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Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-0011-P
P.O. Box 8014
Baltimore, MD 21244-8014

The American Society of Consultant Pharmacists is pleased to offer comments on the proposed rule for electronic prescribing to be implemented as a part of the Medicare Part D program.

The American Society of Consultant Pharmacists (ASCP) is the international professional association that provides leadership, education, advocacy, and resources to advance the practice of senior care pharmacy. Consultant pharmacists specializing in senior care pharmacy practice are essential participants in the health care system, recognized and valued for the practice of pharmaceutical care for the senior population and people with chronic illnesses. In their role as medication experts, consultant pharmacists take responsibility for their patients' medication-related needs; ensure that their patients' medications are the most appropriate, the most effective, the safest possible, and are used correctly; and identify, resolve, and prevent medication-related problems that may interfere with the goals of therapy.

ASCP's 6,500+ members manage and improve drug therapy and improve the quality of life of geriatric patients and other individuals residing in a variety of environments, including nursing facilities, subacute care and assisted living facilities, psychiatric hospitals, hospice programs, and home and community-based care.

I. Background

A. Statutory Basis

2. State Preemption

The proposed interpretation of Section 1860D-4(e)(5) of the Act is unnecessarily narrow and, by creating a scheme that applies only to Medicare-covered prescriptions as an overlay on the current 50-state scheme for regulating electronic prescribing, will severely undermine the success of the electronic prescribing program envisioned by the Act. Without creating a clearer, more predictable national scheme, physicians and pharmacists will be uncertain as to their obligations, which will impact their willingness to participate in electronic prescribing.

The interpretation proposed in the NPRM creates a system whereby the prescriber and the electronic software vendor with which the prescriber is affiliated must answer coverage questions before knowing whether to apply the standards promulgated under the Act - questions which are not currently answered by the prescriber and for which there are no processes in place to answer. "Standards" for electronic prescribing are meaningless if they only apply to a subset of prescriptions for any given drug and will be extremely difficult to put into practice if applying them requires information at the point of prescribing, which is not available in the current system.

Creating a single, national, comprehensive set of regulations applicable to all electronic prescriptions would provide a clear path for all prescribers seeking to participate in electronic prescribing while eliminating the risks inherent in having a wide variety of federal and state laws affecting electronic prescriptions.

In the long-term care setting, the numerous changes in residents' level of care illustrates the need for the e-prescribing model to be available for prescriptions covered by all payment types - not just Medicare Part D. For example, a nursing facility resident who has Part D benefits might be hospitalized, return to the facility under Medicare Part A, and revert to Part D after their Medicare Part A benefits conclude. Without consistent, overarching e-prescribing standards, using electronic prescribing while maneuvering through the frequent pay status changes would be overwhelmingly burdensome to the pharmacy, facility staff and prescribers.

In addition, for e-prescribing to work in the long-term care setting, the state and federal survey processes must accept electronic records and electronic signatures. Since state survey agencies within the Department of Health usually conduct both state and CMS surveys, these agencies and their surveyors will need to become educated in accessing electronic prescription information. Regulations and guidelines might also need to be revised to accommodate current and emerging electronic processes.

These proposed rules also do not address the fact that the Drug Enforcement Agency (DEA) has not adopted e-prescribing regulations for controlled substances. There are numerous different state-specific regulations pertaining to the record keeping of controlled substance prescriptions and these state-specific regulations are even more unique for long-term care pharmacies and facilities.

