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ONE HUNDRED THIRTEENTH CONGRESS
Congress of the United States
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MEMORANDUM

July 26, 2014

To: Committee on Energy and Commerce Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Subcommittee Markup on *H.R. 4067*, a bill to provide for the extension of the enforcement instruction on supervision requirements for outpatient therapeutic services in critical access and small rural hospitals through 2014; and, *H.R.* ____, a bill to require the Secretary of Health and Human Services to provide for recommendations for the development and use of clinical data registries for the improvement of patient care.

The Subcommittee on Health has scheduled a markup on **Monday, July 28, 2014, at 3:00 p.m. in 2123 Rayburn House Office Building**. The Subcommittee will consider the following:

- H.R. 4067, a bill to provide for the extension of the enforcement instruction on supervision requirements for outpatient therapeutic services in critical access and small rural hospitals through 2014; and,

- H.R. ____, a bill to require the Secretary of Health and Human Services to provide for recommendations for the development and use of clinical data registries for the improvement of patient care.

I. H.R. 4067

In the 2009 outpatient prospective payment system (OPPS) final rule, CMS clarified existing policy for physician supervision of outpatient therapeutic services as a condition of payment which has been in place since 2001. CMS policy requires direct supervision by an appropriate physician or non-physician practitioner in the provision of all therapeutic services to hospital outpatients, including CAHs. These services include clinic services, emergency room services, and observation services. All of these services are provided incident to a physician's service so this implies a physician or non-physician practitioner should be around, as such "incident to" services by definition must be performed by or under the supervision of such personnel.

Depending on the service, Medicare either requires "personal", "direct" or "general" supervision for therapeutic services. Direct supervision is the requirement unless otherwise noted. "General supervision" means the service or procedure is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure. Personal supervision" means the physician must be in attendance in the room during the performance of the service or procedure. Direct supervision means the physician or other practitioner has to be immediately available—generally at the site where the services are occurring but not personally in the room while the service is being provided. Direct supervision requirement does not mean a supervising professional must be within the four walls of the facility, but only that the professional must be "immediately available to furnish assistance and direction throughout the performance of the procedure". Immediate availability requires the immediate physical presence of the supervisory provider. Direct supervision may be furnished from a providers' office or other nonhospital space that is not officially part of the hospital or CAH campus where the service is being furnished as long as the supervising provider is immediately available.

As a result of concerns raised by critical access hospitals (CAHs) and small rural hospital providers, CMS delayed the enforcement of the supervision requirements in a non-enforcement instruction on March 15, 2010 for critical access hospitals and small rural providers. This non-enforcement instruction was in place from that time through 2013. During that period of non-enforcement, CMS made adjustments to the definition of direct supervision, established an advisory panel (the Hospital Outpatient Payment Panel) to obtain advice on the appropriate supervision levels for individual hospital outpatient therapeutic services, and expanded the list of outpatient therapeutic services for which direct supervision is not required. CMS made these changes in response to concerns and requests made by CAHs and other stakeholders. As of January 1, 2014, however, the non-enforcement instruction has not been in effect, and providers are expected to comply with the supervision rules.

The legislation, H.R. 4067, would mandate that the Secretary of Health and Human Services apply the enforcement instruction dated November 1, 2012 for the remainder of Calendar Year 2014 (i.e., the next five months). This would halt the enforcement of these supervision requirements that have been in effect for the past seven months.

Non-enforcement of supervision requirements can have patient safety implications. For example, this would mean that hospital outpatient departments giving toxic doses of chemotherapy medicine would not have to ensure there is a supervising professional in the facility when the patient was being treated.

The Medicare Payment Advisory Commission (MedPAC) had the following to say about the enforcement of these requirements in their 2013 Hospital Outpatient Comment Letter, "In light of the decision to enforce the supervision instructions, we advocate that CMS continue working with the Hospital Outpatient Payment Panel to define services that are appropriate for general supervision. Similarly, we encourage CMS to review Conditions of Participation (CoPs) for CAHs to ensure that the CoPs are consistent with regulations."

II. H.R. ____, a bill to require the Secretary of Health and Human Services to provide for recommendations for the development and use of clinical data registries

Clinical data registries are used for many different purposes, quality improvement, tracking patient outcomes, etc. Some provider organizations have developed registries to collect data for the development of clinical practice guidelines. The Society of Thoracic Surgeons (STS), for example, established a registry in 1989 as an initiative for quality improvement and patient safety among cardiothoracic surgeons. There are drug and device registries that collect information on outcomes and adverse events related to specific products. Some organizations maintain patient registries that provide an organized system to collect data for scientific assessment of patient outcomes.

Both the public sector and the private sector have taken action to develop registries, and also have collaborated, to develop guidelines, best practices, and technical assistance for the development and operation of registries. The Agency for Health Research and Quality (AHRQ) has issued extensive guidance on how to create registries, for example *Registries for Evaluating Patient Outcomes: A Users Guide*. This extensive document was recently updated with assistance and support from a range of stakeholders, including government agencies, industry groups, medical professional societies, and other experts in the field. AHRQ also maintains a registry of patient registries (RoPR) where the public can search to identify registries on various topic of interest and to prevent duplication in the development of registries.

The American Medical Association (AMA) operates the National Quality Registry Network (NQRN®) which is a voluntary network of organizations operating registries and others interested in increasing the usefulness of clinical registries to measure and improve patient health outcomes. The NQRN Council is composed of members, plus Federal Government liaisons, who represent registry stewards and participants, non-delivery system registry users, and supporting technologies.

To date, the largest impediment to registry development by medical providers has not been lack of knowledge or guidance, but funding for the creation and maintenance of the registry. The bipartisan bicameral sustainable growth rate (SGR) repeal bill (H.R. 4015) would have given registries access to CMS claims data so the registries could pair the claims data with the clinical data and track both outcomes and efficiencies.

The Committee Print, H.R. ___ would direct the Secretary of Health and Human Services (HHS) to make recommendations for the development and use of clinical data registries that are integrated with clinical practice guidelines and best practices or standards of care. The legislation provides five paragraphs of extensive instruction for what these recommendations should cover. Because of the varied nature of registries and various uses for the registries, this approach could limit flexibility and stymie development of registries, forcing current innovation into a one-size-fits all registry approach. It is unclear how the directive in this legislation would fit in with the existing, extensive stake-holder developed User Guide published by AHRQ, or with the AMA's NQRN process and Council.