TESTIMONY TO
DEPARTMENT OF HEALTH AND HUMAN SERVICES NATIONAL COMMITTEE
ON VITAL HEALTH STATISTICS SUBCOMMITTEE ON STANDARDS

February 16, 2016

Presented by: Debra Strickland
Xerox Government Health Services

Members of the Subcommittee, I am Debra Strickland; I am a Client Service Consultant at Xerox Government Healthcare. I would like to thank you for the opportunity to present testimony today on behalf of Employer groups, concerning the matter of Phase IV operating rules for **Claim.**

- **Does the operating rule meet the industry's business need/use/problem resolution?**

  The Claim infrastructure rule itself is specifically related to the use of the acknowledgements and this has been a part of the CAQH operating rules in the past and has been removed when the phases have been adopted. That is due to the fact that the Acknowledgement transactions are not Part of the HIPAA mandated suite of transactions. We want to acknowledge that the practice of using acknowledgements is necessary and as such the industry is using them in abundance. The industry has done this voluntarily without an operating rule. If there was to be a mandate for acknowledgements we would support the Inclusion of the Acknowledgement transactions from ASC X12 N and the Acknowledgement Reference Model TR2 for guidance as these already exist and are the foundation for the voluntary adoption.

  ASC X12 creates transactions and defines how they interact and flow within the EDI environments in order to achieve the goal of reconciliation. As the transactions change ASC X12 has a harmonization Workgroup that ensures that other impacted transactions make necessary modifications to keep in alignment.

  We do not support the Connectivity rule 470. This rule puts undue cost and burden on the industry and requiring this in an operating rule limits the freedom of organizations to seek out their own secure methods of transport which may be far more secure than the.509 certificates. We are concerned to see CAQH CORE offering rules around security and privacy as there are other national bodies(ie: NIST) that have this role in the industry and this practice can cause confusion on who is the holder of the role nationally and who trumps whom when it comes to compliance.

- **Does the operating rule decrease cost and/or administrative processes?**

  No the rule will have little to no effect on the industry as the claims are already processing at over 4 billion claims transactions per year and adding additional rules that the payers have to adhere to will not decrease cost or administrative processes.

- **Is the operating rule flexible/agile to meet changes in technology and/or healthcare delivery systems?**

  The Claim Operating Rule is not necessary for the above mentioned reasons. Operating rules are not very agile and have a long lead time to develop and institute changes. While it was thought that operating rules would be more agile and adaptive they have not proven to be.

  Operating rules institutionalized the use of SOAP/WSDL for system to system data transfers while the industry is moving toward more "mobile friendly" such as JSON and restful services. The industry did not take to the SOAP and MIME yet the payers had to build it at cost with no ROI.

- **Can the standard/operating rule be operationalized?**

  Yes

- **Can the standard/operating rule be enforced?**

  This is hard to say, can any standard be enforced? While it is said that the HIPAA standard transactions can be enforced they are not. They should be but are not widely audited allowing many to remain out of compliance. Even some still on the last version 4010.

  These rules are no different they will be put out there as law some will follow them and some will not but no one will really know the level of compliance. Even the testing of health plan compliance is a point in time test and does not measure a payer's true daily production compliance with transactions. The only way to verify is unannounced spot checks on the transactions via surprise audit.

Proposed Operating Rules – Questions for Industry **CLAIM**

(To be covered in written testimony. For oral testimony – 5 minutes for each testifier – please focus on the most important highlights)

Describe the industry's perspective on the proposed operating rules regarding the following:

1. **Do the proposed operating rules comply/support with the existing standards?**
   - **Does the standard require modification before implementing the proposed operating rules?**
     - *These rules do not contradict the standard and do not require additional changes to the standard in order for them to be used.*

2. **Do the proposed operating rules support the intended business function/intended use?**
   - **Do they provide a complete set of information needed to achieve the purpose of the transaction?**
     - *Yes*
   - **Do the operating rules achieve the transaction in the fastest, simplest, and cost –effective manner?**
     - *No, the rules are an unnecessary burden on the industry. Establishing this set of Phase IV rules is costly with not ROI,*

3. **What is the potential impact of the proposed operating rules to various health care entities (providers, payers, etc.) on the**

