| **ID #** | **Stage 2 Final Rule** | **Stage 3 Recommendations** | **Proposed for Future Stage** | | **HITPC Questions / Comments** |
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| **Engage patients and families in their care** | | | | | |
| **SGRP204A** | **EP Objective:** Provide patients the ability to view online, download, and transmit (VDT) their health information within 4 business days of the information being available to the EP. **EP Measure:** 1. More than 50 percent of all unique patients seen by the EP during the EHR reporting period are provided timely (within 4 business days after the information is available to the EP) online access to their health information subject to the EP's discretion to withhold certain information. 2. More than 5 percent of all unique patients seen by the EP during the EHR reporting period (or their authorized representatives) view, download, or transmit to a third party their health information. **EH Objective:** Provide patients the ability to view online, download, and transmit information about a hospital admission1. More than 50 percent of all patients who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH have their information available online within 36 hours of discharge 2. More than 5 percent of all patients (or their authorized representatives) who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH view, download or transmit to a third party their information during the reporting period. | * EPs should make info available within 24 hours if generated during course of visit * For labs or other types of info not generated within course of visit, it is made available to pts within four business days of info becoming available to EPs * Potential to increase both thresholds (% offer and % use) based on experience in Stage 2 * Additional items: High priority family history, ability to request an amendment online, images   **Note:** Depending on experience in Stage 2, CMS may want to give credit to some providers (e.g. specialists) for view/download/transmit where the patient has requested that they prefer info to be sent to a location they specify (such as another provider portal or PHR), rather than only making available information on the provider’s portal.  **MENU item:** Automated Transmit\*: (builds on Automated Blue Button Initiative (ABBI)): Provide 50% of patients the ability to designate to whom and when (i.e. pre-set automated & on-demand) a summary of care document is sent to patient-designated recipient\*\* (for example, a one-time request to send information from specialist to primary care, or a standing request to always send an updated care summary when certain events arise, such as a change in medication or the completion of new tests or procedures). \*Subject to the same conditions as view, download, transmit  \*\*Before issuing final recommendations in May 2013, HITPC will also review the result of Automated Blue Button pilots, in addition to considering public comments received. | | Building on Automated Transmit:  1a. Create the ability for providers to review patient-transmitted information and accept updates into EHR.  1b. Related certification criteria: Standards needed for provider directories in order to facilitate more automated transmissions per patients’ designations. | Explore the readiness of vendors and the pros and cons of including certification for the following in this objective:   * Images (actual images, not just reports) * Radiation dosing information from tests involving radiation exposure in a structured field so that patients can view the amount of radiation they have been exposed to   Add a MENU item to enable patients to view provider progress notes (re: [Open Notes: Doctors and Patients Signing On. *Ann Intern Med*. 20 July 2010;153(2):121-125](http://annals.org/article.aspx?articleid=745909))  What is the best way to ensure that individuals access their health information through the view/download/transmit capability are provided with transparency and education about the benefits and potential risks of downloading health information, consistent with the HIT Policy Committee's recommendations of August 16, 2011? Is certification an appropriate vehicle for ensuring such transparency is part of CEHRT?  If so, what would the certification requirement look like?  If not, what are other mechanisms for ensuring transparency to consumers using the view/download/transmit capabilities?  In its recent final rule, and in response to comments, ONC adopted Level A conformance as the standard for the accessibility web content in accordance with the Web Content Accessibility Guidelines (WCAG). ONC indicated per commenters suggestions that WCAG Level AA conformance would be considered for the next edition of certification criteria. Given that all EHR technologies certified to the view, download, transmit to a 3rd party certification criterion will have met Level A, how difficult would it be for EHR technology to have to meet Level AA conformance? |
