

# Public Comment Summary Report

**Project Title:** *Clinical and Anatomic Pathology Measure Development*

**Dates:**

The Call for Public Comment ran from August 11, 2020 to September 13, 2020.

**Project Overview:**

The Centers for Medicare & Medicaid Services (CMS) has provided funding to the American Society for Clinical Pathology (ASCP) to develop pathology electronic clinical quality measures (eCQMs). The cooperative agreement name is Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) Funding Opportunity: Measure Development for the Quality Payment Program. The cooperative agreement number is 1V1CMS331635-03-02. As part of its measure development process, ASCP has requested interested parties to submit comments on the candidate or concept measures that may be suitable for this project. The purpose of this project is to develop electronic clinical quality measure (eCQM) specifications for use in MIPS from existing registry-based pathology measures.

**Information About the Comments Received:**

The measure developer solicited public comments via the CMS Measures Management System (MMS) web site, via ASCP electronic member communications, LinkedIn and other social media sites. As we anticipated the known and inherent challenges of re-tooling measures of varying models such as registry, claims, and manually abstracted measures, the ASCP measure development team solicited preliminary feedback early in the measure development process. We requested qualitative information for several questions specific to the workflows in their particular laboratory information system (LIS) and its interaction with the corresponding electronic health record (EHR). We sought feedback on the mechanism of communication and documentation of communications in LISs and EHRs as well as how that may vary widely across practice sites. The questions included in the call for public comment specifically solicited feedback on the feasibility of capturing provider to provider communication given the various mechanisms of communication and how the communication is documented, as we expected this also to vary widely across practice sites.

We received 52 responses on this topic from a total of 4 commenters in response to questions focused on the feasibility of communication capture for the eCQMs.

**Stakeholder Comments**

**General Stakeholder Comments:**

N/A – all comments were measure-specific.

**Measure-Specific Stakeholder Comments:**

**Stakeholder Comments on Measure 6: Rate of Notification to the Responsible Provider of a New Diagnosis of Malignancy within 5 Days of Pathology Report**

- Three out of four commenters noted that Measure 6 was “very useful” or “somewhat useful” in assessing pathologist performance and improving quality of care for patients.
- Commenters suggested that the following definitions might help to clarify the measure specifications:

- New diagnosis - initial first cancer of any type, or would it include second primaries or metastatic site
  - Communication methods – which communication methods meet the numerator criteria
- Clinical concepts documented in lab workflow:
  - Yes
  - No; may be reported verbally by the Pathologist and may not be documented
  - Yes
  - No; communication not well defined
- Clinical concepts in structured extractable fields in EHR:
  - All except “new diagnosis”
  - Call to physician may not be documented in the EHR
  - All clinical concepts are documented in EHR
  - Some EHRs capture communication in a structured fashion
- How is communication performed?
  - All commenters noted that communication was performed via telephone conversation or voice mail message.
  - Three of four commenters noted that communication was also performed via notes in the EHR/LIS, via e-mail, and via an automatic notification or alert system.
- Response: The measure developer would like to thank the commenters for their helpful feedback. We will take this feedback into consideration and consider further defining “new” diagnosis and listing acceptable methods of communication as the measure implementation guidance is further refined post-feasibility testing.

**Stakeholder Comments on Measure 7: Rate of Communicating Results of an Amended Report with a Major Discrepancy to the Responsible Provider**

