

HR 3590 Enrolled Bill signed into Law by President March 23rd

The HR 3590 Bill (Reconciliation) passed the house on March 21 2010 accepting the Senate Bill which was passed on December 24 2009. The bill was signed into law by President Obama on March 23rd. It includes substantial provisions related to Shared Decision Making.

In Summary the law:

- 1) Creates a new shared decision-making program and calls for:
 - establishing a process to certify decision aids;
 - awarding funding to produce and update aids;
 - creating Shared Decision Making Resource Centers; and
 - providing grants to health care providers for development, use and assessment of shared decision making using certified decision aids;
- 2) Under a new Center for Medicare and Medicaid Innovation (CMI) provides support to test innovations that assist individuals in making informed health care choices Provides support for new measures to assess shared decision making tools; and
- 3) Provides support for new measures to assess shared decision making tools

In pertinent part the law creates:

1) *Section 936 Program to Facilitate Shared Decision Making*

- The bill creates a Program to Facilitate Shared Decisions-Making whose **purpose is “to facilitate collaborative processes between patients, caregivers or authorized representatives, and clinicians that engages the patient, caregiver or authorized representative in decision making, provides patients, caregivers or authorized representatives with information about trade-offs among treatment options, and facilitates the incorporation of patient preferences and values into the medical plan”** (Sec. 936 p.409).
- **Patient decision aid is defined** as “an educational tool that helps patients, caregivers or authorized representatives understand and communicate their beliefs and preferences related to their treatment options, and to decide with their health care provider what treatments are best for them based on their treatment options, scientific evidence, circumstances, beliefs, and preferences” (Sec 936 p. 409).
- **Preference sensitive care is defined** as “care for which the clinical evidence does not clearly support one treatment option such that the appropriate course of treatment depends on the values of the patient or the preferences of the patient, caregivers or authorized representatives regarding the benefits, harms and scientific evidence for each treatment option, the use of such care should depend on the informed patient choice among clinically appropriate treatment options” (Sec 936 p. 409).
- The bill calls for independent standards for patient decision aids for preference sensitive care and contracting with an entity (refers to NQF section 1890 of SSA) **to establish standards and a certification process for patient decision aids** for preference sensitive care for use in federal programs and by other interested parties. Contract to be entered into as soon as practicable and shall be for a period of 18 months renewable through a subsequent bidding process. The Entity designated (NQF) shall **synthesize** evidence, **convene** a broad range of experts and key stakeholders and **identify consensus based standards** to evaluate preference sensitive patient decision aids. Entity shall review and **develop certification process** as to whether patient decision aids meet the certification process and will give priority to review and certification of patient decision aids for preference sensitive conditions. (Sec 936 p.410).

- The Secretary, in coordination with other relevant agencies such as CDC and NIH, is required to establish a program to **award grants or contracts to develop, update and produce patient decision aids for preference sensitive care** to assist in educating patients and others concerning the **relative safety, relative effectiveness, and relative cost of treatment**, or, where appropriate, **palliative care**. The program shall also test the materials to ensure they are **balanced and evidence based** and can easily be incorporated into a broad array of practice settings. The program shall also **educate providers** in the use of the materials. (Sec 936 p. 410)
- Patient decision aids shall be designed to engage patients in informed decision making with providers and are required to present up-to-date clinical evidence about the risks and benefits of treatments in a form that is **age appropriate** and can be **adapted for people from a variety of cultural and educational backgrounds** with diverse health literacy. They must also explain where appropriate why there is a lack of evidence to support one treatment option over another and address decision across the age span including vulnerable populations. (Sec 936 p. 411).
- Patient **decision aids** produced pursuant to these grants or contracts **must be made available to the public. Secretary charged with phased in development and implementation with the objective of improving patient understanding of medical treatment options.** (Sec 936 p. 411).
- The Secretary is required to provide grants for the **establishment and support of Shared Decision Making Resource Centers to provide technical assistance** to providers and to develop and disseminate best practices to support and accelerate the adoption, implementation and **effective use of patient decision aids** (Sec 936 p.411).
- The stated objectives of the Shared Decision Making Resource Centers are to **promote adoption** of patient decision aids and shared decision making through providing assistance to eligible providers with implementation, effective use, and training on patient decision aids and dissemination of best practices. (Sec 936 p 411)
- The Secretary is required to provide **grants to health care providers for the development, use and assessment of shared decision making techniques using certified decision aids.** Preference will go to providers who are trained by Shared Decision Making Resource Centers or comparable training (Sec 936 p. 411-412).
- Funds shall not be used to purchase or implement use of patient decision aids that are **not certified under the process.** The Secretary may issue **guidelines** to grantees on the use of patient decision aids. (Sec 936 p. 412)

2) Section 3021 Center for Medicare and Medicaid Innovation CMI

The bill establishes within the Centers for Medicare and Medicaid Services a **Center for Medicare and Medicaid Innovation (CMI)** to “test innovative payment and service delivery models to reduce program expenditures...while preserving or enhancing the quality of care...” The Secretary is required to select models to be tested where there is evidence that the model addresses a defined population for which there are deficits in care leading to poor outcomes or avoidable expenditures. (Sec 3021 p. 271)

The models **may** include listed include up to eighteen different types such as: (i) practice reform in primary care including patient centered medical home; and (ix) those that **assist individuals in making informed health care choices by paying providers of services and suppliers for using patient decision support tools** that meet the standards of section 936 In selecting models the Secretary may consider whether the model includes a process for updating the patient care plans **consistent with the needs and preferences of the applicable individual and places the applicable individual at the center of the care team.** (Sec 3021 p. 274).

The secretary may through rulemaking expand implementation of a successful model on a nationwide basis. There is appropriated \$5,000,000 for design, implementation and evaluation of models in fiscal 2010 and \$10,000,000,000 for activities initiated under this section for first 10 year period. (Sec 3021 p. 275-276)

3) Section 931 Quality Measure Development related to Shared Decision Making

The bill calls for **quality measure development** and requires the secretary to award grants, contracts or intergovernmental agreements to develop, improve, update or expand quality measures. The bill calls for giving priority to certain measures including those that allow **assessment of the experience, quality and use of information provided to and used by patients to inform decision making including the use of shared decision making tools and preference sensitive care** (Sec 931 p. 264).