D. Current Prescribing Environment

The current prescribing process environment outlined in the proposed rule focuses primarily on the ambulatory setting (e.g., community-dwelling beneficiaries, retail pharmacies and prescribers' offices). The Part D program is indeed an outpatient benefit, but residents residing in skilled nursing facilities and assisted living facilities are considered "outpatients," despite the location of their residence. Many of these residents, actually the majority, will qualify and receive Medicare Part D benefits. Residents in long-term care facilities are among the frailest elderly largely because of their numerous comorbidities. In 2000, a national survey of nursing facilities found that the average nursing facility resident took 8.1 routine medications, and 41.1% took nine or more routine medications.¹

These long-term care settings have a different prescribing process involving more entities than the typical two parties (pharmacy and prescriber) seen in the ambulatory environment. In fact, there are at least three parties involved in the medication use process in nursing facilities and assisted living facilities:

- Nursing facility staff
- Dispensing pharmacy (or pharmacies)
- Prescriber

Currently in these long-term care settings, the prescribing process can be summarized in the following steps:

1. The facility nurse usually performs the initial assessment of the resident upon onset of a new symptom(s), unless the prescriber happens to be visiting the facility at that time. According to the nursing facility regulations found in the State Operations Manual at Tag F-387, "*A physician must see the resident at least once every 30 days for the first 90 days after admission and at least once every 60 days thereafter.*"
2. The nurse contacts the prescriber, whose office is offsite, for appropriate treatment options and subsequent orders. Whether the nurse or prescriber initiates assessment, the prescriber ultimately utilizes resident-specific information from the medical chart, which is housed at the facility – not the prescriber's office. Reviewed information includes current medications, medication history, demographics (e.g., weight, height, age), drug allergies and concurrent diagnoses and/or symptoms.

¹ Tobias DE, Sey M. General and psychotherapeutic medication use in 328 facilities: a year 2000 national survey. *Consult Pharm* 2001;16:54.

3. Orders (prescriptions) are usually received in a verbal or faxed format.
4. The nurse enters this order into the resident's medical chart.
5. The nurse then faxes or phones in the prescriber's order to the dispensing pharmacy chosen by that facility/resident.
6. The dispensing pharmacist conducts a prospective medication review by examining potential drug allergy conflicts, drug-drug and other interactions, and other potential medication-related problems. The pharmacy fills the prescription using the NCPDP Telecommunication 5.1 Standard for claim submission. Messages received pertaining to third party coverage, such as formulary information or prior authorization, are considered by the pharmacy and communicated to the facility and prescriber by phone or fax for resolution. Documentation necessary to fulfill these coverage requirements is usually provided by the facility staff, since they have primary access to the resident's medical chart. Although, prescribers and pharmacy staff are also involved in the process.
7. The dispensing pharmacy delivers the medication to the facility where the nurse accepts and notates receipt of the medication. Nursing facilities are required by federal regulation to provide prescribed medications to residents in a "timely manner." Regulations located at Tag F-425 of the State Operations Manual from the Centers for Medicare and Medicaid Services states, "*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.*"
8. Prescription renewal is documented by the physician when he/she signs each resident's current orders during the recapitulation process, usually occurring every 30 days. For medications warranting refills, this need is either communicated to the pharmacy by the facility or it is automatically refilled by the pharmacy based on the days supply of the dispensed medication.

E. Current E-Prescribing Environment

The current e-prescribing environment is virtually non-existent in the long-term care industry due to many of the same barriers outlined in the NPRM, including the costs of buying and installing a system, training involved, time and workflow impact, lack of reimbursement for costs and resources, and lack of knowledge about the benefits. However, the distinct difference in the long-term care setting is that all of these potential barriers apply not only to prescribers and pharmacies, but also the nursing facilities. To reiterate the current prescribing environment in long-term care, there are at least three parties involved rather than the two parties currently involved in the ambulatory setting,

While pharmacies rely heavily on computer technology and some are already capable of utilizing e-prescribing due to their use of NCPDP communication standards, many nursing facilities have yet to adopt technology on a large scale other than the one or two computers in their administrative and billing offices. Computer access at nurses' stations is quite limited. In fact, most long-term care facilities still utilize manual charting processes. Therefore, introducing e-prescribing into the long-term care setting will be a challenge. Nonetheless, the closed system created by the nursing facility and limited number of prescribers and pharmacies provides an atmosphere that would enable long-term care to be a leader in e-prescribing if the stated barriers are overcome.