| **PUBLIC COMMENTS:**   * **Summary statement: VDT**: Commenters had a split in responses related to the threshold increase. A few were concerned about the increase, while others asked for the threshold to be even higher. A large number of commenters expressed concerns regarding being held accountable for patients’ actions. Another concern was physicians being responsible for making patient information available (if generated during the patient visit) from 4 days and making labs available to patients’ within 4 days. (Where as a few commenters thought the time span was too long).   **ABBI:** Overall commenters supported this measure, but there were a number of areas of concern (e.g. Provider liability, privacy and security risks (42 CFR Part 2 data needs to be clearly identified)).  **Imaging and Radiation Dosing:** Most commenters were supportive of including imaging and/or radiation dosing levels for patients, but had a few concerns (e.g. availability of standards, educating patients on radiation dosing, providing a link to PACS to avoid bandwidth issues). There were only a few comments about the future state recommendations, but they were supportive.   * **Key points:**   + A large number of commenters expressed concern about providers being accountable for patient actions.   + A large number of commenters were concerned about accelerating the timing for making patient information available to 24 hours and labs available within 4 days.   + Commenters supported Automated Blue Button Initiative, but there were a number of areas of concern (e.g. provider liability, privacy and security risks.   + Most commenters were supportive of including imaging and/or radiation dosing levels for patients.   + Guidance to patients should be offered at the time the patient indicates a desire to download electronic health information and should, at a minimum, address the following three items: (1) remind patients that they will be in control of the copy of their medical information that they have downloaded and should take steps to protect this information in the same way that they protect other types of sensitive information; (2) include a link or links to resources with more information on such topics as the download process and how the patient can best protect information after download; and (3) obtain independent confirmation that the patient wants to complete the download transaction or transactions.   + Disclosures at the point of download and consider other options such as public education, and certifying individual users’ knowledge through a teach-back or test-back strategy that is independent of/separate from the download event, to demonstrate that users appreciate the risks of data transmission, especially on public computers.   + With respect to the view functionality, patient guidance should address the potential risks of viewing information on a public computer, or viewing sensitive information on a screen that may be visible to others, or failing to properly log out after viewing. Providers should also: (1) utilize techniques, if appropriate, that avoid or minimize the need for patients to receive repeat notices of the guidance on view and/or download risks; (2) request vendors and software developers to configure the view and download functionality in a way that no cache copies are retained after the view session is terminated; and (3) request that their view and download functionality include the capability to automatically terminate the session after a period of inactivity.   + Incorporate identity proofing as part of this process for view, download, and transmit in accordance with, at a minimum, NIST level of assurance (“LOA”) 3 and continue working with the Standards Committee to issue guidance on this.   + Patients should be provided with transparency and education on the benefits and risk of downloading health information and support the idea of certification requirements that seek to accomplish this goal. In formulating these certification requirements, we request that you consider the special risks associated with downloading sensitive health information. Sensitive health information includes sexual and reproductive health, mental and behavioral health, and substance abuse and treatment. Downloading sensitive health information poses a set of risks that are distinct from the risks associated with downloading other health information. | | | | | |
| **HITSC COMMENTS:**  Allow innovative and flexible approaches in addition to ABBI.  Suggest adding dosing information as a requirement for radiology reports.  Agree [MENU item to enable patients to view provider progress notes] could be a menu item  Careful testing required. This data will be incomplete and therefore deceptive for the foreseeable future. Evidence-based recommendations would need to be validated.  SGRP 204 A - Images  • Images as currently required in Stage 2 are being currently implemented in EHRs. Comments on the expansion of this requirement are contained in the next two bullets.  • Radiology Images are currently being uploaded today to inpatient records. Cardiology and other images are in early stages of integration.  • –Eligible Providers and Patients may not have the need or desire to view the image. Concern was expressed over the ability of patients to be able to receive large images.  SGRP 204 A Radiation Dosing  • The current software applications provide the ability to capture this data and it could be made available to the patient portal. Consideration should be given to the patient’s ability to understand and use the data. Radiation dosing is specific to the disease process, patient condition etc and will require the clinical community to engage on effective communication parameters.  • Concerns around patient’s ability to use the information correctly and effectively  SGRP 204 A – WCAG  • A cursory examination of the AA requirements identifies issues that indicate significant challenges with the standard as written.  • A thorough evaluation could lead to exclusions/exceptions to the AA conformance that would make this requirement acceptable. | | | | | |