- Three out of four commenters noted that Measure 7 was “very useful” or “somewhat useful” in assessing pathologist performance and improving quality of care for patients.
- All commenters noted that the term “major” diagnostic discrepancy might be subjective and that it may be better to define what constitutes a “major” discrepancy. One commenter noted that while major discrepancies are a clinically important phenomenon, they are and should be very rare. It is not unusual to have a high number of cases undergo secondary review, but major discrepancies may indicate poor performance as a pathologist.
- Regarding the ideal turn-around time for results of any amended reports due to a major discrepancy will be communicated to the clinical care team:
  - 48 hours
  - 3 days
  - ASAP. Ideally within the same day the discrepancy is discovered
  - Before the amendment is signed out
- Clinical concepts documented in lab workflow:
  - Half of the commenters noted that all clinical concepts are documented in lab workflow. Commenters also suggested that major discrepancies are reported but as a manual process, not in EHR directly, and that results sent immediately to the treating physician or bedside care team for review. One commenter noted that it may not be routinely documented or may only be documented at the secondary review site.
- Clinical concepts in structured extractable fields in EHR:
  - One commenter noted that all clinical concepts are captured in structured extractable fields in the EHR. One commenter noted that some EHRs capture communication in a

structured fashion. One commenter noted that diagnostic discrepancies were not discreetly captured. One commenter was unsure if the discrepancies would be captured in a discreet field or not.

- How is communication performed?
  - All commenters noted that communication would be performed via a note in the EHR/LIS systems. Three out of four commenters noted that communication may also be performed via telephone conversation, voice mail, or e-mail message. Half of the commenters noted that communication would be performed via an automatic notification or alert system. In addition, one commenter also noted that communication may occur via in-basket messages in Epic, as a note loaded into the EMR, or in a Best Practice Advisory to the care team.
  
- Response: Thank you for your feedback. The measure developer understands the issues of accurately capturing provider to provider communications in addition to system generated electronic alerts in EHRs. We will take this feedback into consideration and further define a “major” diagnostic discrepancy as the measure implementation guidance is refined post-feasibility testing.

### **Preliminary Recommendations**

We plan to update the measure implementation guidance to further detail the concepts of “new” diagnosis, “major” diagnostic discrepancy, and also list the methods of communication suitable to meet the numerator criteria for the measures. The overall comments also confirmed our anticipation of the breadth of communication practices and capture in both LIS and EHR systems. We expect further refinements may be necessary based on feasibility test results which will provide us with more specific quantitative information from several additional EHRs and several additional sites. Using both the quantitative and the qualitative information obtained, we will make additional recommendations for further refinements to Measures 6 and 7 to the ASCP Technical Expert Panel (TEP) to get additional stakeholder feedback on those refinements for the next iterative version of Measures 6 and 7.

### **Overall Analysis of the Comments and Recommendations**

The TEP received a summary of the public comments via email on October 13, 2020. We plan to discuss potential specification updates to the list of candidate measures (Measures 6 and 7) with the TEP following receipt of preliminary alpha testing results.

<sup>1</sup>Centers for Medicare & Medicaid Services. (n.d.). Making documents Section 508 compliant. Retrieved June 20, 2020 from <https://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/Section508/508-Compliant-doc>

## Public Comment Verbatim Report

Comment Number*	Date Posted/ Received	Name, Credentials, and Organization of Commenter	Type of Organization*	Email Address*	Measure Set or Measure	Text of Comments	Response*
<i>Do you think Measure 6's denominator and numerator are clearly defined and clinically meaningful?</i>					Measure 6		
1	8/10/20	Denise Morse, Hospital professional (e.g., Risk Management, Quality Improvement, Chief Information Officer, etc.)	Individual		Measure 6	No (please provide your suggestions) Define "New diagnosis" - is it initial first cancer of any type, or would it include second primaries or metastatic site. What are the communication methods allowed in the numerator?	
2	8/12/20	Lynnette Chakkaphak, Laboratory Professional	Individual		Measure 6	Yes	
3	8/17/20	Gary Procop, Pathologist	Individual		Measure 6	Yes	
4	9/11/20	College of American Pathologists	Medical Specialty Society		Measure 6	In particular, the numerator is not well-defined. The method of communication is not fully specified: for instance, the pathology report itself is a form of communication. Does this measure require communication beyond that? If so, does the action have to be performed by a pathologist or could it be performed by an assistant? The numerator also omits communication before a report is finalized in favor of communication after a report is finalized. That is, if a pathologist notifies the ordering provider as soon as he or	

