September 4, 2012

Marilyn Tavenner, Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
200 Independence Avenue, SW, Room 314-G
Washington, DC 20201

Dear Administrator Tavenner:

The American Health Care Association (AHCA) appreciates the opportunity to comment on Updating Existing Standards for E-prescribing under Medicare Part D and Lifting the LTC Exemption (Section III.M) of the Centers for Medicare & Medicaid Services (CMS) proposed rule, Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, DME Face-to-Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013 (77 Federal Register, 45011).

AHCA’s mission is to improve lives by delivering solution for quality care. As the nation’s leading long term care organization, AHCA and our membership of more than 11,000 non-profit and for-profit facilities are dedicated to continuous improvement in the delivery of professional and compassionate care provided daily by millions of caring employees to more than 1.5 million of our nation’s frail and elderly as well as people with disabilities who live in nursing facilities, assisted living residences, sub-acute centers, and homes for persons with developmental disabilities.

On July 6, 2012, CMS issued a proposed rule that would establish new policies and payment rates for physicians and other providers who are paid under the Medicare physician fee schedule. Included in the Medicare Physician Fee Schedule Notice of Proposed Rule Making (NPRM) is a provision that proposes to adopt National Council for Prescription Drug Programs (NCPDP) SCRIPT 10.6 as the official Part D e-prescribing standard, adopt NCPDP formulary and benefit standard 3.0, and eliminate the exemption from the requirement to use the NCPDP SCRIPT standard in transmitting prescription and prescription-related information for non-prescribing long-term and post-acute care (LTPAC) providers.

As described in more detail below, AHCA supports the retirement of NCPDP SCRIPT 8.1 on October 31, 2013 and the adoption of NCPDP SCRIPT 10.6 as the official Part D e-prescribing standard effective November 1, 2013. AHCA further supports the adoption of NCPDP SCRIPT 10.6 as the official Part D e-prescribing standard in LTPAC settings, but recommends that the lifting of the LTPAC exemption be delayed by an additional year to November 1, 2014 to allow sufficient time for LTPAC vendors to modify the necessary software, for LTPAC providers to upgrade their systems to implement the NCPDP SCRIPT 10.6 standard, and for state Boards of Pharmacy and Drug Enforcement Administration (DEA) related regulatory issues to be overcome.

As the nation’s largest association of long term and post-acute care providers, the American Health Care Association (AHCA) advocates for quality care and services for frail, elderly and disabled Americans. Compassionate and caring employees provide essential care to one million individuals in our 11,000 not-for-profit and proprietary member facilities.
LTPAC and Medication Management Complexities

As CMS knows, LTPAC facilities bear the primary responsibility for safe and effective drug distribution to their patients. The core mandate is that “Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental and psychological well-being in accordance with the comprehensive assessment and plan of care” (42 CFR 483.25). Furthermore, “[a] drug whether prescribed on a routine, emergency, or as needed, basis must be provided in a timely manner. If failure to provide a prescribed drug in a timely manner causes the resident discomfort or endangers his or her health and safety, then this requirement is not met” (42 CFR 383.60 and 483.75(h)). In addition, as a vital part of the quality of care requirements, the facility must ensure that it is free of medication error rates of 5 percent or greater; and residents are free of any significant medication errors (42 CFR 483.25(m)).

Taken together, these regulatory mandates place the ultimate responsibility for safe and effective medication distribution within the LTPAC facility. A critical aspect of this responsibility is having the information necessary in the medical record of the patient in the LTPAC facility to provide quality, effective, and efficient care. Thus, a key operative concept in designing an operative LTPAC medication management and e-prescribing system is to acknowledge the responsibilities and information needs of the LTPAC facility, the role, responsibility and requirements of physicians, pharmacists and facility staff, and the key role of LTPAC facility staff in providing quality care. Irrespective of how streamlined medication management and e-prescribing may become, the LTPAC facility stands at the heart of any medication management process for LTPAC patients.

Medication management in a LTPAC facility is a complex process. It involves direct communication between LTPAC nursing staff and the physician, between LTPAC nursing staff and the pharmacy, and often between the physician and the pharmacy directly of which the LTPAC nursing staff need to be aware. In addition to communicating new prescriptions orders, these three members of the LTPAC medication management team also need to communicate to inform each other of order changes, cancellations, dispensation details, medication resupply, and changes in clinical and administrative patient information.

