

## Alert: CMS seeking public comment on new informed consent payment proposal

There is an exciting new opportunity to support patient-centered care and make a meaningful impact on the quality of care in hospitals across the US. CMS is seeking public comment on a proposed Medicare rule (regulation) for how hospitals are paid that includes a new measure assessing the quality of hospital informed consent documents given to patients before elective procedures. If adopted, this measure could be included in new payment models; meaning that, if adopted, the 4,700 US hospitals that treat Medicare members would be paid, in part, based on the quality of their informed consent documents. The measure could also be included in public quality comparisons such as Hospital Compare, allowing patients to use this measure in choosing between hospitals for their care. **Comments are due by 5:00 pm EDT on June 13<sup>th</sup>.** Tools and supports for organizations to submit their own comments are below.

There is [growing evidence](#) that patients who are engaged in their health care decisions enjoy better health outcomes and lower health costs. Effective informed consent documents complement and validate robust shared decision making that helps patients actively engage in their care. The proposed rule describes the goals of the measure, “As described in the literature and reported by patients, comprehensive informed consent documents can improve patient comprehension and satisfaction, and support patients in making decisions that are aligned with their expectations, preferences, and goals.”

Unfortunately, **the current state of hospital informed consent documents is very poor.** The proposed rule states that, “Despite their importance, and our regulations . . . informed consent documents are frequently generic, lack information that is relevant to the procedure, and include illegible, hand-written information. Moreover, patients are often given and asked to sign the informed consent document minutes before the start of a procedure when they are most vulnerable and least likely to ask questions.”

The proposed measure was developed by researchers for CMS with **significant patient and advocate input throughout the year-long process.** Consumers and advocates on the design workgroup were supported by independent experts and facilitators so they could fully participate in the measure’s design. The proposal reflects substantial consumer input about what is meaningful to patients at the point of choosing treatment options.

The informed consent document measure includes:

- A clear description of the procedure
- How the procedure will be performed
- Rationale for why the procedure will be performed
- Risks, benefits and alternatives to the procedure

- If the document was signed by the patient at least one day before the procedure date

Initial testing of the tool across US hospitals found very low performance and significant variation. There is lots of room for improvement. The proposed rule states, “It is hoped that adoptions of the measure, and inclusion in new payment models, will support and improve patient-centered care across the health care system.”

As promising as the proposed rule is, it is only a proposal. CMS has not made a decision whether to support the informed consent document measure for implementation. CMS is seeking feedback to help with their decision. Public comment from patients and consumer advocates is essential.

A customizable template based on the CT Health Policy Project’s comments is [here](#). Our comments emphasize the importance of including consumer input in quality measure development from the beginning and throughout the process and the importance of truly informed consent to achieve the promise of patient-centered care. We specifically support disclosure of alternative treatment options to achieve the highest score on the proposed measure. While over-treatment is a serious concern across the health system, underservice is also a serious problem, particularly for underserved populations. With the proliferation of new payment models that reward providers for lowering the total cost of care, it is even more important that patients are informed and understand all their options, regardless of the impact on providers’ and health systems’ bottom lines.

The informed consent portion runs from pages 1049 to 1063 of the very lengthy [proposed rule](#); relevant pages are [here](#). The specifics of the informed consent document measure is on [page 27](#) of the longer [methodology paper](#). A customizable Word Public Comment template is [here](#).

Comments are due by 5 pm EDT June 13<sup>th</sup>. [Submit comments here](#). The form asks for basic information and includes a button to upload your comments. There is no minimum or maximum length for effective comments. All comments are posted online and CMS’s final rule includes responses from the agency to each comment topic.

For help or questions, feel free to contact Ellen Andrews, PhD at [Andrews@cthealthpolicy.org](mailto:Andrews@cthealthpolicy.org).