- Daily workflow/transaction process; *There is no value to the rule on the daily workflow as the claim transaction is processing at such a high rate in the industry today.*
- Administrative costs, *HIGH cost (No ROI) for the connectivity rule and if the payers are distracted from other industry activities in order to implement this Phase IV set of rules.*
- Required capabilities and – *Adding these rules are going to be a burden on the industry.*
- Agility to implement the operating rules changes? *They are not necessary.*

4. **Do the proposed operating rules provide efficiency improvement opportunities for administrative and/or clinical processes in health care?**

- *No the claim rule covers acknowledgements which should be done by ASC X12 and are being moved forward, Down time requirements which all have in place, Companion guide which all have in place and connectivity which is not their purview.*

5. **Has the potential for decrease in cost and improved efficiency been demonstrated by using the proposed operating rules?**

- *In Past operating rules Phase I, II and III the industry was required to implement a number of transport and security standards among other items. In some cases such as the requirement to support SOAP and MIME this came at a significant cost to payers and other covered entities to support these with the thought that if we build it they will come… that has not been the case. Many of the payers that Xerox supports and that were interviewed have had no one ask for these connectivity methods. So we challenge the REAL necessity of the rules and the application of critical criteria to assess the impacts to the industry before requiring the industry to adopt rules that return no value.*

6. **Do the proposed operating rules support changes in technology and health care models?**

- *No the establishment of this set of rules is being done simply because the law was written and included them. There needs to be a way to undue language in a law or amend it to say that Operating rules are not necessary for Claims due to high volume of adoption and use in the industry, service authorization because of the lack of use in the industry and enrollment and premium payment because they involve non covered entities who will not exchange the transactions as a requirement of law.*

7. **How will the operating rules provide consistency or limit the degree of variability to achieve optimal intended results?**

- *The operating rules will not provide consistency and there is no results stated to achieve except they were written into law.*

8. **How does the new set of proposed operating rules relate to, or affect the implementation of the operating rules already adopted?**

- *No*

9. Are there any consistency issues between the two versions?
    - *There are inconsistency issues between the two versions the connectivity of Phase I and II say SOAP and MIME is the way to go then Phase IV says now implement .509 certificates. This creates an inconsistency and there are other national bodies that govern the communications protocols across the industry that should remain in that role.*
10. What are the benefits or concerns with implementing the two versions concurrently?
    - *Phase IV is not necessary and the ROI is not there for the payers to have to focus on this set of rules.*
11. **Will system changes be required by the industry to implement the proposed operating rules?**
    - *It is likely that changes would need to be made if the claim rule is dictated to have the payers do the processes that they do already today in very specific ways. The industry has adapted to the needs of communicating claim information and this is working today – it is not broken so why fix it.*
12. **Have the proposed operating rules demonstrated ease in adoption and use?**
    - *No the Operating rules to date have been very costly for the entire industry but have not found there to be the ROI that was promised. The cost has been higher then what was originally thought and the return did not result in savings.*
        - *For example: Medicaid Example: the application form for a provider into the Medicaid provider network included ERA and EFT information as options for them within the enrollment form (very long single form).*

          The ERA EFT enrollment rule required them to make vast changes to the enrollment process to separate these forms (because it had to be a single form/page)– reiterate information that was already collected in different portions of the enrollment form pre-fill the data already entered – and format them specifically to the letter of the law.

          This caused more disruption than benefit to the payer and the providers filling out the data. Things were not fully vetted to see how this process would impact payers and providers.

13. **What amount of time is needed for the industry to implement the proposed Operating Rules?**
    - *We do not support the claim Operating rule. However if it were imposed upon us 18 months to 24 months would be recommended.*
14. **What lessons learned from previously adopted operating rules have been applied/addressed in the proposed operating rules?**
    - *It appears that CAQH is keeping consistent the Acknowledgement requirements (which have to date been excluded by law), Down time notification and Companion guide usage.*
15. **Do the proposed operating rules incorporate the concerns raised by the industry at the June 2015 Review Committee hearing? Which concerns? How?**

- *No, these rules were pretty much written although not formally released to the industry at that time. The rules did not change as a result of the review committee hearing that we are aware of.*

