Summary Report of Public Comments

Screening for Pregnancy Measure

June 12, 2018

This document was prepared by the Measure & Instrument Development and Support Contractor for the Inpatient Psychiatric Facility Outcome and Process Measure Development and Maintenance Task Order, under contract with the Centers for Medicare & Medicaid Services, an agency of the U.S. Department of Health and Human Services. The contents presented do not necessarily reflect CMS policy.

Public Comment Summary Report

Project Title

Inpatient Psychiatric Facility (IPF) Outcome and Process Measure Development and Maintenance

Dates

The Call for Public Comment was open from May 4, 2018 and closed on May 31, 2018.
The Public Comment Summary was made on August 6, 2018.

Project Overview

The Centers for Medicare & Medicaid Services (CMS) has contracted with Health Services Advisory Group, Inc. (HSAG), to develop, maintain, reevaluate, and support the implementation of quality outcome and process measures for the CMS Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program under the Measure & Instrument Development and Support (MIDS) Contract (Contract #: HHSM-500-2013-13007I), and Task Order Inpatient Psychiatric Facility Outcome and Process Measure Development and Maintenance (Task Order #: HHSM-500-T0004). As part of its measure development process, CMS requested interested parties to submit comments on the candidate or concept measures that may be suitable for this project.

Project Objectives

The primary project objectives are:

- To develop new measures that drive quality improvement, are patient centered, are aligned with other programs, and that fill critical gaps for future inclusion in the CMS IPFQR Program.
- To maintain and reevaluate existing IPF measures.
- To support measure implementation in the IPFQR Program.

To provide an important indicator of the quality of care patients receive in the IPF setting, the project team developed a *Screening for Pregnancy* measure that assesses the percentage of female patients of childbearing age (15–44 years) admitted to an IPF who have documentation in their medical record of a pregnancy status.

Public comments were solicited for this proposed *Screening for Pregnancy* quality measure to obtain input from stakeholder organizations and interested parties,

Information About the Comments Received

The announcement for the Call for Public Comment was posted on the CMS Public Comment webpage. The Methodology Report, which included the Measure Information Form, Data Dictionary, and Data Collection Tool, were available to the commenters to review.

Public comments were solicited from 27 organizations by email notification about the opening of the public comment. In addition, the measure developer notified 41 individual experts, which included

current and past technical expert panel members, and measure workgroup members regarding the Call for Public Comment announcement and requested that they share the announcement with interested colleagues. Appendix A lists the stakeholder organizations.

IPFs were notified of the opportunity to provide comments. The national Support Contractor for the Hospital Inpatient Value, Incentives, and Quality Reporting (VIQR) Outreach and Education Support Programs distributed an email to the IPFQR Program listserv of facilities participating in the program. IPFs that participated in the field testing of the measure were contacted directly about the public comment period.

Sixteen participants submitted comments. Of the 16 participants, 10 (62.5%) represented an individual perspective and 6 (37.5%) reflected an organizational perspective.

Stakeholder Comments—Criteria-Specific and General Comments

Stakeholders were requested to provide feedback on the proposed *Screening for Pregnancy* measure concerning the measure evaluation criteria:

1. Importance/Relevance/Support of the measure in that the measure addresses a high-impact or meaningful aspect of healthcare;
2. Scientific Acceptability of measure properties such that the measure produces reliable and valid results about the intended area of measurement;
3. Feasibility of the measure, which assesses the extent to which the required data are available, retrievable without undue burden, and the extent to which the measure can be implemented for performance measurement.

Respondents were invited to provide General Comments on the measure. Appendix B contains the unedited verbatim comments received from stakeholders.

The summary of verbatim comments is presented below with corresponding responses.

Summary of Public Comments

1. <u>Importance/Relevance/Support</u>

    a. Twelve participants (75%) emphasized the importance of screening female patients of childbearing age for pregnancy status and/or expressed support for the measure. Several entries noted the opportunity for improvement in this setting and highlighted the harm that could come from not knowing the pregnancy status during an inpatient stay. They agreed that the measure would serve as a relevant and excellent indicator of care for females admitted to an inpatient psychiatric facility.

