Omnibus Burden Reduction Rule CMS-3346-F

On September 26, 2019, the Centers for Medicare & Medicaid Services (CMS) took action at President Trump's direction to "cut the red tape," by reducing unnecessary burden for American's healthcare providers allowing them to focus on their priority – patients. The Omnibus Burden Reduction (Conditions of Participation) Final Rule removes Medicare regulations identified as unnecessary, obsolete, or excessively burdensome on hospitals and other healthcare providers to reduce inefficiencies and moves the nation closer to a healthcare system that delivers value, high quality care and better outcomes for patients at the lowest possible cost.

This rule advances CMS's Patients over Paperwork initiative by saving providers an estimated 4.4 million hours of time previously spent on paperwork with an overall total projected savings to providers of $800 million annually.

This rule finalizes the provisions of the following three distinct proposed rules:

- *Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction ("Omnibus Burden reduction")*, published September 20, 2018;
- *Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care*, published June 16, 2016; and
- *Fire Safety Requirements for Certain Dialysis Facilities*, published November 4, 2016.

While each proposed rule was published separately, CMS is finalizing them in one final rule for administrative efficiency as well as to promote transparency. Each of these rules includes reforms to Medicare regulations that are identified as unnecessary, obsolete, or excessively burdensome on health care providers and suppliers. In addition, the hospital and CAH rule addresses one of the top priorities for the President and his Administration-- advancing the overall quality and safety of patient care— by modernizing and updating the requirements for hospitals and CAHs to have infection prevention and control and antibiotic stewardship programs that are not only active and facility-wide, but which also demonstrate adherence to nationally recognized guidelines for the surveillance, prevention, and control of HAIs and other infectious diseases, as well as best practices for the optimization of antibiotic use through stewardship in order to effectively reduce the development and transmission of antibiotic-resistant organisms.

Background
Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction ("Omnibus Burden Reduction"), published September 20, 2018.

In a continued effort to balance patient safety and quality of care while limiting unnecessary procedural burdens on providers, and in accordance with the January 30, 2017 Executive Order "Reducing Regulation and Controlling Regulatory Costs" (Executive Order 13771), CMS has conducted a comprehensive review of the

regulatory health and safety standards for applicable provider and supplier types. CMS issued this final rule to revise the applicable regulations as a continuation of our efforts to reduce regulatory burden in accordance with the aforementioned Executive Order.

CMS is finalizing changes that will simplify and streamline the current regulations, increasing provider flexibility and reducing excessively burdensome regulations. This will allow providers to focus on providing high-quality healthcare to their patients, while maintaining robust health and safety standards for patients.

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

Emergency Preparedness

- *Emergency program:* We have decreased the requirements for facilities to conduct an annual review of their emergency program to a biennial review. However, based on industry feedback, long term care (LTC) facilities will continue to review their emergency program annually.

- *Emergency plan:* Eliminating the 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;

- *Training:* Decreasing the training requirement from annually to every two years. Nursing homes will still be required to provide annual training.

- *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; and
- *Testing (for **outpatient** providers/suppliers):* Decreasing the requirement for facilities to conduct two testing exercises to one testing exercise annually.

Hospitals

- Allowing multi-hospital systems to have unified and integrated Quality Assessment and Performance Improvement (QAPI) programs and unified and integrated infection control and antibiotic stewardship programs for all of their member hospitals;

- Removing the requirement for a hospital's medical staff to attempt to secure autopsies in all cases of unusual deaths and of medical-legal and educational interest.

- 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;

- For psychiatric hospitals, CMS is also finalizing the clarification of the requirement to allow the use of non-physician practitioners and doctors of medicine/doctors of osteopathy (MD/DOs) to document progress notes of patients receiving services in psychiatric hospitals.

