



#### September 21, 2018

## CMS Proposes Rule to Lift Unnecessary Regulations and Ease Burden on Providers

The Centers for Medicare and Medicaid Services (CMS) has issued a proposed rule that is intended to "revise the applicable conditions of participation (CoPs) for providers and conditions for coverage (CfCs) as a continuation of its efforts to reduce regulatory burden in accordance with the January 30, 2017 Executive Order Reducing Regulation and Controlling Regulatory Costs."

The document is available in the *Federal Register* at: https://bit.ly/2QSpCPd. A 60-day comment period is provided.

CMS says that "these updates would save healthcare providers an estimated \$1.12 billion annually."

#### Comment

The changes being proposed do not impact Medicare payments nor change Medicare payment polices directly. Rather, these changes are aimed at Medicare Conditions of Participation items and coverage issues.

In addition to CMS's regulatory notice, the agency has produced an excellent "fact sheet" containing a very helpful summary of the proposal. Below are excerpts of the fact sheet:

#### **Proposed Requirements**

The proposed rule would "reduce the frequency of certain required activities and, where appropriate, revise timelines for certain requirements for providers and suppliers and remove obsolete, duplicative or unnecessary requirements. These proposals would balance patient safety and quality, while also providing broad regulatory relief for providers and suppliers. The proposed rule would reduce burden for participating providers and suppliers in the following ways:"

### **Emergency Preparedness**

"We continually assess our Emergency Preparedness policies to ensure that facilities maintain access to services during emergencies, provide safety for patients, safeguard human resources, maintain business continuity and protect physical resources. This proposed rule will continue to ensure that these expectations are met. At the same time, we are proposing to reduce the complexity of the requirements to ensure that providers are spending more time and resources on actual patient care."

- "Emergency program: Give facilities the flexibility to review their emergency program every two years, or more often at their own discretion, in order to best address their individual needs. A comprehensive review of the program can involve an extensive process that may not yield significant change over the course of one year. Facilities may review the plan more frequently should significant changes become necessary as determined by the individual needs of the facility. The combination of all Emergency Preparedness requirements (policies and procedures, testing, communication plan) will continue to hold facilities accountable for their outcomes while allowing them more time to focus on their unique needs and specific circumstances."
- "Emergency plan: Eliminating the duplicative requirement that the emergency plan include documentation of efforts to contact local, tribal, regional, State and federal emergency preparedness officials and a facility's participation in collaborative and cooperative planning efforts. This information is already contained in other regulations requiring that these activities occur."
- *"Training*: Give facilities greater discretion in revising training requirements to allow training to occur annually or more often at their own discretion. Overly restrictive training requirements can have unintended consequences in preventing facilities from focusing their training efforts on what makes sense in unique circumstances."
- *"Testing (for inpatient providers/suppliers)*: Increasing the flexibility for the testing requirement so that one of the two annually-required testing exercises may be an exercise of the facility's choice. While two annual tests are still required, flexibility is provided so that one of those training sessions can be done through various innovative methods such as simulations, desk top exercises, workshops or other methods that may best meet the needs of the facility and the patients that they serve. The second training must continue to be a full scale community exercise."
- "Testing (for outpatient providers/suppliers): Revising the requirement for facilities to conduct two testing exercises to one testing exercise annually. Additional testing will be at the facilities' discretion based on unique needs. This will allow facilities to modernize their testing to use innovative methods such as desktop drills and simulations."

# Hospitals

- "Allowing multi-hospital systems to have unified and integrated Quality Assessment and Performance Improvement and unified infection control programs for all of its member hospitals."
- "Allowing discretion on when an autopsy is indicated in certain instances. CMS believes it is appropriate to defer to State requirements in this area and that this change will allow facilities to make better use of limited resource."
- "Allowing hospitals the flexibility to establish a medical staff policy describing the circumstances under which a pre surgery/pre procedure assessment for an outpatient could be utilized, instead of a comprehensive medical history and physical examination. By moving away from a standard requirement of not more than 30 days for these assessments, this change will allow facilities to focus on what makes sense clinically based on the individual needs of each patient."
- "Clarifying for psychiatric hospitals the requirement that allows for the use of non-physician practitioners or doctors of medicine/doctors of osteopathy (MD/DOs) to document progress notes of patients receiving services in psychiatric hospitals."

# Critical Access Hospital (CAHs), Rural Health Centers (RHCs) and Federally Qualified Health Centers (FQHCs)

#### Hospital and CAH swing-bed providers:

• "Removing cross-references to requirements for long term care facilities that do not apply because of the short amount of time patients are in swing-beds."