        Response: Thank you for your comments and support of the measure focus. The measure is an important indicator of patient safety.

    b. Two participants (12.5%) expressed concern that the measure would have limited impact on quality improvement. One participant interpreted the measure impact as applying only to pregnant patients who otherwise would not have been screened.

        Response: Thank you for your comments about the measure. There were approximately 400,000 female patients of childbearing age out of the 1.7 million IPF admissions in 2016. Approximately 16,000 of these patients might have been pregnant when they were

admitted to IPFs based on the 2015 fertility rate.[1] If 20% are not screened for pregnancy, over 3,000 patients a year could receive treatment that is potentially harmful to them or the fetus and an opportunity may be missed to educate patients about prenatal care and about lower risk treatment options. This can be considered an important impact for quality improvement given the potential severity of negative consequences for these patients and society compared to the relatively low burden of the screening activity. Furthermore, the measure has the potential to significantly impact all females of childbearing age who are admitted to the IPF, regardless of pregnancy status. Documentation of findings improves communication among the care team and can serve as an opportunity to provide counseling to the patient about the importance of birth control while taking medications that can be harmful to the fetus and to inform the patient of drug interactions with oral contraceptives.

2. Scientific Acceptability
    - Face Validity

    a. One participant (6.3%) expressed concern that the measure requirement for documentation of pregnancy status in the record does not ensure that facilities are providing appropriate care to patients like having conversations around the risks of medications during pregnancy.

        Response: The *Screening for Pregnancy* measure was developed to ensure that providers document the pregnancy status of the patient early in the admission process so that they can establish an appropriate treatment plan. The measure evaluates documentation of pregnancy status rather than the appropriateness of care for pregnant patients because a measure of appropriate care would require more complex documentation and would be more burdensome for facilities to implement. However, the *Screening for Pregnancy* measure will be a first step toward improving the quality of care for female patients of childbearing age. Appropriate care cannot be provided if pregnancy status is unknown by the care team and pregnancy status is currently not documented for 1 in 5 patients.

    - Measure Specification

    a. One participant (6.3%) suggested expanding the age range from (15 to 44) to (12 to 50).

        Response: The measure is specified to include females between the ages of 15 to 44 because review of existing evidence and feedback from the Technical Expert Panel confirmed that all patients within this age range should be screened for pregnancy. Using a conservative age range ensures that the measure does not lead to inappropriate screening and allows providers the discretion and flexibility to determine when screening is appropriate for adolescents under age 15 or adults over age 44.

    b. One participant (6.3%) suggested including transgender males in the measure because some patients may identify themselves as male but are biologically female and can be pregnant.

        Response: To reduce abstraction burden, the current measure aligns with other existing measures in the IPFQR program to identify patient sex. The measure inclusion is restricted to females on admission and excludes any patient with a

[1] Martin JA, Hamilton B, Osterman MJK, Driscoll AK, Mathews TJ. *Births: Final Data for 2015.* Hyattsville, MD: National Vital Statistics Reports; Vol 66, no 1; National Center for Health Statistics; 2017.

"Male" or "Unknown" gender. Per the Data Definitions and Abstraction Instructions for the *Sex* data element, a patient is considered to have an "Unknown" gender when there is contradictory information in the record, or there is documentation that the patient refused to provide their sex, or there is documentation that the patient is a Transgender, Transsexual, or Hermaphrodite. However, providers are encouraged to conduct a pregnancy screening on any patients who could be pregnant regardless of inclusion in this measure.

c. Two participants (12.5%) suggested that the measure should apply an exception when patients refuse to be screened.

   Response: While any patient has the right to refuse to be screened, patient refusal was rare in the test sample, with only 0.3% of patients refusing to be screened. The measure does not specifically allow an exception for patient refusal because IPFs are encouraged to educate their female patients of childbearing age about the importance of confirming pregnancy status through screening. However, the measure does account for extreme cases of patient non-compliance by applying an exclusion for patients who leave Against Medical Advice (AMA).

d. One participant (6.3%) suggested that the measure include an exemption if the medical record had documentation that the patient was unable to become pregnant, such as a history of hysterectomy.