16. **Has the industry developed strategies to measure the impact of adopting the proposed operating rules on the industry?**
    - *Not in any formal and consistent manner. Organizations such as WEDI should be used to help develop these strategies and measurement criteria to see what real ROI or lack of ROI is for Operating rules, with the help of other partner organizations.*
17. **Has the industry developed metrics to measure the effectiveness and value of adopting the proposed operating rules? What are they?**
    - *No at this point there are not consistent metrics being used across the industry. Perhaps there should be a portion of any future operating rules that says and this is how the effectiveness and ROI of this rule is measured*.
18. **How do the proposed operating rules facilitate potential emerging or evolving clinical, technical and/or business advances?**
    - *These rules do not facilitate potential emerging or evolving clinical, technical and/or business advances*
19. **Do the proposed operating rules provide potential impact and/or improvement to health care related data and/or data infrastructure?**
    - *No these rules do not impact and/or make improvements to health care related data and/or data infrastructure*
20. **If applicable, do the proposed operating rules incorporate privacy, security and confidentiality?**
    - *These rules do require connectivity .509 certificates but we feel they should not be able to require this.*
21. **Do the proposed operating rules sufficiently align with the HITECH Stage 3 Final Rules on interoperability/Health Information Exchange so as to be reasonable for effectiveness and efficiency of the industry?**
    - *We believe that as part of the development process for operating rules that the requirement be that the rules must align with all regulatory rules across the industry.*
22. **Can the proposed operating rules be enforced? How?**
    - *Not anymore than the HIPAA transactions can today.*
23. **Should NCVHS recommend the adoption of the proposed Operating Rules? Please explain.**
    - *We do not feel that the Phase IV claims or other Operating rules should be recommended for adoption.*
        - *For the following reasons we do not support the Phase IV operating rules.*

          The Claim – this is well established as mentioned before. The communications that the industry has needed to employ over the last two decades have been established the "highway is paved". The industry has to adhere to the HIPAA Privacy and Security laws in order to secure that data that is sufficient.

The Prior Authorization – is not a heavily used transaction in the industry today. Not nearly enough to justify the entire industry applying rules to a transaction that does not yet have a large uptake in usage. The proposed operating rules do not provide enhancements that would encourage the stakeholders to implement.

Premium Payment – This transaction has had a great deal of focus through the advent of the HIE's. Payers have had to implement various flavors of this transaction with companion guide guidance from entities such as CCIIOO (Center for Consumer Information & Insurance Oversight). These are now up and running and it would seem that they are not having major issues. In our opinion requiring further changes to transactions that the payers just got all set is not necessary and would constitute a barrier to the success of the other mandates they need to adhere to.

Enrollment / Disenrollment

The main users of this transaction are employer groups such as Xerox. However, employer groups are not covered entities and have absolutely no motivation to change what they are doing today and have no regulations mandating compliance or use of this transaction.

The adoption of these rules requires payer compliance to accept these transactions in real time in accordance to the rules, but they will receive little to no transaction volume from the non-covered entities.

In prioritizing the EDI rules, this transactions has the least likely adoption or benefit by employer groups

END CLAIM WRITTEN TESTIMONY

START ENROLLMENT / DISENROLLMENT TESTIMONY

Enrollment / Disenrollment

1. **Do the proposed operating rules comply/support with the existing standards?**
   - **Does the standard require modification before implementing the proposed operating rules?**
     - *The standard would not have to change in order for the operating rules to be used.*

2. **Do the proposed operating rules support the intended business function/intended use?**
   - Do they provide a complete set of information needed to achieve the purpose of the transaction?

- *The operating rules do provide information however, when the entity that has to create and send the transaction is not required to do so you can expect adoption of the standard transaction never mind operating rules will be very low.*
- *Inclusion of this transaction in the Phase IV rules is a waste and drain on the payers to have to implement changes that will never get used.*

3. **Do the operating rules achieve the transaction in the fastest, simplest, and cost – effective manner?** *No*