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						<p>she has the information but before the report is signed out, does that satisfy the quality action? If so, this is not clear in the measure. With respect to notification after the report is finalized, current EHRs and patient portals already address the concern raised by this measure by ensuring that the ordering physician is notified when a result is ready and providing patients access to their results. Similarly, if the intent of the measure is to show closure of the communication loop, the specifications of the measure do not fully satisfy that. It is not clear whether a text or email without read receipts is sufficient; if not, without knowing that the ordering physician received the information, is the loop really closed? Given that most facilities have a standard operating procedure in place addressing when critical results/unexpected findings should be directly communicated to the ordering provider (this is an accreditation requirement), it is unlikely that a significant performance gap exists for this measure. Therefore,</p>	

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						rationale is needed to add burden to pathologists for additional documentation/communication. Particularly given the practice of many pathologists to communicate such findings prior to signing out the report, additional rationale is needed to justify the increased burden on clinicians who are performing better than the measure requires.	
<i>How useful is Measure 6 in assessing pathologist performance and improving quality of care for patients?</i>					Measure 6		
1	8/10/20	Denise Morse, Hospital professional	Individual		Measure 6	Somewhat useful	
2	8/12/20	Lynnette Chakkaphak, Laboratory Professional	Individual		Measure 6	Very useful	
3	8/17/20	Gary Procop, Pathologist	Individual		Measure 6	Very useful	
4	9/11/20	College of American Pathologists	Medical Specialty Society		Measure 6	Not useful	
<i>For Measure 6, are these clinical concepts routinely documented in the normal course of clinical and laboratory workflows in your organization or in your experience?</i>					Measure 6		
1	8/10/20	Denise Morse, Hospital professional	Individual		Measure 6	Yes	
2	8/12/20	Lynnette Chakkaphak, Laboratory Professional	Individual		Measure 6	No (please describe which concepts are not routinely documented in the workflows): These reports may be reported verbally by the Pathologist and may not be documented.	
3	8/17/20	Gary Procop, Pathologist	Individual		Measure 6	Yes	
4	9/11/20	College of American Pathologists	Medical Specialty Society		Measure 6	No (please describe which concepts are not routinely documented in the	

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						workflows): Because the exact expectations around “communication” are not clearly specified in the measure, it is difficult to say. A form of communication above and beyond the pathology report itself may or may not be documented. In complicated cases in which the diagnosis is delayed, pathologists communicate with the bedside care team as appropriate but there is no routine communication beyond the pathology report. Current EMR and patient portals already address the concern raised by this measure by ensuring that the ordering physician is notified when a result is ready and providing patients access to their results.	
<i>For Measure 6, are all clinical concepts readily available in structured, extractable fields in your organization’s EHR system?</i>					Measure 6		
1	8/10/20	Denise Morse, Hospital professional	Individual		Measure 6	No (please tell us which concepts are not available in your organization’s EHR system): New diagnosis	
2	8/12/20	Lynnette Chakkaphak, Laboratory Professional	Individual		Measure 6	No (please tell us which concepts are not available in your organization’s EHR system): Call to physician may not be documented in EHR	
3	8/17/20	Gary Procop, Pathologist	Individual		Measure 6	Yes	
4	9/11/20	College of American Pathologists	Medical Specialty Society		Measure 6	No (please tell us which concepts are not available in your organization’s	