   Response: As currently specified and proposed, the measure allows IPFs to meet the measure numerator by having acceptable documentation in the medical record of pregnancy status, including inability to become pregnant due to a history of hysterectomy (total, radical or partial), tubal ligation, genetic disorder, or birth defect.

e. One participant (6.3%) suggested enhancing the allowable documentation of current pregnancy to include "currently pregnant" and "pregnant by ultrasound".

   Response: As currently specified and proposed, the measure allows IPFs to meet the numerator by documenting current pregnancy identified through either self-report or clinical verification. It would not be appropriate for a provider to assess a patient's pregnancy status without confirming with the patient or through some other method. We agree with the suggestion to allow the documentation of current pregnancy as identified through ultrasound. The measure specifications will be revised, and the data abstraction tool and instructions will be updated accordingly.

f. Two participants (12.5%) suggested setting more stringent requirements to meet the numerator. One participant recommended that patient self-report should be paired with a confirmation of lab work or auscultation of positive fetal heart sounds because patients might not know they are pregnant, might inaccurately report that they are pregnant, or might not be able to reliably self-report due to behavioral health symptoms (i.e., disorganized thoughts, cognitive impairment, and/or possible denial of pregnancy). One participant indicated that histories obtained from the patient may not be reliable in this population.

   Response: The measure specifications allow the patient to self-report a current pregnancy to avoid over testing and minimize provider burden with measure implementation and reporting. For self-reported pregnancies, the measure allows the providers discretion to decide whether a patient is a reliable source or if pregnancy status should be confirmed through other means. If the patient self-reports that they

are not pregnant, the measure does require additional documentation of an inability to become pregnant or negative hCG test result.

g. Two participants (12.5%) expressed concern over the timeframes specified for completing the screening. One participant felt that the timeframe for obtaining lab results from transferring facilities was too long because they could be obtained after treatment was initiated. One participant felt that having any time restrictions was too stringent because it could lead to patients being held in Emergency Departments until tests are done.

Response: The measure establishes maximum timeframes for the results of lab testing to be completed during the stay or at transferring facilities based on the results of testing. The measure does not rely on the dates lab results were entered into the medical record or reviewed by the care team because it was determined in field testing that those dates may not be reliably documented. However, IPFs are encouraged to complete the screening as close to the start of the admission as possible and before initiating treatment when feasible. It is up to the discretion of the treatment team whether to conduct an additional hCG test during the admission if they have not received the results from a transferring facility in a timely manner. It is not the intent of the measure that transferring facilities hold patients until pregnancy screening tests are done because those tests can be completed by the IPF after transfer.

3. Feasibility
   a. Four participants (25%) thought that the measure, as specified, was highly feasible to abstract, that the pregnancy screening tests could be performed with relative ease considering the low cost of testing, and that the screening could feasibly be performed within the timeframe specified by the measure.

      Response: We thank you for your comments and support of the measure focus. We agree that the measure requirements should be highly feasible for most facilities to perform within the specified timeframe.

   b. One participant (6.3%) expressed concerns with the cost burden on facilities if the measure were to be implemented in the IPFQR program.

      Response: The measure was determined to be highly feasible to implement with minimal burden to facilities. The scoring elements were readily identified in the medical records during testing and the average abstraction time was 4.6 minutes per record. Concerning the cost associated with the implementation of the measure, facilities can meet the measure by:
      1) Documenting self-reported pregnancy or an inability to become pregnant, which should be a standard part of the patient history and information gathering process and would not require additional cost or burden to the facility;
      2) Obtaining the results of pregnancy screening tests from transferring facilities, which should be part of existing transfer procedures and care coordination activities and would not require additional cost or burden to the facility;
      3) Conducting a blood or urine pregnancy test during the inpatient stay, which may incur additional, but minimal costs. Facilities that do not have in-house labs can perform a urine point-of-care pregnancy test, which is widely available and may be more cost effective and efficient than sending the labs externally for analysis.