Given the complexity, electronic medication management in LTPAC is still in its infancy. A LTPAC electronic medication management system however should facilitate and support the ability of the LTPAC facility to provide the highest quality of care for its residents and meet all of the mandates of law and regulation pertaining to the provision of pharmacy services. As CMS moves forward with implementing e-prescribing standards and considers lifting the LTPAC exemption, it is essential that the proper framework be designed and developed for electronic medication management and more broadly all medication management for LTPAC patients.
E-Prescribing Standards and NCPDP SCRIPT 10.6

A robust health information technology (HIT) system that supports improved care coordination and decision making will be critical to achieving the CMS Triple Aim of better health, better care, at reduced cost. Irrespective of whether the components for improved information flow include health information exchanges (HIEs), electronic health records (EHRs), direct messaging, among others, the transfer of information across settings require a clear system of standards.

As CMS notes in the proposed rule and as AHCA has commented on previously, previous e-prescribing standards such as NCPDP SCRIPT 5.0 and SCRIPT 8.1 were inadequate to support workflows and legal responsibilities of LTPAC providers. As such, CMS provided an exemption from the requirement to use the adopted NCPDP SCRIPT standard in transmitting prescription or prescription related information in LTPAC settings, and noted that it would consider removing the LTPAC exemption “when there was an NCPDP SCRIPT standard that could address the unique needs of long-term care settings.” As illustrated by testimony to the National Committee on Vital and Health Statistics that CMS notes in the proposed rule, a consensus among pharmacies, providers, and vendors is forming that LTPAC facilities could carry out e-prescribing using NCPDP SCRIPT 10.6 if it were adopted as the official Part D e-prescribing standard.

AHCA agrees. NCPDP SCRIPT 10.6 is an evolutionary backward compatible e-prescribing standard that largely addresses the needs of LTPAC and will help to reduce complexities and remove barriers to electronic medication management and perhaps at some point e-prescribing in LTPAC settings.

More Effective and Efficient Medication Management: Beyond E-Prescribing Standards

AHCA is pleased that CMS is not mandating e-prescribing. While technology standards for electronic medication management have largely caught up, LTPAC is not ready for e-prescribing. Complexities in medication management notwithstanding, most state Boards of Pharmacy do not consider a prescription from a facility to be a valid prescription. Furthermore, the DEA imposes additional conditions and requirements for prescriptions of controlled substance medications. Given these two major issues, the time is not ripe for widespread adoption of electronic medication management in LTPAC settings.

AHCA is however confident that stakeholders could utilize electronic standards and devise a solution to these issues. AHCA calls on CMS to encourage state Boards of Pharmacy to reexamine the medication management process in LTPAC settings and develop and allow more effective and efficient mechanisms for e-prescribing in LTPAC. If the e-prescribing system could be suitably, sufficiently and appropriately modified, such that state Boards of Pharmacy were to consider a physician’s order from a facility as a valid prescription, the conditions would be in place for electronic medication management and e-prescribing to be more widely adopted in LTPAC settings. AHCA
recognizes that these are complex issues. We ask CMS to facilitate, encourage and work with regulators, industry and other stakeholders to resolve these issues.

Extension of LTPAC Exemption Needed

In the proposed rule, CMS requests comments on lifting the LTPAC exemption effective November 1, 2013 in conjunction with the effective date of NCPDP SCRIPT 10.6 adoption. While AHCA is supportive of the adoption of NCPDP SCRIPT 10.6 on November 1, 2013, the proposed lifting of the LTPAC exemption on November 1, 2013 is premature.

In reaching out to our provider members and in discussions with other stakeholders (i.e. pharmacies, vendors, etc), the consensus is that additional time will be needed to transition to the new standard. Most vendors of LTPAC facility-based systems have not utilized NCPDP SCRIPT. These vendors will need to replace their current HL7 or proprietary system with the new NCPDP SCRIPT 10.6 standard. This reengineering and testing of software interfaces is not trivial and will take time. The proposed implementation date does not offer sufficient time to allow vendors to practically update their systems.

Further, given the low level of adoption among LTPAC providers, considerable and significant investments will need to be made to introduce electronic medication management with the new standards into facilities. This includes not only costs for infrastructure, software upgrades and maintenance, but also additional costs related to training nursing staff to understand and utilize the new systems.