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						EHR system): Data in EHRs is difficult if not impossible for MIPS-reporting pathologists to access. Even if some EHRs capture communication in a structured fashion (which has not been our experience), data that is not owned by the MIPS reporting pathologist has proven almost impossible to access in our experience. Additionally, due to the variability among laboratory information systems, it is even more difficult to generalize about the availability of EHR data to laboratories.	
<i>For Measure 6, are all clinical concepts available in structured, extractable fields in your organization's LIS?</i>					Measure 6		
1	8/10/20	Denise Morse, Hospital professional	Individual		Measure 6	I don't know	
2	8/12/20	Lynnette Chakkaphak, Laboratory Professional	Individual		Measure 6	No (please tell us which concepts are not available in your organization's LIS): Call to physician may not be documented in the EHR.	
3	8/17/20	Gary Procop, Pathologist	Individual		Measure 6	No (please tell us which concepts are not available in your organization's LIS): An EHR "read or opened" receipt will be needed. This will not be in the LIS	
4	9/11/20	College of American Pathologists	Medical Specialty Society		Measure 6	No (please tell us which concepts are not available in your organization's LIS): Forms of communication are not captured in structured	

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						fields. Diagnosis of malignancy is captured but is not always in structured fields, depending on the LIS and pathologist in question. To use the measure a standardized structured and extractable method of documentation would have to be created. This would create additional burden for the IT team and additional burden for busy pathologists to make this documentation for something that is not expected to improve the quality of care.	
<i>For Measure 6, how is this type of communication performed in your organization? Select all that apply:</i>					Measure 6		
1	8/10/20	Denise Morse, Hospital professional	Individual		Measure 6	Notes in the EHR/LIS, Telephone conversation or voice mail message, Email, Automatic notification/alert system	
2	8/12/20	Lynnette Chakkaphak, Laboratory Professional	Individual		Measure 6	Telephone conversation or voice mail message	
3	8/17/20	Gary Procop, Pathologist	Individual		Measure 6	Automatic notification/alert system	
4	9/11/20	College of American Pathologists	Medical Specialty Society		Measure 6	Notes in the EHR/LIS, Telephone conversation or voice mail message, Automatic notification/alert system	
<i>Do you think Measure 7's denominator and numerator are clearly defined and clinically meaningful?</i>					Measure 7		
1	8/10/20	Denise Morse, Hospital professional	Individual		Measure 7	No (please provide your suggestions) Better define "major diagnostic discrepancy" so it can be properly abstracted reliably among centers.	

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2	8/12/20	Lynnette Chakkaphak, Laboratory Professional	Individual		Measure 7	No (please provide your suggestions) Major discrepancy does not appear to be defined, nor does it indicate whether this applies to Pathology reports only	
3	8/17/20	Gary Procop, Pathologist	Individual		Measure 7	No (please provide your suggestions) Please add a footnote to further define "major."	
4	9/11/20	College of American Pathologists	Medical Specialty Society		Measure 7	No (please provide your suggestions): As written, this measure has a significant risk of unintended consequences by incentivizing poor performance. It is uncommon and in fact undesirable for a pathologist to have a significant number of major discrepancies within a performance period. Given that the CMS-mandated minimum is 20 cases within a performance period (one calendar year), only clinicians who are performing poorly and have more than 20 major discrepancies within a year would be eligible for the measure. CMS has previously expressed a desire to avoid "never event" or very rare event measures such as a fire in the operating room. While major discrepancies are a clinically important phenomenon, they are and should be very rare. It is not unusual to have a high	

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						<p>number of cases undergo secondary review, but 20 cases of major discrepancy indicates poor performance as a pathologist irrespective of the performance score on this measure. As well, the definition of a major discrepancy is not clear. What is being considered the gold standard for purposes of this measure? If a pathologist disagrees with the second opinion provided on his or her diagnosis, does that automatically count as a major discrepancy? Is any consideration given to the correct diagnosis? Reporting all cases that undergo secondary review to the ordering physician would likely be highly confusing for both the ordering clinician and the patient. Similarly, if a pathologist disagrees with a secondary review site (particularly if he or she is correct), is he or she required to document that difference? If not, this information would only be available from a secondary review site.</p>	
		<p><i>In your practice, is it a standard that results of any amended reports due to a major discrepancy will be communicated to the clinical care team?</i></p>			Measure 7		
1	8/10/20	Denise Morse, Hospital professional	Individual		Measure 7	Yes (what do you think is the ideal turnaround time?): 48 hours	