## CAHs:

- "Reducing the frequency of the requirement that CAHs perform a review of all their policies and procedures from annual to biennial, in order to allow facilities to better utilize their limited resources; and
- Removing the duplicative requirement for CAHs to disclose the names of people with a financial interest in the CAH, as this information is also collected outside of the conditions of participation."

## RHCs and FQHCs:

• "Reducing the frequency of review of the patient care policies from annually to every two years, in order to allow these clinics to direct their limited resources to patient care. Facilities are always permitted to conduct reviews as they deem appropriate."

## **Ambulatory Surgical Centers (ASCs)**

- "Reducing burden for ASCs by removing the provisions requiring ASCs to have a written transfer agreement with a hospital that meets certain Medicare requirements or ensuring that all physicians performing surgery in the ASC have admitting privileges in a hospital that meets certain Medicare requirements. This long standing requirement is now duplicative of other regulatory requirements and has been rendered obsolete by other patient protections; and
- Removing the current requirements that a physician or other qualified practitioner conduct a
  complete comprehensive medical history and physical assessment (H&P) on each patient not
  more than 30 days before the date of the scheduled surgery. Additionally, we propose to require
  that each ASC establish and implement a policy that identifies patients who require an H&P
  assessment prior to surgery."

#### **Transplant Centers**

- "Updating the terminology and proposed nomenclature change used in the regulations to conform to the terminology that is widely used and understood within the transplant community, thereby reducing provider confusion; and
- Removing requirements for transplant centers to re-submit clinical experience, outcomes, and
  other data in order to obtain Medicare approval. CMS proposes to remove this requirement in
  order to address unintended consequences of existing requirements, which have resulted in
  transplant programs potentially avoiding performing transplant procedures on certain patients
  and many organs going unused. We will continue to monitor and assess outcomes and quality
  of care in transplant programs after initial Medicare approval."

# Hospices

- "Allowing hospices to defer to State licensure requirements for their aides regardless of the State content or format, and would allow states to set forth training and competency requirements that meet the needs of their populations. This change will streamline the hiring process for most hospices."
- "Encouraging more seamless integration of information provided by the hospice's drug management expert into routine interdisciplinary group meetings rather than having to use the more cumbersome "check box" approach that hospices currently implement in order to demonstrate compliance with the regulation."
- "Replacing a requirement that hospices provide a physical paper copy of policies and procedures with a requirement that hospices provide information regarding the use, storage and disposal of controlled drugs to the patient or patient representative, and family, which can be developed in a manner that speaks to the perspectives and information needs of patients and families. This information would be provided in a more user-friendly manner, as decided by each hospice, which we believe can improve comprehension and maximize the effectiveness of the education effort."
- "Assuring requirements for hospices that provide hospice care to residents of a skilled nursing facility/nursing facility or Intermediate Care Facilities for Individuals with Intellectual Disabilities to move the requirement for facility staff orientation to the standard related to the written agreement established between hospices and facilities. We believe this would ensure that both entities negotiate the mechanism and schedule for assuring orientation of facility staff, encourage collaboration between both entities, and avoid duplication of efforts with other hospices that are orienting the same facility staff.

#### **Comprehensive Outpatient Rehabilitation Facilities**

• "Implementing a proposed decrease in the frequency and implementation of a utilization review plan from four times per year to annually. This effort would allow for an entire year to collect and analyze data to inform changes to the facility and services it provides."

# **Community Mental Health Centers (CMHCs)**

• "Removing a requirement for CMHCs to update the client comprehensive assessment every 30 days for all CMHC clients and only retain the minimum 30-day assessment update for those clients who receive partial hospitalization program services. We believe this will allow for an efficient use of CMHC clinician time, allowing for more time with their clients."

# Portable X-Ray Services

- "Adjusting the four training and education requirements that focus on accreditation of the school where a technologist received training from the personnel requirements for non-physician personnel used by an independent testing facility to perform tests. CMS proposes to replace these four different qualifications with a single, streamlined qualification that focuses on the skills and abilities of the technologist."
- "Allowing for portable x-ray services to be ordered in writing, by telephone, or by electronic methods to streamline the ordering process."