4. General Comments
   a. One participant suggested simplifying the "case selection process" to include only females in the sample population.

      Response: Per the Measure Narratives described on page 42 of the Methodology Report, IPFs are instructed to select cases that are included in the Initial Patient Population by finding patients for which the performance measure is designed to address. For the *Screening for Pregnancy* measure, the population includes all female patients between the ages of 15 and 44 years old, who were admitted to the inpatient facility with a length of stay greater than two days. The first question in the Abstraction Tool is the *Sex* data element. This data element serves to ensure that only females were selected by the IPF for abstraction. If the IPF selected only cases that the measure is designed to address, there should be very few cases where the abstractor would need to stop the abstraction to select another case.

   b. One participant (6.3%) who was involved in the pilot testing of the measure suggested streamlining the data collection tool.

      Response: Thank you for the comment and for providing feedback on your testing experience. Measure developers often collect more information than necessary during the testing of a measure to ensure that the correct population is included and to determine whether there is a clinical basis for defining a measure in a specific way. For the *Screening for Pregnancy* measure, we collected additional information about the reasons why a pregnancy test was not performed in the IPF to understand all the possible circumstances and barriers that might preclude an IPF from performing a pregnancy screen. After the measure specifications were finalized, the data collection tool was simplified and the 17 supplemental questions that were not essential for calculating the measure score were eliminated. The version of the data collection tool that was put forth for public comment has been simplified and contains only eight data elements.

   c. One participant (6.3%) expressed concern that only one freestanding IPF was included in the test sample. They added that freestanding IPFs had fewer admissions from emergency departments (ED) than IPF units within larger facilities, suggesting that freestanding IPFs would be at a disadvantage. The participant suggested that allowing ED lab tests appears to reflect system performance rather than IPF performance.

      Response: The number of freestanding IPFs was limited in the testing sample due to voluntary participation in the project. In Medicare fee-for-service data from January 2016 through September 2017, freestanding IPFs generally had fewer admissions from EDs than other IPFs. However, they generally have more admissions from acute inpatient units than other IPFs. Results from either transfer setting are acceptable to meet the requirements for the measure. Furthermore, results from transferring facilities are included in the numerator as an assessment of IPF performance to give facilities credit for the effort to obtain and document pregnancy status and to reduce the potential for over testing. Some facilities will be required to do more in-house screenings because they see fewer transfer patients and clinicians need information on pregnancy status to provide safe and high-quality care to their patients. Therefore, facilities with fewer patients from transfers are not at a disadvantage for this measure because it would not be appropriate to hold those facilities to a lower standard of care.

d. One participant (6.3%) expressed concern that some Federal or State laws may preclude providers from sharing patient information with outside facilities, which could lead to redundant testing.

Response: The Privacy Rules for the Protection of Health and Mental Health Information permit covered entities to use or disclose Protected Health Information (PHI) for treatment purposes without the authorization of the individual who is the subject of the PHI. Therefore, facilities are permitted to share information about the patient's pregnancy status when information is to be used to treat the patient. However, if there are instances where pregnancy status could not be obtained from a transferring facility, the redundant testing in the IPF is necessary to establish an appropriate treatment plan, particularly if medications are being administered that have teratogenic risks. It would not be appropriate to hold facilities to a lower standard of care for those patients.

Summary of Recommendations and Actions Taken

The feedback from all participants is appreciated and the following clarification to the measure documentation will be made:

1. Revise the measure specifications, the data abstraction tool, and data abstraction instructions to allow the documentation of current pregnancy as identified by ultrasound.

Overall Analysis of the Comments and Recommendations

This measure was highly supported by 75% of the stakeholders that provided feedback on the *Screening for Pregnancy* process measure and will be recommended to CMS for inclusion in the IPFQR Program.

Public Comment Verbatim Report

Verbatim comments from each participant are listed in the order in which they were received by date in Appendix B. Comments have not been edited for spelling, punctuation, grammar, or any other reasons. If the responder chose to remain anonymous, *Anonymous* is entered in the table, other missing information is entered as, *Not indicated*.