4. **What is the potential impact of the proposed operating rules to various health care entities (providers, payers, etc.) on the daily workflow/transaction process; administrative costs, required capabilities and agility to implement the operating rules changes?**
   - Do the proposed operating rules provide efficiency improvement opportunities for administrative and/or clinical processes in health care?
     - *There will be none because the adoption of the transaction will be low. This will be all cost to the payer and no ROI.*
   - Has the potential for decrease in cost and improved efficiency been demonstrated by using the proposed operating rules?
     - *These rules will increase cost and burden the industry with additional unused coding such as real time support of the Enrollment transaction.*
5. **Do the proposed operating rules support changes in technology and health care models?**
   - *No these rules will not support changes in technology until the senders of the transactions are included in the law as covered entities or at least BAs.*
   - *Until the employers are required to send these transactions they will not and the payers will have to continue with the litany of various ways that employers send in enrollment data which is costly.*
6. **How will the operating rules provide consistency or limit the degree of variability to achieve optimal intended results?**
   - *The content of the rule will not change even the very low amount of transactions that are exchanged today.*
7. **How does the new set of proposed operating rules relate to, or affect the implementation of the operating rules already adopted?**
   - *This set of rules follows the request for Acknowledgement, Downtime schedules, companion guides.*
8. **Are there any consistency issues between the two versions?**
   - *No*
9. **What are the benefits or concerns with implementing the two versions concurrently?**
   - *No impacts as the rules that are written presently are for other transactions.*
10. **Will system changes be required by the industry to implement the proposed operating rules?**
    - *Yes since the Standard HIPAA implementation guide does not support Real time Enrollments and this operating rule does the payers would need to modify their systems to support this mode even though the employers will not send in this mode.*

11. Have the proposed operating rules demonstrated ease in adoption and use?

- *No the Operating rules to date have been very costly for the entire industry but have not found there to be the ROI that was promised. The cost has been higher then what was originally thought and the return did not result in savings and there was no evaluation after the first set of operating rules to measure this fact.*
    1. *For example: Medicaid Example: the application form for a provider into the Medicaid provider network included ERA and EFT information as options for them within the enrollment form (very long single form).*
        - *The ERA EFT enrollment rule required them to make vast changes to the enrollment process to separate these forms (because it had to be a single form/page)– reiterate information that was already collected in different portions of the enrollment form pre-fill the data already entered – and format them specifically to the letter of the law.*
        - *This caused more disruption than benefit to the payer and the providers filling out the data. Things were not fully vetted to see how this process would impact payers and providers.*

12. What amount of time is needed for the industry to implement the proposed Operating Rules?

- *In general about 18-24 months is needed to implement the Operating rules. Perhaps more time for government agencies that have to apply for federal funding for these efforts*
- *We want to remind all that for this set of operating rules which will have a net neutral effect on the industry they are paid for by federal dollars of our tax payer money for Medicaid's. It is one thing to say oh the commercial payers make enough money to cover this stuff but there are many Medicaid payers that have to also implement these rules and that comes from our tax dollars.*

13. Do the proposed operating rules incorporate the concerns raised by the industry at the June 2015 Review Committee hearing? Which concerns? How?

- *No, these rules were pretty much written although not formally released to the industry at that time. The rules did not change as a result of the review committee hearing that we are aware of.*

14. Has the industry developed strategies to measure the impact of adopting the proposed operating rules on the industry?

- *Not in any formal and consistent manner. Organizations such as WEDI should be used to help develop these strategies and measurement criteria to see what real ROI or lack of ROI is for Operating rules, with the help of other partner organizations.*

15. Has the industry developed metrics to measure the effectiveness and value of adopting the proposed operating rules? What are they?

- *No at this point there are not consistent metrics being used across the industry. Perhaps there should be a portion of any future operating rules that says and this is how the effectiveness and ROI of this rule is measured.*

16. How do the proposed operating rules facilitate potential emerging or evolving clinical, technical and/or business advances?

- *These rules do not facilitate potential emerging or evolving clinical, technical and/or business advances*

17. Do the proposed operating rules provide potential impact and/or improvement to health care related data and/or data infrastructure?

- *No these rules do not impact and/or make improvements to health care related data and/or data infrastructure*

18. If applicable, do the proposed operating rules incorporate privacy, security and confidentiality?

- *These rules do require connectivity .509 certificates but we feel they should not be able to require this.*

19. Do the proposed operating rules sufficiently align with the HITECH Stage 3 Final Rules on interoperability/Health Information Exchange so as to be reasonable for effectiveness and efficiency of the industry?