| **SGRP204B** | **New** | **MENU:** Provide 10% of patients with the ability to submit patient-generated health information to improve performance on high priority health conditions, and/or to improve patient engagement in care (e.g. patient experience, pre-visit information, patient created health goals, shared decision making, advance directives, etc.). This could be accomplished through semi-structured questionnaires, and EPs and EHs would choose information that is most relevant for their patients and/or related to high priority health conditions they elect to focus on.  Based upon feedback from HITSC this should be a MENU item in order to create the essential functionality in certified EHRs. | |  | Readiness of standards to include medical device data from the home?  What information would providers consider most valuable to receive electronically from patients?  What information do patients think is most important to share electronically with providers? How can the HITECH incentive program support allowing doctors and patients to mutually agree on patient-generated data flows that meet their needs, and should the functionality to collect those data be part of EHR certification? Please provide published evidence or organizational experience to support suggestions. |
| **PUBLIC COMMENTS:**   * Summary statement: Most commenters supported this measure, but needed clarification on the definition of high priority health conditions and how the EP and EH are to measure this. Concerns were also presented about providers being accountable for patient actions and burdening providers with too much information. Commenters also voiced concerns about the availability of standards to differentiate between provider and patient data. There was a wide disparity in comments related to the timing of this measure, some wanted it pushed to core, others thought menu was appropriate, and still others thought it should be pushed out to a future stage. * Key Points   + 36 of the 47 comments received directly supported this measure with 11 comments directly not supporting this measure.   + Commenters requested clarification regarding whether this was both an EP and EH measure.   + Commenters asked for a definition of high priority health conditions.   + Some commenters were split as to the threshold some felt it was too high, while others thought it was not high enough.   + Commenters requested direction on how they were supposed to measure this recommendation.   + Commenters were very concerned with providers being accountable for patient actions.   + A number of commenters were concerned that with having standards available to differentiate between provider and patient entered data.   + Commenters were concerned with the burdening providers with too much information which could become a legal issue.   + There was a wide disparity in comments related to the timing of this measure, some wanted it pushed to core, others thought menu was appropriate, and still others thought it should be pushed out to a future stage.   + 21 comments about medical device data and 18 of those did not feel that standards were ready to include medical device data. | | | | | |
| **HITSC COMMENTS:**  Multiple issues.  1. Applicable device messaging standards must mature further before being mandated.  2. Device ID is needed first, before including device data standards in MU. Defer home device data until after FDA UDI final rule and align MU dates with UDI implementation for Class III devices.  3. Processes and policies for incorporation of external device data is needed and not sufficiently mature.  Need to define “high priority health conditions” ( e.g. cancer, diabetes, heart disease ?) in order to define relevant standards. Standards and policies are immature and this should be a multiyear work plan item for HITSC.  This is too immature and fluid for specification. Evidence of the usefulness of the information must be factored in with patient and clinician preferences. | | | | | |
| **SGRP205** | **EP Objective:** Provide clinical summaries for patients for each office visit  **EP Measure:** Clinical summaries provided to patients or patient-authorized representatives within 1 business day for more than 50 percent of office visits. | The clinical summary should be pertinent to the office visit, not just an abstract from the medical record.  **EP Objective:** Provide clinical summaries for patients, per their preferred method of communication, for each office visit | |  | What specific information should be included in the after visit summary to facilitate the goal of patients having concise and clear access to information about their most recent health and care, and understand what they can do next, as well as when to call the doctor if certain symptoms/events arise? |
| **PUBLIC COMMENTS:**   * Summary statement: Commenters were supportive of evaluating this measure to ensure that the clinical summary is pertinent to the office visit. Many commenters provided lists of items that should be included which the workgroup can dive into, but one common theme was to provide patients with information that facilitates the goal of patients having concise and clear access to information about their most recent health and care, and understand what they can/should do next. Commenters were concerned about the current format of many vendor summaries, these concerns included: summaries being too long, not in plain language, and language limitations. Quite a few commenters were confused as to what the HITPC was actually asking and wanted clarification on what “pertinent to the office visit actually meant”.   In reference to the question posted regarding what specific information should be included in the after visit summary include changes in the treatment regimen, medications, BMI (weight), immunizations, reason for visit and findings, assessments, goals, outcomes, when to call the provider, future appointments and wellness reminders. | | | | | |