Appendix A: Listing of Stakeholders Invited to Participate in Public Comment

Table A.1. Stakeholder Organizations Invited to Participate in Public Comment

	Stakeholder Organization Name
1.	America's Essential Hospitals
2.	American Academy of Pediatrics
3.	American Association of Community Psychiatrists
4.	American Board of Professional Psychology
5.	American College of Obstetricians and Gynecologists
6.	American College of Psychiatrists
7.	American Hospital Association
8.	American Medical Association
9.	American Medical Informatics Association
10.	American Nurses Association
11.	American Pharmacists Association
12.	American Psychiatric Association
13.	American Psychiatric Nurses Association
14.	American Psychological Association
15.	American Society of Health System Pharmacists
16.	Association of VA Psychologist Leaders
17.	Federation of American Hospitals
18.	Institute for Healthcare Improvement
19.	International Society for Bipolar Disorder
20.	Mental Health America
21.	National Alliance for the Mentally Ill
22.	National Association of Psychiatric Health Systems
23.	National Association of Social Workers
24.	National Association of State Mental Health Program Directors
25.	National Council for Behavioral Health
26.	National Institute of Mental Health
27.	US Office of Population Affairs

Appendix B. Listing of Verbatim Comments from Responders

All comments in the table appear as they were received and have not been edited for spelling, punctuation, grammar, or any other reasons.

Table B.1. Public Comment Verbatim Report for the *Screening for Pregnancy* Measure

Entry ID.	Date Comment Posted	Name, Credentials, Title, and Organization of Commenter	Type of Organization	Perspective	Text of Comments
1.	5/4/2018	Benny Lucas, RN, CNO/VP Behaviroal Health, Cone Health	Provider Organization (e.g., hospital, nursing home, home health agency, ambulatory care center)	Organizational	Im in support.
2.	5/4/2018	Ann Simpkins, RN, Team Leader OB, Mercy Health St Charles	Provider Organization (e.g., hospital, nursing home, home health agency, ambulatory care center)	Individual	I am reading this report from the viewpoint of an obstetrical healthcare worker. I am puzzled as to why every woman of childbearing age is not screened for pregnancy when admitted to an IPF. The effects of medications on the developing fetus and the pregnant mom, the psychological aspect of pregnancy itself, making sure they are receiving appropriate prenatal care during hospitalization and when discharged are areas of concern. Much harm could be done if this information is not known.
3.	5/4/2018	David J Fariello, RN, Manager Mental Health In Patient Unit, St Mary's Healthcare Amsterdam, NY	Provider Organization (e.g., hospital, nursing home, home health agency, ambulatory care center)	Individual	I believe this to be an important measure due to the toxic effects many of the medications have on a fetus. I believe this to be excellent patient care.
4.	5/4/2018	Sarah Butler, RN, Director of Psychiatric Services, Hillsdale Hospital	Health Professional Organization	Organizational	Considering the several psych medications which are contra-indicated to pregnant females, this information in imperative on admission. Pregnancy results are mandatory prior to admittance to our facility. Pregnancy testing is feasible considering the low cost of testing.
5.	5/7/2018	JOAN LAHR, RN, MSN, CPHQ, QM COORDINATOR, CHAMBERSBURG HOSPITAL	Provider Organization (e.g., hospital, nursing home, home health agency, ambulatory care center)	Individual	I believe that it violates the patient's rights to screen them, there had better be a refused otion, with no penalty.