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2	8/12/20	Lynnette Chakkaphak, Laboratory Professional	Individual		Measure 7	Yes (what do you think is the ideal turnaround time?): 3 days	
3	8/17/20	Gary Procop, Pathologist	Individual		Measure 7	Yes (what do you think is the ideal turnaround time?): ASAP. Ideally within the same day the discrepancy is discovered.	
4	9/11/20	College of American Pathologists	Medical Specialty Society		Measure 7	Yes (what do you think is the ideal turnaround time?): Before the amendment is signed out	
<i>How useful is Measure 7 in assessing pathologist performance and improving quality of care for patients?</i>					Measure 7		
1	8/10/20	Denise Morse, Hospital professional	Individual		Measure 7	Somewhat useful	
2	8/12/20	Lynnette Chakkaphak, Laboratory Professional	Individual		Measure 7	Very useful	
3	8/17/20	Gary Procop, Pathologist	Individual		Measure 7	Very useful	
4	9/11/20	College of American Pathologists	Medical Specialty Society		Measure 7	Not useful	
<i>For Measure 7, are these clinical concepts routinely documented in the normal course of clinical and laboratory workflows in your organization or in your experience?</i>					Measure 7		
1	8/10/20	Denise Morse, Hospital professional	Individual		Measure 7	No (please describe which concepts are not routinely documented in the workflows): Major discrepancies are reported but as a manual process, not in EHR directly. Results sent immediately to MD for review	
2	8/12/20	Lynnette Chakkaphak, Laboratory Professional	Individual		Measure 7	Yes	
3	8/17/20	Gary Procop, Pathologist	Individual		Measure 7	Yes	
4	9/11/20	College of American Pathologists	Medical Specialty Society		Measure 7	No (please describe which concepts are not routinely documented in the workflows): Major discrepancies are documented and communicated to	

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						the bedside care team. However, not all secondary review may be documented so if a pathologist disagrees with the idea of a major discrepancy, it may not be routinely documented or may only be documented at the secondary review site.	
<i>For Measure 7, are all clinical concepts readily available in structured, extractable fields in your organization's EHR system?</i>					Measure 7		
1	8/10/20	Denise Morse, Hospital professional	Individual		Measure 7	No (please tell us which concepts are not available in your organization's EHR system): Diagnostic discrepancies not discreetly captured	
2	8/12/20	Lynnette Chakkaphak, Laboratory Professional	Individual		Measure 7	Yes	
3	8/17/20	Gary Procop, Pathologist	Individual		Measure 7	I don't know	
4	9/11/20	College of American Pathologists	Medical Specialty Society		Measure 7	No (please tell us which concepts are not available in your organization's EHR system): Data in EHRs is difficult if not impossible for MIPS-reporting pathologists to access. Even if some EHRs capture communication in a structured fashion (which has not been our experience), data that is not owned by the MIPS reporting pathologist has proven almost impossible to access in our experience. Additionally, due to the variability	

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						among laboratory information systems, it is even more difficult to generalize about the availability of EHR data to laboratories.	
<i>For Measure 7 Are all clinical concepts available in structured, extractable fields in your organization's LIS?</i>					Measure 7		
1	8/10/20	Denise Morse, Hospital professional	Individual		Measure 7	I don't know	
2	8/12/20	Lynnette Chakkaphak, Laboratory Professional	Individual		Measure 7	Yes	
3	8/17/20	Gary Procop, Pathologist	Individual		Measure 7	No (please tell us which concepts are not available in your organization's LIS): Who the information was conveyed to may be buried in the amendment note and difficult to extract.	
4	9/11/20	College of American Pathologists	Medical Specialty Society		Measure 7	No (please tell us which concepts are not available in your organization's LIS): When there is documentation, it is in the form of a free text comment and the language used is not standardized between pathologists in the group. This also raises a larger question of feasibility. If documentation is not in structured fields, it is possible that all cases with amendments would be pulled into this measure and the burden would fall on clinicians to determine which are actually major	