NCPDP, at the request of industry participants, has created a new work group to address these special needs of the long-term care industry. NCPDP Work Group 14 for Long Term Care, in conjunction with the other NCPDP Work Groups, will:

- Guide and advise payers and providers of the long term care industry and institutional pharmacy programs and their agents on standards implementation,
- Support data processing initiatives, and
- Provide design alternatives for standards used within the long-term care industry.

It is expected that long-term care participants will be bringing standards requirements forward through NCPDP for the electronic prescribing environment, as their workflow and needs are different than community pharmacy. Some of these unique needs include the following:

1. The billing offices of the pharmacy and nursing facility communicate residents' billing status to one another, which can change according to the level of care deemed necessary by a resident's medical condition. Because these billing changes can directly impact the resident's prescription benefit, including eligibility and co-insurance, real-time eligibility information must be communicated electronically from the facility to the pharmacy, prescriber, and the PDP to facilitate the formulary and prior authorization processes. Including this specification in the e-prescribing process will allow coordination of benefits (COB). As outlined previously, there is an increased need for process adaptations and communication between health care professionals in long-term care to assure nursing facilities meet the required federal regulation to provide prescribed medications to nursing home residents in a "timely manner".
2. In the long-term care setting, prescribers and facility nurses often do not know a resident's pharmacy benefit eligibility and coverage, making prior authorization and formulary processes more difficult and time-consuming. The industry has relied on the long-term care pharmacy provider to obtain and provide this information. If this information were made available to prescribers and facility staff at the time of prescribing, much time would be saved by all parties.

3. Medical records for nursing facility residents are located at the nursing facility, not in the physician's office. This causes difficulty when resident information housed in the medical chart is needed by the prescriber or pharmacy. Currently, the information gathering process is often left up to the facility staff.

For these reasons, an electronic health record (EHR) is ultimately needed for e-prescribing to work most efficiently in the long-term care setting.

F. Evolution and Implementation of an Electronic Prescription Drug Program

As a participant of the National Council for Prescription Drug Programs (NCPDP), ASCP appreciates CMS acknowledging NCPDP SCRIPT Standard Version 5.0 as a minimum standard for electronic prescribing programs. It is important to reiterate that this standard is a minimum or a "floor" from which to grow in the future. By naming this standard as the minimum, industry is provided a "floor" that it can support in a timely manner. We feel that this will ensure adoption of electronic prescribing without stifling industry movement to future versions, as business needs arise.

ASCP is in agreement with an NCPDP proposal whereby newer versions are adopted and older versions are retired to allow maximum flexibility for the industry as it upgrades systems. It is important not to negatively impact the long-term care setting by naming an e-prescribing version that the industry is not able to support.

It is expected that long-term care participants of the NCPDP Work Group 14 will be bringing recommendations specific to long-term care to NCPDP for the development of future electronic prescribing standards.

G. Electronic Prescription Drug Program **- Formulary and Medication History Standards**

As stated above, currently the billing offices of the pharmacy and nursing facility communicate billing status to one another, which can change according to the level of care deemed necessary by the resident's medical condition. Because these billing changes can directly impact the resident's prescription benefit, including eligibility and co-insurance, real-time eligibility information must be communicated electronically from the facility to the pharmacy, prescriber, and the PDP to facilitate the formulary and prior authorization processes. Including this specification in the e-prescribing process will allow COB and the timely delivery of medications to facility residents. To our knowledge, no current formulary and benefit data standards accommodate these specific needs.

- Drug Information

Research suggests that significant inconsistencies exist in the creation of drug information databases utilized in health care software. In addition, the assignment of clinical significance to drug interactions and other drug information is critical to the acceptance and accurate utilization of such facts by health professionals.