Entry ID.	Date Comment Posted	Name, Credentials, Title, and Organization of Commenter	Type of Organization	Perspective	Text of Comments
6.	5/7/2018	Robert Munjal, MD, Associate Medical Director In-patient service, St. Patrick Hospital - Providence-St. Joseph	Provider Organization (e.g., hospital, nursing home, home health agency, ambulatory care center)	Individual	Whether it is in regard to appropriate risk/dangerousness assessment, treatment planning, or selection of appropriate medication, I think that establishing the possibility or absence of pregnancy is a critical aspect of medical clearance for treatment in an in-patient psychiatric facility. I would actually be surprised and shocked if this was not a uniform habit (e.g. checking Beta-HCG before admission) and will imagine that the percentage of facilities obtaining percentages at or above 90% will be quite high. Certainly establishing the data and identifying outliers is important. Given that psychiatric medications that are commonly used in-patient hospitals such as benzodiazepines, depakote and lithium - can all have serious implications for developing babies - I think this is a very important safety measure. Also given the unique risks that expecting mothers may face in terms of intimate partner violence, and the high risk of psychiatric decompensation in post-partum periods, and the difficult decisions to make about retaining a pregnancy in a patient with life-threatening psychiatric illness and or substance use - this is data that can simply not be ignored. I would not want one of my female family members to receive in-patient (or outpatient) psychiatric treatment in the broader context of ignorance about pregnancy status. Given the limitations of many in-patient psychiatric patients, history from the patient is not a sufficient source of data on this important piece of information. I am always skeptical of new monitoring and documentation requirements (I seldom think that we can make better doctors through more bureacratic requirements). This is one I fully support. Thank you for soliciting feedback from providers.
7.	5/8/2018	Robert McCarley, M.D. Vice President of Medical Affairs Intensive Service Line & Spring Harbor Hospital	Provider Organization (e.g., hospital, nursing home, home health agency, ambulatory care center)	Individual	This one is easy for me. I 100% support it. It is a relevant measure that our emergency departments no longer do despite it being the one required feature for all female patients of childbearing age- and I think we could have a better systemic process in tracking and ensuring this is done 100% of the time. It speaks to better patient care in a simple relevant manner.

Entry ID.	Date Comment Posted	Name, Credentials, Title, and Organization of Commenter	Type of Organization	Perspective	Text of Comments
		Maine Behavioral Healthcare			
8.	5/11/2018	Melissa Hodge, APRN, CNS, Manager Data Abstraction, Premier Health	Provider Organization (e.g., hospital, nursing home, home health agency, ambulatory care center)	Individual	This is a very relevant issue and very feasible to abstract.
9.	5/14/2018	Alyssa Woodling, RN, Senior Quality and Patient Advisor, Vanderbilt Psychiatric Hospital/ Vanderbilt Behavioral Health	Provider Organization (e.g., hospital, nursing home, home health agency, ambulatory care center)	Organizational	At VPH, we suggest the number of female patients who are between the ages of 12 and 50 on admission be screened for pregnancy at an IPF. We also suggest some language and inclusion of of transgender people as we have had patients who identify as male but biologically are female and were pregnant.
10.	5/14/2018	Stephanie Alicea, CNMT, Clinical Review Analyst, Hutchinson Regional Medical Center	Provider Organization (e.g., hospital, nursing home, home health agency, ambulatory care center)	Individual	I was part of the pilot program to test abstract this measure. My area of expertise is in reviewing the chart to find the answers. My opinion is that the questions should be configured differently. How the test questions were configured is the question that stated "was there documentation in the inpatient medical record of a hCG lab test to detect pregnancy?" Then you choose Yes or No. Most often I would see that the patient had a preg test done in ED. This was before being admitted to the psych floor, so the answer to this question would be "No." Then the next question would be "What reason(s) was documented to justify why a pregnancy test was not done? Select all that apply." One of the choices in the list of choices was "result of preg test available from ED dept, etc." However, the way the questions are written, you cannot just click this answer and move on. You have to look "select all that apply." So I spent extra time searching through the whole record (including the outside records that had been scanned into the chart) to make sure I didn't miss that the patient had a tubal ligation or clinical cause of sterility or that the patient is not actively menstruating, etc. I felt the question "result of pregnancy test available from ED dept..." should be its own question. ONLY IF the preg test was NOT done in ED, then you should have to look through the chart to find other reasons why it was not done. I do not understand the importance/relevance of having to look for this