| **HITSC COMMENTS:**  To identify standards please clarify that clinical summary content should include only specific pertinent visit information – i.e. what was done, what patient needs to do, any tests to be done by specified dates, patient instructions related to goals and follow up care. Also need to ensure this is not duplicative of care plan requirements, progress note requirements, etc.  S: patient-reported signs and symptoms (including those prompting the visit)  O: clinician observations (including test results  A: clinician’s assessment of the patient’s clinical situation  P: the care plan negotiated by the patient and clinician (short-term and long-term) | | | | | |
| **SGRP206** | **EP/EH Objective:** Use Certified EHR Technology to identify patient-specific education resources and provide those resources to the patient **EP CORE Measure:** Patient specific education resources identified by CEHRT are provided to patients for more than 10 percent of all unique patients with office visits seen by the EP during the EHR reporting period **EH CORE Measure:** More than 10 percent of all unique patients admitted to the eligible hospital's or CAH's inpatient or emergency departments (POS 21 or 23) are provided patient- specific education resources identified by Certified EHR Technology | **Additional language support:** For the top 5 non-English languages spoken nationally, provide 80% of patient-specific education materials in at least one of those languages based on EP’s or EH’s local population, where publically available.  **EP/EH Objective:** Use Certified EHR Technology to identify patient-specific education resources and provide those resources to the patient per preferred means of communication | |  |  |
| **PUBLIC COMMENTS:**   * Summary statement: There are several key themes regarding this recommendation. Many comments referenced that this recommendation needs to be reworded to reference the top 5 non-English languages in the EP/EH/CAP’s local population not the top 5 nationally. There are areas within the nation that the top 5 non-English languages are not in the top 5 national non-English languages. Many healthcare and provider organizations have voiced a concern regarding a financial burden as well as how they would measure this recommendation. Suggestions were provided for improvement and clarification of this recommendation. There were several suggestions that pertained to the fact that many non-English speaking patients may not be able to read the materials or the materials may be printed at too high of a reading level. Another suggestion was the importance of adding visual/pictorial materials as well as braille. There were three comments which supported this recommendation and suggested increasing the threshold. The majority of the other comments that supported this recommendation suggested changing the non-English language from the top 5 national to the top 5 local. | | | | | |
| **HITSC COMMENTS:**  95% of patients are offered to usable, useful electronic messaging. (The percent of users varies in research, depending on the patient’s perceived need and access to electronic communications.) | | | | | |
| **SGRP207** | **EP Objective:** Use secure electronic messaging to communicate with patients on relevant health information   **EP Measure:** A secure message was sent using the electronic messaging function of Certified EHR Technology by more than 5 percent of unique patients (or their authorized representatives) seen by the EP during the EHR reporting period | **Measure:** More than 10%\* of patients use secure electronic messaging to communicate with EPs | | Create capacity for electronic episodes of care (telemetry devices, etc) and to do e-referrals and e-consults | \*What would be an appropriate increase in threshold based upon evidence and experience? |
| **PUBLIC COMMENTS:**   * Summary statement: The majority of the comments for this recommendation were to not increase the threshold. The greatest rational was not knowing the success of Meaningful Use Stage 2. The commenters suggested research to identify the actual percentage from stage 2 and then identify a threshold. There was also clarification requests and suggestions made to include family members, caregivers, healthcare agents as well as include staff from the EP’s practice in the measure. Of the comments that supported this measure many also recommended including family, and caregivers in the measure. Only 7 recommended an increase in the threshold (2 -50%, 3 – 30%, 3 – 20%). Comments that did not identify support or not support and those that clearly did not support the measure identified concerns about the providers being held accountable for the actions of patients. A couple of responses suggested a bidirectional assessment with measuring the timing of the EP’s response to the patient, family or caregiver. | | | | | |
| **HITSC COMMENTS:**  We recognize that this measure is intended to motivate EPs to encourage their patients to use secure electronic messaging. But we have no evidence or experience that might inform what an appropriate increase in threshold might be.   * Providers using patient portals are nowhere near 10% threshold * We do not think the threshold should be increased above 10%. Definitely an ambitious goal to keep in mind * Current threshold is 5 and recommend leaving the threshold at 5%. | | | | | |
| **Certification Criteria ONLY** | | | | | |
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| **SGRP204D** | **New** | **Objective:** Provide patients with the ability to request an amendment to their record online (e.g., offer corrections, additions, or updates to the record) through VDT in an obvious manner.  Certification criteria: "Branded button" that takes the burden of proof off of the provider for amendments. The problem is how to require documentation that the provider has offered the amendment ability in an obvious manner - new "button" would take care of this. Create the button because it is patient facing. |  | |  |