## **Religious Nonmedical Health Care Institutions (RNHCIs)**

- "Creating a more condensed and flexible process for discharge planning and instructions for RNHCIs by requiring them only to provide discharge instructions to the patient and/or the patient's caregiver when the patient is discharged home. This flexibility would provide for an alternative to traditional discharge plan requirements, which may not be consistent with patient needs in this setting."
- "Improving the process for RNHCIs discharge planning that includes medical care once a
  patient leaves the RNHCI facility, because doing so is not in keeping with the religious tenets
  and goals of the facility. CMS has an expectation that RNHCIs have policies and procedures
  that address their discharge processes. If the RNHCI determines that a patient either does or
  does not require discharge instructions, this decision must be made based on the RNHCI's
  existing policies."

## **Final Comment**

CMS has provided the following analysis of anticipated savings:

Provider and Supplier Type and Description of Proposed Provisions	Frequency	Number of Affected Entities	Estimated Annual Savings or Benefits (\$millions)
Religious Nonmedical Health Care Institutions			
Discharge Planning	As patients are discharged (Estimated 619 annual discharges)	18	*
Ambulatory Surgical Centers			
Governing Body & Management	Upon failed hospital transfer agreement attempts	5,557	*
<ul> <li>Patient Admission, Assessment and Discharge (History and Physical)</li> </ul>	Every patient registration at an ASC or at a hospital outpatient/ ambulatory surgery department	5,557 (ASCs) 5,031 (Hospitals)	454
Medical Records	Recurring annually	5,557	0
Hospices			
<ul> <li>Drugs and Biologicals, Medical Supplies, and Durable Medical Equipment</li> </ul>	Recurring annually	1,151	80
Hospices That Provide Hospice Care to residents of a SNF/NF or ICF/IID	Recurring annually	4,602	*
Hospice Aide and     Homemaker Services	Recurring annually	3,498	2
Hospitals			
<ul> <li>Quality Assessment and Performance Improvement Program</li> </ul>	Recurring annually	5,031	28
Medical staff: Autopsies	Recurring annually	5,031	0
Infection Control	Recurring annually	5,031	105

#### Section-by-Section Economic Impact Estimates

Provider and Supplier Type and	Frequency	Number of	Estimated Annual Savings or Benefits
Description of Proposed Provisions		Affected Entities	(\$millions)
<ul> <li>Special requirements for hospital providers of long- term care services ("swing-beds")</li> </ul>	Recurring annually	1,724	30
<ul> <li>Special Requirements Psychiatric Hospitals</li> </ul>	Recurring annually	574	62
Transplant programs			
Various provisions related to performance**	Recurring annually	750	Not Quantified
Home Health Agencies			
Patient rights	Recurring annually	12,624	55
Home health aide services	Recurring annually	12,624	0
Clinical records	Recurring annually	12,624	0
Critical Access Hospitals	-		
Provision of Services	Recurring biennially	1,343	2
Organizational structure	Recurring annually	1,343	*
<ul> <li>Special requirements for CAH providers of long-term care services ("swing-beds").</li> </ul>	Recurring annually	1,246	86
Comprehensive Outpatient Rehabilitation Facilities			
Utilization ReviewPlan	Recurring annually	188	*
Community Mental Health Centers			
Assessment Update	Recurring annually	52	*
Portable X-Ray Services			
<ul> <li>Qualifications of X-ray technicians***</li> </ul>	Annual	500	31
Removing written orders	Annual	500	29
RHC (4,160 clinics) & FQHC (7,874 center locations)			
Provision of Services	Recurring biennially	12,034	7
Program Evaluation	Recurring biennially	12,034	9
Emergency Preparedness for Providers and Suppliers			
Annual Review of Emergency     Preparedness Program	Recurring annually	72,844	94
Emergency Plan	Recurring annually	68,254	7
Training and Testing-Training     Program	Recurring annually	69,196	33
Training and Testing-Testing	Recurring annually	36,971	9
Total Annual Savings			1,123
Life-extending benefits for transplant patients			Not Quantified

\* Amount is less than one million dollars

\*\* These include proposed changes to the following requirements: Special Requirements for Transplant Programs; Data submission, Clinical Experience, and Outcome Requirement for Re- approval of Transplant Programs; and Special Procedures for Approval and Re-Approval of Organ Transplant Programs.

\*\*\*This estimate is for first full year savings only and will increase in future years.

Our Washington liaison, Larry Goldberg of Larry Goldberg Consulting, has provided us with this summary and comments. For questions, please contact Jeff Weegar, NCHA, at 919-677-4231, jweegar@ncha.org or Ronnie Cook, NCHA, at 919-677-4225, rcook@ncha.org.