Entry ID.	Date Comment Posted	Name, Credentials, Title, and Organization of Commenter	Type of Organization	Perspective	Text of Comments
					information for patients who have had the pregnancy test performed in the ED. Thank you for allowing comments.
11.	5/14/2018	*Anonymous*, RN, MSN, CNS, Nurse Manager	Not indicated	Individual	It is extremely relevant that patients of childbearing age be assessed for pregnancy upon admission to an IPF. The medications that are prescribed may have an effect on an unborn child. The ability to provide accurate history by some of the patients makes this needed screening much needed.
12.	5/21/2018	Erin Langford, MSN, RN-BC, Administrative Director for Behavioral Health, Monmouth Medical Center	Provider Organization (e.g., hospital, nursing home, home health agency, ambulatory care center)	Individual	This is an important measure that considers both the health of the patient as well as the fetus. The test can be performed with relative ease as most patients have some type of medical clearance prior to, or at the time of, admission. Exemptions should be included if there is a medical history that is known that the patient is unable to become pregnant, i.e., has undergone a hysterectomy. I would also recommend that there not be a time limit (i.e., first 24 hours of admission) placed on this information, as I would not like to see any barriers to treatment such as a patient being held in the Emergency Dept. until the test is done. Lastly, this information directs the plan of care in terms of medications as well as medical treatment and support services.
13.	5/25/2018	Andrea Tull, PhD, Director, Reporting & Analytics, Massachusetts General Hospital	Provider Organization (e.g., hospital, nursing home, home health agency, ambulatory care center)	Organizational	Thank you for the opportunity to comment on this proposed measure. MGH supports the collection of quality data to improve care for our psychiatric patients. As a whole, we support this proposed measure for pregnancy screening, with the following comments to strengthen and improve data collection: 1) We propose simplifying the case selection process to include only females in the sample population. This will prevent the need to continually re-select cases when males fall into the sample. Limiting the sample to females will significantly reduce the administrative burden of chart abstraction. Rationale: Proposed case selection process seems burdensome. Proposed specifications state to stop abstraction and select another case if patient sex is “male” or “unable to determine” (UTD is for pts who refuse to answer, contradictory documentation, transgender, transsexual, or hermaphrodite). It is time consuming to review cases and then drop the case and reselect another. 2) Regarding the “Documented Pregnancy Status” data element: we propose enhancing the allowable provider documentation to include: o “currently pregnant” o “pregnant by ultrasound” Rationale: There are additional ways to document pregnancy other than the proposed allowable documentation of ‘patient self-reporting’ or ‘fetal heart tones’. Request that simple provider statement of ‘currently pregnant’ be allowed.

Entry ID.	Date Comment Posted	Name, Credentials, Title, and Organization of Commenter	Type of Organization	Perspective	Text of Comments
					Also that ultrasound be allowed since providers rarely mention fetal heart rate when patient is less than 3 months gestation, but often document ultrasound results. 3) Regarding the "Pregnancy Laboratory Test" data element, we suggest that patient refusal to be tested be an allowed response, either excluding the case as UTD, or passing as attempted. Rationale: It is not uncommon for psychiatric patients to refuse laboratory testing. Thank you for the opportunity to comment on this proposed measure, and feel free to reach out with any follow up questions.
14.	5/25/2018	*Anonymous*	IPFQR vendor	Organizational	We are concerned about the time and cost burden on facilities for minimal patient impact. The documentation mentions not having exact admission numbers for women of childbearing age but claims "…[the measure] would impact a significant portion of the IPF population…". We have data for 508,454 admissions to IPFQR facilities in 2017. Of those admissions, 28% were females aged 15-44 at admission. Based on beta testing results finding that only 20% of eligible admissions were not screened across all facilities, that 28% is reduced to 5.6% of our entire IPFQR population that is eligible and not screened. Using the birth rate of 62.5/1,000 in the documentation, only 0.35% of our entire IPFQR population is likely pregnant and not screened. The actual rate is presumably lower than 0.35% as there will be patients who already know they are pregnant. Measure developers themselves define minimal impact as 0.7% when they state, "…only 0.7% of females were discharged AMA. These results demonstrate minimal impact of the exclusion on the measure denominator." Furthermore, if the intent is to provide an opportunity for conversation about the impact of psychiatric medications during pregnancy as is repeatedly mentioned in the documentation, then the measure should be about the conversation rather than the testing. As a vendor supporting over 200 IPFQR facilities and having conducted hundreds of site visits to evaluate processes and make recommendations, we are confident that nearly all processes implemented to address this measure will not include such a conversation. Rather, the process will be to simply conduct the test. Measure developers repeatedly mention the importance of timely knowing whether or not a patient is pregnant so that care can take this into consideration, however lab results from the transferring facility can be added to the chart at any time. Without timely insertion of results, care may be well underway and include psychiatric medications before pregnancy status is known. Despite the measure developer's claims that "…the testing sample contained diversity in the type

