



American Association on Health & Disability

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AAHD - Dedicated to better health for people with disabilities through health promotion and wellness



LAKESHORE

June 1, 2017

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

Re: **Public Comment – CMS-1677-P**
**Informed Consent as a Quality Measure for Medicare Hospital-
Performed Elective Procedures**

The American Association on Health and Disability and the Lakeshore Foundation write in support of the CMS-1677-P proposed rule as it applies to Informed Consent as a Quality Measure for Hospital-Performed Elective Procedures

The American Association on Health and Disability (AAHD) (www.aahd.us) is a national non-profit organization of public health professionals, both practitioners and academics, with a primary concern for persons with disabilities. The AAHD mission is to advance health promotion and wellness initiatives for persons with disabilities.

The Lakeshore Foundation (www.lakeshore.org) mission is to enable people with physical disability and chronic health conditions to lead healthy, active, and independent lifestyles through physical activity, sport, recreation and research. Lakeshore is a U.S. Olympic and Paralympic Training Site; the UAB/Lakeshore Research Collaborative is a world-class research program in physical activity, health promotion and disability linking Lakeshore's programs with the University of Alabama, Birmingham's research expertise.

There is growing evidence that engaging patients, beneficiaries, participants, and consumers in their own care, services, and supports can improve health outcomes and fully informed consent is critical to effective patient, beneficiary, participant, and consumer engagement. People need to understand their health conditions, what treatments are available, and appreciate the risks and benefit of each so they can 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, beneficiary, participant, and consumer 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.

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. 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, beneficiaries, participants, and consumers 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.

We commend CMS for the process used to develop the informed consent document measure proposal.

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, Beneficiary, participant, and consumer engagement. **We strongly recommend that CMS preserve all of these criteria in the final regulation.**

We appreciate both the proposal to improve informed consent documents and your consideration of these comments. We commend the Connecticut Health Policy Project and National Health Law Program for their leadership and work within the consumer advocacy movement.

Thank you for the opportunity to comment. If you have any questions please contact Clarke Ross at clarkross10@comcast.net.

Sincerely,



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<http://www.qualityforum.org/>) and NQF representative of the Consortium for Citizens with Disabilities (CCD) Task Force on Long Term Services and Supports (<http://www.c-c-d.org/>).

2017 member, NQF MAP workgroup on Medicaid adult measures. 2016-2017 NQF duals workgroup liaison to the NQF clinician workgroup. 2015-2016 and 2014-2015 NQF duals workgroup liaison to the NQF PAC/LTC workgroup. Member, ONC (Office of the National Coordinator for Health Information Technology) Health IT Policy Committee, Consumer Workgroup, March 2013-November 2015; Consumer Task Force, November 2015-April 2016.

<http://www.healthit.gov/policy-researchers-implementers/federal-advisory-committees-facas/consumer-empowerment-workgroup>). Member, SAMHSA Wellness Campaign National Steering Committee – January 2011-September 2014.

<http://promoteacceptance.samhsa.gov/10by10/>).

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