Hospital swing-bed providers, Critical Access Hospitals, Rural Health Centers, and Federally Qualified Health Centers

Hospital and CAH swing-bed providers:

- Removing the requirement for a facility to request or allow swing-bed patients to perform services for the facility;
- Removing the requirement for the facility to provide an ongoing activities program that is directed by a qualified professional because the patient's activity needs are addressed in the nursing care plan;
- Removing the requirement for facilities with more than 120 beds to employ a qualified social worker on a full-time basis because of the hospital swing-bed and CAH bed limit requirements; and
- Removing the requirement for facilities to assist residents in obtaining routine and 24-hour emergency dental care because of the existing requirement for hospitals and CAHs to provide care in accordance with the needs of the patient (emergent and non-emergent).

CAHs:

- Reducing the frequency that is currently required for CAHs to perform a review of all their policies and procedures; and
- Removing the duplicative requirement for CAHs to disclose the names of people with a financial interest in the CAH.

RHCs and FQHCs:

- Reducing the frequency of review of the patient care policies and facility evaluation from annually to every two years.

Ambulatory Surgical Centers

- 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. Instead, ASCs will be required to periodically provide the local hospital with written notice that outlines the ASC operation and patient population served by the ASC facility. All ASCs must continue to have an effective procedure for immediate transfers to a hospital for patients requiring emergency medical care beyond the capabilities of the ASC; and

- Removing the current requirements that a physician or other qualified practitioner conduct a complete comprehensive medical history and physical assessment on each patient not more than 30 days before the date of the scheduled surgery. Additionally, CMS is finalizing the requirement that each ASC establish and implement a policy that identifies patients who require an H&P prior to surgery.

Transplant Centers

- Updating the terminology 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 the requirement for transplant centers to submit clinical experience, outcomes, and other data in order to obtain Medicare re-approval. This policy seeks to address the unintended consequences of the existing requirements that have resulted in transplant programs potentially avoiding performing transplant procedures on certain patients and many organs going unused. Although we are finalizing the removal of this requirement, CMS will continue to monitor and assess outcomes and quality of care in transplant programs after initial Medicare approval.

Home Health

- Removing the requirement that the Home Health Agency (HHA)_conduct a full competency evaluation of a home health aide when deficiencies are identified in aide services, and replacing it with a requirement to retrain the aide regarding the identified deficient skill(s), and requiring the aide to complete a competency evaluation related only to those skills; and

- Limiting the requirements for verbal (meaning spoken) notification of all patient rights to those rights related to payments made by Medicare, Medicaid, and other federally funded programs, and for potential patient financial liabilities, as specified in the Social Security Act. HHAs will still be required to provide written notice of all patient rights to all HHA patients.

Hospices

- Allowing hospices to defer to State licensure requirements for qualification of their hospice aides, regardless of the State licensure content or format, thus allowing states to set forth training and competency requirements that meet the needs of their populations. We anticipate this change will streamline the hiring process for most hospices;

- Removing the prescriptive requirement that hospices must consult with an individual with expertise in drug management in addition to the hospice's own expert clinicians; and

- For hospices that provide hospice care to residents of a Skilled Nursing Facility or Intermediate Care Facilities for Individuals with Intellectual Disabilities, CMS is requiring hospices to work with their chosen Skilled Nursing Facility and intermediate care facility partners to educate facility staff about the hospice philosophy of care and specific

hospice practices. CMS believes this will encourage collaboration between both entities; and will avoid duplication of efforts with other hospices that are orienting the same facility staff.

Comprehensive Outpatient Rehabilitation Facilities

- Reducing the frequency of the implementation of a utilization review plan from four times per year to annually, which will allow an entire year to collect and analyze data to inform changes to the facility and the services provided.

Community Mental Health Centers

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

Portable X-Ray Services

- Removing the four training and education requirements, which focus on the accreditation of the school where the technologist received training, and replacing it with a streamlined qualification that focuses on the skills and abilities of the technologist; and

- Allowing for portable x-ray services to be ordered in writing, by telephone, or by electronic methods, streamlining the ordering process.

Religious Nonmedical Health Care Institutions (RNHCIs)

Since RNHCIs provide health care furnished under religious tenets that prohibit medical care, we have reduced burden by not requiring them to prepare discharge instructions to a medical facility. We are allowing a more condensed and flexible discharge process by requiring RNHCIs only to provide discharge instructions to the patient and/or the patient's caregiver when the patient is discharged home.

Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care, published June 16, 2016.

CMS is finalizing several of the proposed changes in order to modernize the hospital and CAH requirements, improve quality of care, and support HHS and CMS priorities. CMS believes that benefits of these finalized requirements will include: reduced incidence of hospital-acquired conditions (HACs), including reduced incidence of healthcare-associated infections (HAIs); reduced inappropriate antibiotic use; a proactive approach to quality assessment and performance improvement in CAHs; potential cost savings for some hospitals, CAHs, and insurers; and strengthened patient protections overall. We estimate an annual cost of approximately $98 million. The benefits of these finalized requirements will include:

- Changing the term "Licensed Independent Practitioner" in the hospital Patient's Rights CoP to "Licensed Practitioner." This revision reflects our goal of allowing healthcare

professionals, such nurse practitioners and physician assistants, to care for patients to the full extent of their licenses and scopes of practice as well as allowing hospitals to more effectively utilize these highly trained and effective clinical professionals.to fully benefit patients. By making this change, we will reduce regulatory burden for hospitals and remove the unnecessary obstacles that prevent nurse practitioners, physician assistants, and other qualified advanced practice providers from effectively working to the highest level of their training and education;

- Updating the hospital CoPs to specify that hospital QAPI programs must incorporate existing quality indicator data, including patient care data submitted to, or received from, quality reporting and quality performance programs. This requirement gives hospitals increased flexibility, while continuing to promote patient safety and quality of care;

- Clarifying requirements for nursing services that have been ambiguous or confusing due to unnecessary distinctions between hospital inpatient and outpatient services. This change will add flexibility to account for the variety of ways through which a hospital might meet its nurse staffing requirements;

- Updating hospital requirements for infection prevention and control programs, which do not fully conform to current standards of practice for the surveillance, prevention, and control of HAIs and other infectious diseases, and also requiring that hospital programs demonstrate adherence to nationally recognized infection prevention and control guidelines for reducing the transmission of infections within their hospitals;

- Requiring hospitals to establish and maintain antibiotic stewardship programs to help reduce inappropriate antibiotic use and antimicrobial resistance. By requiring that hospitals have antibiotic stewardship programs that are not only active and hospital-wide, but also demonstrate adherence to nationally recognized guidelines for the optimization of antibiotic use through stewardship, the changes are aimed at effectively reducing the development and transmission of HAIs and antibiotic-resistant organisms that ultimately will greatly improve the care and safety of patients while adding cost benefits for hospitals;

- Adding flexibility to the hospital CoPs by specifying that a unified and integrated infection prevention and control program may also include a unified and integrated antibiotic stewardship program for a multi-hospital system;

- Allowing registered dietitians in CAHs to order therapeutic diets for patients in accordance with State scope-of-practice laws to allow for flexibility and to produce savings in this area;

- Requiring CAHs to have infection prevention and control and antibiotic stewardship programs similar to those being finalized for hospitals; and
- Requiring CAHs to develop, implement, and maintain proactive QAPI programs. This requirement replaces the current reactive annual evaluation requirement and provides greater flexibility for improving health care.

Fire Safety Requirements for Certain Dialysis Facilities, published November 4, 2016.

We are updating requirements for certain higher-risk dialysis facilities from the 2000 edition of the fire safety code to the 2012 edition of the fire safety code. This change aligns with state requirements and with the requirements for all other facility types. It also removes an existing obsolete requirement for facilities to comply with the 2000 edition of the fire safety code. There is no additional burden for these facilities as all states have adopted the 2012 edition of the NFPA 101 and 99. CMS is finalizing this rule as proposed. Specifically, CMS is finalizing as proposed the adoption of the 2012 editions of the NFPA 101 and 99 for dialysis facilities that do not provide one or more exits to the outside at grade level from the treatment area level.

The final rule was published in the *Federal Register* on September 30, 2019. The Rule went into effect on November 29, 2019