Entry ID.	Date Comment Posted	Name, Credentials, Title, and Organization of Commenter	Type of Organization	Perspective	Text of Comments
					of facility, facility location, and bed size…" we have serious concerns about the lack of freestanding facility representation in beta testing. These concerns are only exacerbated when taken in context of beta testing results. Beta testing top performers relied heavily on pregnancy screening being conducted in the ED prior to admission. It should be noted that even if the highest performing IPF did not perform a single screening of their own and instead relied on the transferring ED to do hCG tests, their performance would have only dropped to second place. In fact, only one IPF from the top half of pilot IPFs would drop out of the top half even if they did not do any screening of their own. We should not be surprised the lone freestanding facility in the entire pilot had the second lowest performance and statistically did not differ from the lowest performing facility. Point of origin data for over 480,000 patients aged 15-44 admitted in 2016 and 2017 shows that only 37% of admissions were transferred from a hospital/health care facility (although there is no data available specifically addressing ED transfers, but it is relatively safe to assume it is only a portion of this number). The reliance on ED lab capture is more accurately described as a measure of SYSTEM performance not UNIT performance. As the IPFQR measures are purportedly targeted to the specific psychiatric facility this does not appear to be a valid measure squarely addressing Psychiatric quality.
15.	5/30/2018	St. Luke's Health System	Provider Organization (e.g., hospital, nursing home, home health agency, ambulatory care center)	Individual	This is not a high-impact measure that would safeguard public health. Many IPFs are restricted by federal or state laws on what information they can share with outside facilities. Even if IPFs screened for pregnancy, most facilities are not setup to act on that information, or to share it with other acute care facilities. Most patients would have to go through the screening again either with their primary care provider or during a subsequent hospitalization. This would be adding a redundant process that just increases reporting burden without meaningful impacts to health outcomes for the psychiatric population.
16.	5/31/2018	Samantha Shugarman, MS, Deputy Director of Quality, American Psychiatric Association	Health Professional Organization	Organizational	APA supports the implementation of this measure, given further consideration to the recommendation outlined below. With "96.1% of female patients of childbearing age admitted to nine beta testing IPFs received medications which can be harmful to fetal development and obstetrical outcomes;" and lab tests administered as part of the ED procedure or inpatient admission procedure to an IPF (e.g., patient is willing to provide a urine sample and/or blood draw) and easy to implement verbal

Entry ID.	Date Comment Posted	Name, Credentials, Title, and Organization of Commenter	Type of Organization	Perspective	Text of Comments
					screening, this measure seems appropriate and feasible to include in future pre-rule making. However, we recommend greater refinement to the data element, "documentation in their medical record of pregnancy status." As defined in the data dictionary, sufficient screening consists of patient self-report, among other methods. We recommend that patient self-report, while immensely valuable, should be confirmed through lab work or auscultation of positive fetal heart sounds. APA emphasizes that patients might not know they are pregnant or inaccurately report that they are pregnant. Other reasons to pair a self-report with fetal heart sound monitoring or lab work include patients who are not able to reliably self-report due to symptoms like temporary disorganized thoughts, cognitive impairment, and/or possible denial of pregnancy. We recommend CMS add confirmation of patient self-report to the measure specifications in a way that clearly defines the elements that would inhibit reliable patient-self report.