Given these software development and infrastructural and staff related cost issues, AHCA recommends that the LTPAC exemption be continued until November 1, 2014. The extra year would also allow for additional time to resolve these various complex issues that are impeding electronic medication management adoption in LTPAC.

Electronic Medication Management and Meaningful Use in LTPAC

As CMS begins work on Stage 3 of Meaningful Use, AHCA trusts that CMS is exploring including LTPAC into Meaningful Use criteria and assistance initiatives. Given issues with state Boards of Pharmacy’s reluctance to consider a prescription from a facility to be a valid prescription, e-prescribing will not be meaningful criteria for evaluating and supporting health information technology adoption in LTPAC. Rather than e-prescribing, AHCA encourages CMS to explore electronic receipt of prescription information from the pharmacy or the electronic exchange of non-prescription related medication ordering and other medication management related information between the LTPAC facility and pharmacy as possible Stage 3 Meaningful Use criteria for LTPAC. CMS may also wish to explore and encourage utilization of duplicate messaging (between physician and pharmacy directly, as well as via the LTPAC facility) as an interim step until LTPAC can
accept information that meets state Boards of Pharmacy and DEA prescription requirements and pharmacy needs, and so that physicians can meet their Stage 1 Meaningful Use requirements.

Conclusion

AHCA is supportive of the adoption and utilization of health information technology to achieve the CMS triple aim – better health, better care, at reduced cost. The utilization of HIT such as e-prescribing offers the opportunity for improved information exchange and care coordination needed to achieve the triple aim. Standards, like the proposed NDPCP SCRIPT 10.6 Part D e-prescribing standards, are a critical requirement for the transfer of information to improve the quality of care and patient outcomes. While e-prescribing offers the opportunity for improved medication management, it will not be widely adopted in LTPAC settings until state pharmacy boards and the DEA reexamine the medication management process in LTPAC settings and develop and allow more effective and efficient mechanisms to e-prescribing in LTPAC. Lastly, AHCA recommends that CMS hold off elimination of the exemption for non-prescribing LTPAC providers to November 1, 2014 to allow sufficient time for vendors to upgrade software, for LTPAC providers to allocate resources needed to upgrade infrastructure and software and train nursing staff on the NDPCP SCRIPT 10.6 standard, and to provide time for state Boards of Pharmacy, the DEA, CMS, and LTPAC stakeholders to resolve the regulatory issues that are impeding the adoption of electronic medication management and e-prescribing solutions in LTPAC.

Thank you for providing stakeholders such as AHCA the opportunity to comment on updating existing standards for e-prescribing under Medicare Part D and the lifting of the LTPAC exemption. Our recommendations in brief are listed below. AHCA is ready and willing to assist CMS in moving e-prescribing and State 3 Meaningful Use supported HIT-facilitated medication management in LTPAC to the next level. Please do not hesitate to call on AHCA for assistance.

Sincerely,

Peter Gruhn
Director of Research
AHCA Recommendations in Brief

- AHCA supports the move to a single standard for the exchange of prescriptions between physicians, providers, and pharmacies in the LTPAC setting.

- AHCA supports the adoption of NDPCP SCRIPT 10.6 as the official Part D e-prescribing standard.

- AHCA supports the implementation of NDPCP SCRIPT 10.6 on November 1, 2013.

- AHCA calls on CMS to encourage state Boards of Pharmacy and the DEA to reexamine the medication management process in LTPAC settings and develop and allow more effective and efficient mechanisms to facilitate physician to provider to pharmacist e-prescribing in LTPAC.

- AHCA opposes the elimination of the exemption for non-prescribing LTPAC providers on November 1, 2013.

- AHCA recommends that CMS hold off elimination of the exemption for non-prescribing LTPAC provider until November 1, 2014 to allow sufficient time for LTPAC provider vendors to develop and upgrade software, for LTPAC providers to allocate resources needed to upgrade infrastructure and software and train nursing staff on the NDPCP SCRIPT 10.6 standard, and to provide time for state Boards of Pharmacy, the DEA, CMS, and LTPAC stakeholders to resolve the regulatory issues that are impeding the adoption of electronic medication management and e-prescribing solutions in LTPAC.