Data Policy Committee and Data Release Committee if it determines a complaint is frivolous or without merit.

5. WAC 82-75-610. CHP requested numerous changes to this rule.

- Add to subsection 1 that complaints can be against the lead organizations and data vendor, and must be submitted to OFM.
- Add a subsection that states the lead organization must forward all complaints to OFM.
- Several changes that remove the lead organization from a role in this process.
- Removes subsection 4 as unnecessary.
- Adds a timeframe within which the lead must provide the complaint and information to OFM.
- Requests that only one entity will conduct investigations.

6. WAC 82-75-615. CHP requested changes to subsection (1) that it says clarifies that OFM receives and investigates complaints, and provides notice "when a complaint is received." There is also a request to amend

not appear to be a problem, OFM will add this language. Subsection (2) is meant to apply to all inappropriate uses or disclosures as set forth in chapter 82-75 WAC, which chapter includes malicious intent. There is no basis to tie this subsection to malicious intent; therefore, this subsection will not be changed.

4. OFM does not agree with either change. As to subsection (1), it is appropriate, given its role for the lead organization to receive and review complaints. OFM is the final decision maker, and should be able to rely on the lead organization's expertise and role. As to the additional subsection, OFM agreed to add to the rule the requirement that OFM provide the basis for a determination that a complaint is frivolous or without merit. This information will be posted so anyone can see the results, which is more efficient than providing separate notice to specific entities or the two committees. In addition, this would be outside the scope of these committees, and an unnecessary additional process.

5. These changes are not acceptable to OFM as either inappropriate or unnecessary.

- Unnecessary addition as the rule already states that complaints can be filed against any person or entity that is alleged to have committed a violation.
- This addition is not necessary as it is already required in another subsection.
- The role for the lead organization is appropriate.
- Subsection 4 was specifically added at the request of other stakeholders.
- Without having experience in this process, it would be inappropriate to include arbitrary timeframes.
- This limits OFM's flexibility in selecting the best entity or person to conduct an investigation given the particular circumstances being investigated.

6. The change to subsection (1) would require OFM to investigate frivolous complaints, which is an inefficient use of state resources. It also removes the lead organization from the process, which is inappropriate. To require immediate notification is

subsection (5) as it does not believe it covers continuing violations.

7. WAC 82-75-620. CHP made stylistic changes to subsection (1) for clarification and states that OFM must include other information regarding services of process. It rearranged the rule and broke it down into smaller subsections. CHP also added that notice to data suppliers should be at the same time as notice to alleged violators of the investigation report is given.

8. WAC 82-75-630. The rule is not clear how an inappropriate disclosure or use can not be a breach of that agreement, and does not believe the WA-APCD can make that determination. CHP wants subsection (1)(b) removed as an "inappropriate abdication" of OFM's duties. CHP believes that subsection (2) does not go far enough regarding the destruction of data and recommends certification of destruction. Finally, CHP wants two additional penalties; permanent exclusion for malicious intent and mandatory exclusion for a specified time period for willful neglect-uncorrected.

9. WAC 82-75-635. CHP states that there should not be discretion as to whether the director considers culpability level. In addition, it recommends changes that it believes is needed for clarity.

not feasible and does not allow sufficient time to review the complaint before notification. The change to subsection (5) is not clear. OFM believes the section is clear and strong as written.

7. OFM does not agree with the stylistic changes and rearranging the rule. There has been extensive stakeholder input and there is agreement on the clarity of this rule as written and arranged. In addition, there is not a need to add additional language regarding process. This rule has been reviewed by the agency assigned counsel and is in compliance with the APA, which will be followed for any process that is not specifically covered in these rules. Finally, alleged violators have a right to receive the investigation report, while providing a copy to data suppliers is a courtesy. It may not be appropriate to have that notification occur at the same time.

8. OFM does not predetermine whether a violation is also a breach of agreement. That is the purpose of requiring a review of an agreement. It is appropriate for the WA-APCD director to conduct the review, which would be done with legal counsel. Obviously, only the parties to the agreement can make the ultimate decision regarding a breach and take appropriate action under the agreement. This review and determination will assist in that process. OFM will not strike subsection (1)(b) as it was specifically crafted at the request of stakeholders. In regards to data destruction, this subsection already requires "proof of the destruction in the form and manner" OFM will prescribe. OFM does not believe it is appropriate to make exclusion permanent. There is insufficient experience to set a specified number of years for exclusion. These decisions should be made on a case-by-case basis.

9. OFM agrees to make the change to "will" consider culpability levels although it does not believe the change is needed. Based on the extensive stakeholder input, OFM does not believe the rest of the changes are needed but will monitor

<p>10. WAC 82-75-640. Rule should include whether the alleged violator has prior settlements/stipulations under these rules.</p> <p>11. WAC 82-75-645. The changes requested are stylistic or for clarity.</p> <p>12. WAC 82-75-650. CHP recommends striking the entire rule. In the alternative, settlements should be sent to data suppliers as well as the violator.</p> <p>13. WAC 82-75-655. This rule relates to the hearing process. CHP wants clarification that hearings will not be conducted on a case-by-case basis, disagrees with the process when the hearing is conducted by the director versus a third party, does not think the WA-APCD director should be the petitioner, changes to service of notice and include data providers.</p> <p>14. WAC 82-75-660. CHP requests stylistic changes that it believes is needed for clarity.</p> <p>15. WAC 82-75-665. OFM should be required to maintain a record and post the result.</p>	<p>implementation and can make changes in the future if deemed necessary based on experience.</p> <p>10. OFM agrees, however no change is necessary as that is already covered in this rule.</p> <p>11. OFM does not agree that the changes need to be made. The changes are redundant.</p> <p>12. This rule allows cases to be settled at the lowest level possible in an administrative proceeding. This is consistent with state policy and should be an option that can be exercised when appropriate. In addition, all settlements will be posted on the website, which is more efficient than sending to specific entities.</p> <p>13. OFM disagrees with the changes, and does not believe CHP understands the process. This rule follows the APA and has been reviewed by the OFM assigned AAG. Cases must be reviewed on a case-by-case basis and all decisions based on the particular facts. In addition, there is a difference when a case is heard by the director versus a third party and this rule is consistent with state law. The WA-APCD is the petitioner as he/she will have the burden of proving a violation. Finally, the documents will be posted on the website.</p> <p>14. OFM does not agree. After extensive stakeholder input, it does not appear that changes need to be made for clarity.</p> <p>OFM agrees. State law related to records management already require OFM to maintain the records. Also, the rules require posting.</p>
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