June 12, 2017

From: Georgia Watch

To: Centers for Medicare and Medicaid Services
Department of Health and Human Services

Re: Public comment – CMS-1677-P

Writing on behalf of Georgia Watch, we thank you for this opportunity to voice our strong support for Proposed Rule CMS-1677-P, particularly the proposed regulations related to the Measure of Quality of Informed Consent Documents for Hospital-Performed Elective Procedures.

Founded in 2002, Georgia Watch is a nonprofit, nonpartisan 501(c)(3) organization with a vision to be the trusted and relentless advocate for all Georgia consumers. In addition to being a powerful statewide advocate for Georgia consumers, we are also a trusted information resource for the public, legislators and regulators. We work to ensure access to safe, quality, affordable healthcare, improve transparency, safeguard consumer protections in personal finance, promote access to the courts, and encourage fair utility rates and renewable energy options for consumers. Our mission is to protect and empower Georgia consumers on matters that impact their quality of life through education, advocacy and policy development. We focus our attention on communities that need a champion, particularly those most affected by predatory business practices and the high cost of utilities and healthcare. Promoting healthcare safety, value, and patient-centeredness are objectives at the core of our Health Access Program work.

There is growing evidence that engaging patients in their own care can improve health outcomes and that fully informed consent is critical to effective patient engagement. People need to understand their health conditions, what treatments are available, and appreciate the risks and benefit of each so they can make informed choices and heal. People should be at the center of decisions about their health to ensure that care decisions reflect their expectations, preferences and goals. This process of engaging and informing patients involves important two-way conversations and communications between patients and providers. Effective informed consent documents support and compliment effective patient engagement. An informative, legible, well-timed document can supplement high-quality conversations between patients, caregivers and providers.

Unfortunately, as pointed out in the proposed rule, too often informed consent documents are unintelligible, offer little information that is important to patients, and are given just before treatment is provided when patients are vulnerable, allowing no time for questions, understanding or reflection before signing. Often, the importance of informed consent is understood too narrowly. It is viewed only as a tool to prevent a consumer from having something done to them *without their permission*. However, informed consent, when fully understood, plays a much more expansive role. It should be viewed as a tool to ensure a fully informed shared decision-making process in which the consumer can *proactively identify the best course of action from all the relevant options* and then consent.

As new value-based payment models that could include incentives to steer patients away from more costly treatment options become widely adopted in Medicare and across the health system, informed consent becomes even more important. We are particularly pleased at proposed standards that informed consent documents should include both the benefits and risks of treatment as well as a description of alternative treatment options. **We further recommend that CMS strengthen this regulation, either in the rule or through subregulatory guidance, by being more prescriptive about the content and form of the description of alternative treatments.** That content should include comparative benefits and risks (i.e. the alternatives compared to the recommended treatment) and disclosure of any financial incentives in place. The alternative treatments disclosures should be provided in writing, even if only in a brief summary confirming the options, their major comparative benefits/risks, and the existence of financial incentives (if applicable).

If adopted, the proposed quality measure included in proposed rule CMS-1677-P will ensure that patients have the information they need to make the best decisions for themselves and their families. It will also serve as an important tool to support shared decision making and patient-centered care.

First, we want to commend CMS for the process used to develop the informed consent document measure proposal. Patients, family caregivers, and advocates were formally engaged from the beginning and all through the measure's development. Input from consumers who struggle to access care allowed the developers to better understand what features were critical to include and which were less salient for patients. Feedback on the draft measure allowed researchers to hone the measure and ensure it is effective.

The scoring standard includes a limited number of critical, appropriate elements to an effective informed consent document including:

- Common language descriptions of the procedure
- How it will be performed so patients understand what is coming without surprises
- The reason for the treatment so they understand the goal

- Specifics about what benefits are intended, so they understand how it will help them
- Risks are explicit so patients are aware of the potential for harm
- Alternatives to the treatment are disclosed so patients are engaged in the decision
- Typed rather than hand-written descriptions, improving readability
- Signed at least a day before the procedure so patients have time to consider their decision and ask questions

The scoring standard reflects a minimum list of features critical for informed consent, but it is an important first step toward improving documents and an important support to effective patient engagement. **We strongly recommend that CMS preserve all of these criteria in the final regulation**.

We are concerned that the proposed threshold score of ten out of twenty points is too low. This allows a passing grade for a hospital with informed consent documents that are given to patients on the day of treatment/surgery and do not include the risks and benefits of the procedure or any alternative treatment options (if the documents score at least ten points in other areas)**.** We recommend a higher bar for meeting the standards of the measure instead of scaling expectations higher over time. While the measure is new to hospitals, carefully scrutinized and validated consent procedures are not. Consent is a critical part of hospital operations, well understood in literature and heavily evaluated by hospital leaders and clinicians.

We understand the intent to raise the threshold over time and recognize the importance of not creating undue burden for hospitals. However, we think that a temporary lesser standard, which could misinform and/or harm patients, is unnecessary since, unlike many other quality metrics that require staff behavioral change (e.g. washing hands between patients), improvements to a standard document can be made more quickly. Changing that singular document at multiple intervals to improve the score requires unnecessary repeated corporate and legal review for hospitals and may also confuse providers (and patients). Setting the threshold at a higher level from the beginning better serves both patients and hospitals.

Furthermore, we recommend that a mechanism be put in place to ensure patient satisfaction with the process for gathering signatures on the consent form and that a longer interval of time between signature and elective procedure is adopted. The current measure gives credit for 24 hours; for the gold standard in shared decision-making, the standard should be longer and that is where credit should be awarded.

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We appreciate both the proposal to improve informed consent documents and your consideration of these comments. If there are questions, please contact me at bstephens@georgiawatch.org or (404) 525-1085.

Respectfully submitted,

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