| * The majority of commentors support this item, multiple without challenge but most seeking clarification * Multiple commentors disagreed with the measure and suggested removal altogether due to lack of clarity and perceived redundancy of existing functionality * Multiple commentors suggested defining “in an obvious manner” and documentation requirements * Multiple questions on whether or not the provider must accept all amendments * Many seeking clarification of what parts of the record could have amendments submitted   + Address the differences between requests for changes to clinical data vs. administrative data and potential safety impact on amended data   + In the event that a patient’s amendment is not accepted, suggest patients be given an explanation as to why   + Record should display what is patient versus provider data * Multiple commentors sought clarification that this measure is in line with current HIPAA standards and not in addition to it * Many sought clarification on what the measure and subsequent threshold would be   + Would the provider be required to notify other providers of record amendments? * Many commentors raised concern that this threshold is duplicative of the ability to send direct messages. Some believe can be accomplished currently through patient portal. * Some concerns raised on the functionality of EHRs to meet this and need for this measure to be incorporated into EHR certification standards | | | | | |
| **SGRP208** | **Not included separately (in reminder objective)** | **EP and EH Measure:** Record communication preferences for 20% of patients, based on how (e.g., the medium) patients would like to receive information for certain purposes (including appointment reminders, reminders for follow up and preventive care, referrals, after visit summaries and test results). |  | |  |
| **PUBLIC COMMENTS:**   * The vast majority of commenters support this requirement to document communication preferences and agree that it is a necessary requirement in order to ensure people receive information in a medium that engages them. However, many commenters urged constraint around the menu of communication types to avoid workflow challenges and suggested that certification criteria be developed to specify the menu of options for “preferences” and “purposes”. | | | | | |
| **HITSC COMMENTS:**  Increasing to 95%. Include updating annually. | | | | | |
| **SGRP209** | **New** | **Certification Criteria:** Capability for EHR to query research enrollment systems to identify available clinical trials. No use requirements until future stages. |  | | The goal of this objective is to facilitate identification of patients who might be eligible for a clinical trial, if they are interested.  The EHR would query available clinical trial registries and identify potentially relevant trials based on patient’s health condition, location, and other basic facts. Ultimately, the EHR would not be able to determine final eligibility for the trial; it would only be able to identify possibly relevant trial opportunities. |
| **PUBLIC COMMENTS:**   * Commenters see the value in the EHR being able to query clinical trials database and the intent of this criteria to improve enrollment in trials. However, they expressed a number of concerns regarding the feasibility of including this criteria in Stage 3 citing implementation challenges, including the complex functionality that would be required to query multiple sources and to match up fields; the lack of specification about what fields to query; current lack of standards or a defined use case; workflow challenges; a lack of broad applicability to practitioners (more relevant to specialists) and patients (only a small minority are eligible for the trials); ethical concerns about providers recommending patients for certain studies. Consensus emerged for further study before including this in certification criteria. Some potential intermediary recommendations were to conduct an S&I Initiative to explore this further; to require the EHR to point to one, centralized data source like clinicaltrials.gov rather than to query several databases. Concern that there would need to be interfaces on both ends and that the disease registries may not be able to comply with the requirement. Some discussion about who should have access to this information—some suggested opening it up to researchers or allowing patients to also query. | | | | | |
| **HITSC COMMENTS:**  Building a sophisticated parsing algorithm could limit the quality of information by applying too many filters. May not be applicable to many patients in any case. A low impact approach would simply enable access to “clinicaltrials.gov” from the EHR.  Before this was made a measure, evidence would be needed that it improves the patient’s care or health.  While I support the intent of this proposed criterion, implementation would require knowledge of the service interfaces of all relevant research enrollment systems (since we can’t impose MU standards on them). I think that may be unrealistic. On the other hand, if EHRs implemented a standard service interface to query clinical trials system, developers of these trials system would be encouraged to conform to those standards. So I recommend that ONC sponsor the development of a service interface standard to enable EHRs to query clinical trials systems. (Perhaps CDISC could lead this development?) | | | | | |