In response to the overwhelming number of complaints and errors associated with the multitude of drug information messages in software programs, the United States Pharmacopeia Therapeutic Decisions Making (DTM) Expert Committee formulated a methodology to establish a hierarchy of evidence that defines drug-drug interactions and decides what types of evidence to consider with regard to such interactions. USP and other pharmacy associations have been working with a contracted research team to apply and assess this evidence methodology. In addition, the USP Convention recently passed a resolution pertaining to this issue:

“Evidence-Based Methodologies and Algorithms for Decision Support Used in E-Prescribing and Pharmacy Computer Systems” – USP resolves to work with appropriate stakeholders to continue developing evidence-based methodologies and algorithms for decision support in areas such as drug-drug interactions, and to expand efforts to other alerts and recommendations for use in e-prescribing technologies and pharmacy computer systems. Furthermore, USP resolves to explore the feasibility and advisability of extending this approach to other information domains in the interest of the public health and patient care.”

For these reasons, we recommend that any drug information standards developed as a part of the Medicare Part D electronic prescribing program include mandates for evaluating the evidence base, clinical significance, and accuracy of such information. As learned from past experience, an overload of information to providers does not always result in the provision of efficient and effective health care.

H. Summary of Status of Standards for an Electronic Prescription Drug Program

For electronic prescribing to work in the LTC setting, technology needs to be developed for a three-way communication between off-site physicians, nursing facilities, and long-term care provider pharmacies. Standards for these communications have yet to be developed and utilized. Since pilot testing is proposed in the NPRM to identify and test standards without adequate industry experience, ASCP requests that future pilot testing include the long-term care industry. Including long-term care providers in these pilot projects will help to

identify and define the industry's unique needs and work to promote adoption of electronic prescribing in this setting.

II. Provisions of the Proposed Regulation

B. Proposed Definitions

As mentioned previously, effective electronic prescribing in the long-term care setting must include communication with the nursing facilities where beneficiaries reside. For this reason, we recommend amending the definition of "E-prescribing" to state:

E-prescribing means the transmission, using electronic media, of a prescription or prescription-related information, between a prescriber, dispenser, *nursing facility*, PBM, or health plan, either directly or through an intermediary, including an e-prescribing network.

E-prescribing transactions are defined as "EDI" (Electronic Data Interchange) messages flowing between healthcare providers of prescription or prescription-related information. This definition involves electronic transmission through mechanisms such as the Internet, Extranet, leased lines, dialup lines, private networks, and physical movement of data from one location to another. However, messages that leave or enter a system as an image (e.g. fax or emails) are **not** electronic prescriptions. While it is understood that fax and handwritten prescriptions will continue, these are not e-prescribing EDI transactions. Therefore, we recommend inclusion of a definition for "Non-EDI Messages" to read as follows:

Non-EDI message means a message that leaves or enters a system (including long-term care facilities and/or pharmacies) as an image, either via fax or email, that are not included in the electronic prescribing standards. This does NOT include handwritten prescriptions that are faxed, but does include legal, electronic prescriptions/orders that are formatted to be electronically received by a fax machine. Due to the nature of such an electronic prescription/order, the prescriber's express authorization and credentials have already been validated and documented prior to transmittal.

IV. Regulatory Impact Analysis

A. Overall Impact

In the March 9, 2005 issue of the *Journal of the American Medical Association*, three articles explored the challenges and benefits of computerized physician order entry (CPOE) systems and clinical decision support systems. It can be easily assumed that these study results will compare with the potential

challenges and benefits resulting from electronic prescribing as envisioned by the Medicare Modernization Act. Researchers found, when widely implemented, a CPOE system “facilitated 22 types of medication error risks.” Examples of these errors included:

- Fragmented CPOE displays that prevent a coherent view of patients’ medications
- Pharmacy inventory displays mistaken for dosage guidelines
- Ignored antibiotic renewal notices placed on paper charts rather than in the CPOE system
- Separation of functions that facilitate double dosing and incompatible orders
- Inflexible ordering formats generating wrong orders

Researchers found that 75% of staff reported observing each of these error risks, indicating that they occur weekly or more often.

Based on this evidence-based information, it is reasonable to assume that electronic prescribing will cause or potentate new errors while reducing “traditional” medication errors (e.g., those resulting from poor handwriting). These new types of errors will need to be expected and proactively prevented, to the extent possible. It is important to ensure those participating in electronic prescribing programs are aware of the patient safety benefits of such technology while remembering to watch out for new errors that might come forth.