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						discrepancies. It is also possible that any case that underwent secondary review would be captured by this measure. As noted above, this would only confuse ordering physicians and patients since most of these are not major discrepancies and would not satisfy the intent of the measure.	
<i>For Measure 7, how is this type of communication performed in your organization? Select all that apply:</i>					Measure 7		
1	8/10/20	Denise Morse, Hospital professional	Individual		Measure 7	Automatic notification/alert system, Notes in the EHR/LIS, Telephone conversation or voice mail message, Email	
2	8/12/20	Lynnette Chakkaphak, Laboratory Professional	Individual		Measure 7	Notes in the EHR/LIS	
3	8/17/20	Gary Procop, Pathologist	Individual		Measure 7	Notes in the EHR/LIS, Telephone conversation or voice mail message, Email	
4	9/11/20	College of American Pathologists	Medical Specialty Society		Measure 7	Automatic notification/alert system, Notes in the EHR/LIS, Telephone conversation or voice mail message	
<i>Please share with us how this type of communication is documented in the overall workflow in your organization.</i>					Measures 6 & 7		
1	8/10/20	Denise Morse, Hospital professional	Individual		Measures 6 & 7	Inbasket messages in EPIC Note loaded into the EMR Best Practice Advisory	
2	8/12/20	Lynnette Chakkaphak, Laboratory Professional	Individual		Measures 6 & 7	Measure 6 is communicated verbally	

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3	8/17/20	Gary Procop, Pathologist	Individual		Measures 6 & 7	Amended reports are documented by AP Quality Committee. New diagnosis likely is conveyed in most instances with a "read" receipt in the EHR.	
4	9/11/20	College of American Pathologists	Medical Specialty Society		Measures 6 & 7	<p>Measure 6: As noted above, communication varies widely and documentation will also vary widely. Cases with a delay in diagnosis will likely be communicated and documented differently than standard cases, in which the pathology report is the communication.</p> <p>Measure 7: Cases which actually have major discrepancies are communicated to the bedside care team via phone or email as appropriate. It is likely that communication is captured only in the form of a note in the LIS.</p>	
<i>Is there anything else you'd like to share with us about the measures? (e.g., denominator or numerator exclusions needed, unintended consequences, etc)</i>					Measures 6 & 7		
1	8/10/20	Denise Morse, Hospital professional	Individual		Measures 6 & 7	Respondent skipped this question	
2	8/12/20	Lynnette Chakkaphak, Laboratory Professional	Individual		Measures 6 & 7	NA	
3	8/17/20	Gary Procop, Pathologist	Individual		Measures 6 & 7	Respondent skipped this question	
4	9/11/20	College of American Pathologists	Medical Specialty Society		Measures 6 & 7	Measure 6: It is not clear how basal cell carcinoma and squamous cell carcinoma were chosen for exclusion from the denominator of this measure. It is likely there are other types of cancer/specimens that should also be excluded due to concerns about volume	

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						<p>coupled with the rarity of unexpected malignancy. It is also likely that an exception is needed for cases in which there is a medical reason that the ordering physician was not contacted. While the intent of the measure may have value, it is only reasonable to account for cases in which there is a medical reason for not contacting the ordering clinician, for instance, if a patient has already expressed the intent not to undergo treatment. Measure 7: Unintended consequences are significant, making this concept not a strong candidate for a MIPS measure. A high performance score on this measure runs the risk of suggesting that a pathologist is providing quality care when the very fact of qualifying for this measure (20 cases in a performance period) means he or she is not.</p>	

\*Optional