- *We believe that as part of the development process for operating rules that the requirement be that the rules must align with all regulatory rules across the industry.*

20. Can the proposed operating rules be enforced? How?

- *Not anymore than the HIPAA transactions can today.*

21. Should NCVHS recommend the adoption of the proposed Operating Rules? Please explain.

- *We do not feel that the Phase IV claims or other Operating rules should be recommended for adoption.*
- *For the following reasons we do not support the Phase IV operating rules.*

  The Claim – this is well established as mentioned before. The communications that the industry has needed to employ over the last two decades have been established the "highway is paved". The industry has to adhere to the HIPAA Privacy and Security laws in order to secure that data that is sufficient.

  The Prior Authorization – is not a heavily used transaction in the industry today. Not nearly enough to justify the entire industry applying rules to a transaction that does not yet have a large uptake in usage. The proposed operating rules do not provide enhancements that would encourage the stakeholders to implement.

  Premium Payment – This transaction has had a great deal of focus through the advent of the HIE's. Payers have had to implement various flavors of this transaction with companion guide guidance from entities such as CCIIOO (Center for Consumer Information & Insurance Oversight). These are now up and running and it would seem that they are not having major issues. In our opinion requiring further changes to transactions that the payers just got all set is not

necessary and would constitute a barrier to the success of the other mandates they need to adhere to.

Enrollment / Disenrollment

The main users of this transaction are employer groups such as Xerox. However, employer groups are not covered entities and have absolutely no motivation to change what they are doing today and have no regulations mandating compliance or use of this transaction.

The adoption of these rules requires payer compliance to accept these transactions in real time in accordance to the rules, but they will receive little to no transaction volume from the non-covered entities.

In prioritizing the EDI rules, this transactions has the least likely adoption or benefit by employer groups

Questions for Panelists – Proposed Standard For Attachments – INDUSTRY

(To be covered in written testimony. For oral testimony – 5 minutes for each testifier – please focus on the most important highlights)

Our recommendation for attachments is as follows:

1. HL7 Consolidated Clinical Documentation Architecture & Templates (C-CDA) R2.1

   This is from HL7 and can carry both structured and unstructured data.

2. HL7 Attachment Supplement Specification: Exchange Implementation Guide Release 1

   This is a guide to help implementers similar to a Technical Report 3 – Implementation guide. This is to be used to support the C-CDA.

3. HL7 Clinical Documents for Payers Set 1 (Optional -Payers and Clearinghouses should have this ready in case a Trading Partner wishes to use this however, it is not very likely as this is fairly new and technically harder without HL7 trained staff)

   This should NOT be in any way required for the providers. Much like the HIPAA Transactions the providers should be able to choose the way they want to interact and send attachments. There are already many attachment transactions occurring across the industry and we do not want to stop or hinder what is working now.

4. ASC X12N 277 Health Care Claim Request for Additional Information (optional use)

   This transaction is used to ask for the specific information that the payer is looking for so the provider can send just what is needed.

5. ASC X12N 275 Additional Information to Support a Health Care Claim or Encounter (optional use)

   Because the CDA and the 275 can both be used for Structured and unstructured attachments it is best that they both be options for use. Because there was a lapse in the rule making for attachments the industry adopted many different ways to get attachments to the payers. This is not a bad thing as there is low tech to high tech options that are required to service the entire industry. Any rule making should take into account all levels of ability and NOT create a forced situation for the providers as they may just keep it on paper which would not be in the best interest of the industry.

6. ASC X12N 275 Additional Information to Support a Health Care Services Review

7. LOINC (subset HIPAA Panel)

8. ASCX12 Acknowledgement Reference Model (ARM)

   The ARM is a technical report type 2 which is educational from ASC X12 this TR2 was written to help the industry understand which acknowledgements should be used to respond to which transactions. This and the ASC X12 acknowledgement transactions should be adopted so the industry use will expand.

   The industry already uses acknowledgements even though they are not in any final rule why? Because they are valuable and are a positive add to the EDI transaction processing flow. Those who have to wait for a regulation to implement have not adopted these transactions but they would if there were regulations so it would be in the best interest of the industry to have these as the standard and the ARM as the guidance.