B. Impact on Health Plans/PBMs

The NPRM proposes that “health plans have a substantial incentive to subsidize the cost of physicians’ adoption of e-prescribing because the plans would share in the likely savings in health care spending through reductions in adverse events and improved compliance.” To reduce potential confusion, it is important to differentiate health plans from PDPs. Consequences of medication-related problems (e.g., adverse events) resulting in physicians’ visits, emergency room visits, and hospitalizations are not paid for by the PDP, but are instead paid for by the patient’s medical insurance or general health plan. To maximize profits, PDPs will be motivated to decrease both the costs (per prescription) and usage (number of prescriptions) of medications. Based on this theory, PDPs will not be motivated to improve patients’ compliance with their medication regimens. In fact, the opposite (non-compliance) is financially beneficial to the PDP. Therefore, to minimize misinterpretation, additional language is recommended to clarify the use of the term “health plan.”

C. Impact on Prescribers

If e-prescribing in the long-term care setting is inconsistent with e-prescribing processes in the community, this could add an unnecessary strain to a

prescribers' practices if they serve both ambulatory and nursing home patients. Prescribers who adopt e-prescribing in their community practice may choose not to work in the long-term care setting unless a similar process is utilized in the nursing facility. It is already difficult for some rural nursing facilities to attract or keep prescribers who are willing to provide services to their residents due to time constraints, liability issues, regulatory requirements, and lack of reimbursement. Compounding these existing issues with e-prescribing inconsistencies could potentially impact the willingness of prescribers to practice in the long-term care setting.

F. Impact on others

The overall impact of electronic prescribing on long-term care nursing facilities and the pharmacies and prescribers serving those nursing facilities is not addressed in the NPRM.

- In the long-term care setting, there is a need to develop technology for a three-way communication between off-site prescribers, long-term care provider pharmacies, and nursing facilities.
- The long-term care setting requires a more complex process utilizing a three-way communication for an e-prescribing model to be successful. For this reason, PDPs, long-term care pharmacies, prescribers, and nursing facilities may incur additional costs beyond those incurred in the ambulatory setting.
- In the nursing facility, there needs to be incentives for the training of nursing staff, which frequently turn over, and the purchase of computers. Most nursing facilities currently have very few computer workstations and still use a manual charting process.
- As discussed previously in the "Impact on Prescribers" section, prescribers who serve both ambulatory and nursing facility patients might be unduly strained if the long-term care setting is excluded from a standardized e-prescribing process.

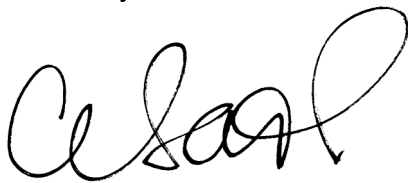
I. Conclusion and Alternatives Considered

In this document, we have identified reasons why the long-term care setting differs from the ambulatory or community setting. For electronic prescribing to work in the LTC setting, technology needs to be developed for a three-way communication between off-site physicians, nursing facilities, and long-term care provider pharmacies. Standards for these communications have yet to be developed and utilized. Since pilot testing is proposed in the NPRM to identify and test standards without adequate industry experience, ASCP requests that future pilot testing include the long-term care industry. We request that CMS prioritize the need for information pertaining to the long-term care industry information as it pertains to electronic prescribing and consider pilot project

proposals from long-term care providers. This will enable identification and definition of the unique needs in this setting. ASCP would be pleased to offer assistance throughout the pilot phase and to provide additional information, as needed, regarding the impact of electronic prescribing in the long-term care setting.

Thank you for your consideration of our comments and suggestions. If you have questions or concerns, you may contact Carla Saxton, Professional Affairs Manager, at the following email address: csaxton@ascp.com, or phone number: (703) 739-1316 ext. 129.

Sincerely,

A handwritten signature in black ink, appearing to read 'Carla Saxton', written in a cursive style.

Carla Saxton, RPh, CGP
Professional Affairs Manager
American Society of Consultant Pharmacists