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

EXECUTIVE SUMMARY

I. Billing for Part B Drugs Administered "Incident to" a Physician's Services

a. Drugs used by a physician to refill any implanted item of DME are within the "incident to" benefit category and not the DME benefit category. The physician must buy and bill for the drug,

b. Only in limited circumstances, for example where a physician's service is not used, the final rule preserves the potential for paying a pharmacy for a drug that is used to refill implanted pumps.

c. Regarding NCPA's comments to the concern of CMS conducting audits and recoupment for past improper billing, the final rule states that CMS does not intend to take enforcement action on pharmacies for incorrect billing of drugs used to refill an implanted item of DME furnished in a physician's office by pharmacies if that incorrect billing stemmed directly from guidance from a Medicare contractor.

d. The final rule prohibits a physician from permissibly reassigning a claim for a drug used to refill an implanted item of DME to a pharmacy supplier.

II. DME Face-to-Face Documentation Requirements

a. Timing

i. The face-to-face requirement is ONLY for new orders. Therefore, covered items ordered on or after July 1, 2013 will require a face-to-face encounter.

ii. NCPA was very concerned that if face-to-face encounters were allowed to occur 30 days after the written order as stated in the proposed rule, patients would not possess their written order when visiting their pharmacies. To address these concerns, CMS removed the option for the face-to-face encounter to occur 30 days after the written order and the timeline has been modified to require that a face-to-face encounter occur within 6 months before the written order.

b. The Written Order Proposal

i. What makes a written order proper under the final rule is important to pharmacists as a written order without the minimum elements would be considered incomplete and would not support a claim for payment.

ii. The final rule eliminates the requirement to include "necessary and proper usage instructions" and the diagnosis from the written order.

iii. The final rule lists the following five elements as the minimum needed for CMS to consider the order valid and supportive of a claim for payment:

1. The beneficiary name;
2. The item of DME ordered;
3. Prescribing practitioner NPI;
4. The signature of the prescribing practitioner; and
5. The date of the order.

c. **Covered Products and Expanding to Additional Products**

i. NCPA was very concerned with the expansion of this face-to-face documentation requirement to additional products and services. To address these concerns, CMS has issued a new list of products. The new list of products can be found starting on page 791 – 797 of the final rule which can be found here: http://www.ofr.gov/OFRUpload/OFRData/2012-26900_PI.pdf

ii. The new list removes items from the covered list of items where regulations explicitly state that a face-to-face encounter is not necessary such as power mobility devices (PMDs).

iii. In addition, the final rule states that CMS "intends to use future rulemaking to determine which prosthetic devices, orthotics, and prosthetics, require, as a condition of payment, a written order before delivery supported by documentation of a face-to-face encounter with the beneficiary."

d. Supplier Notification

i. Regarding supplier notification, NCPA expressed grave concerns with the methods that the proposed rule set forth and stressed that undue burden should not be placed upon pharmacists to obtain this face-to-face documentation.

ii. All documentation to support the appropriateness of the item of DME ordered, including documentation of the face-to-face encounter **must** be available to the supplier.

iii. The pharmacy submitting the claim must maintain access to the written order and supporting documentation relating to written orders for covered items of DME and provide them to CMS upon request.

iv. The final rule does not require a particular method of transmission for supplier notification that the face-to-face encounter has occurred and instead instructs practitioners and suppliers to transmit the required information "through existing business practices."

v. The final rule states that if a pharmacy bills Medicare for one of these covered items, this documentation must be available upon request.

III. Expanding Coverage of Hepatitis B Vaccination and its Administration to Individuals Diagnosed with Diabetes Mellitus

a. NCPA strongly supported the propose rule's efforts to expand coverage for Hepatitis B vaccine and its administration. This would allow community pharmacists to continue to offer a complete spectrum of care to beneficiaries.

b. The final rule with comment expands coverage of Hepatitis B vaccination to individuals diagnosed with diabetes mellitus, not just those individuals with diabetes that are receiving glucose monitoring in facilities, for example, in nursing homes.

IV. Updating Existing Standards for E-prescribing under Medicare Part D and Lifting the LTC

a. The final rule addressed NCPA's concern with the proposed rule and clarifies that while PDP sponsors and MA organizations offering MA prescription drug plans are required to establish electronic prescription drug programs that comply with e-prescribing, there is no requirement that prescribers or dispensers implement e-prescribing.

b. The final rule also retires SCRIPT version 8.1 and adopts SCRIPT 10.6 as the official Part D e-prescribing standard effective November 1, 2013. In terms of eliminating the Long-Term Care e-prescribing exemption, the final rule delays this until November 1, 2014.

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

SUMMARY

I. Billing for Part B Drugs Administered "Incident to" a Physician's Services

NCPA's comments to the Proposed Rule

The proposed rule proposes to clarify payment policies regarding billing for certain drugs under Medicare Part B by stating that CMS considers drugs used by a physician to refill an implantable item of DME to be within the "incident to" benefit category and not the DME benefit category. As such, the proposed rule emphasizes that the physician must buy and bill for the drug, and a nonphysician supplier that has shipped the drug to the physician's office may not do so (except as may be permitted pursuant to a valid reassignment).

NCPA supports this proposal so long as the payment policies are implemented consistently among all suppliers and this clarification does not result in pharmacies facing audits or recoupment of funds from properly following the instructions they were previously given by Medicare contractors. NCPA is very concerned that, while pharmacies were acting in good faith under the instructions that they were given by a CMS' contractor, pharmacies will nevertheless face recoupment for following these instructions. NCPA would strongly oppose any audits or recoupment of funds from pharmacists related to this clarification. In addition, NCPA would like to reiterate the importance of these payment policies being applied consistently among all suppliers.

The Final Rule:

CMS considers drugs used by a physician to refill any implanted item of DME to be within the "incident to" benefit category and not the DME benefit category. Therefore, to bill under the "incident to" benefit, the physician must buy and bill for the drug, and a non-physician supplier that has shipped to the drug to the physician's office may not do so.

The final rule preserves the potential for paying a pharmacy for a drug that is used to refill implanted pumps in certain limited instances where a physician's service is not used. The final rule states that "[a]lthough patients and caregivers do not typically refill implanted pumps, it is our understanding that in rare situations persons other than a physicians could refill the pump, for example, when a patient cannot be transported to a physician's office, but a suitably trained individual is available at the home." In these situations, there is no service incident to a physician's service and the drug is being dispensed directly to the beneficiary in the home for use in an implanted item of DME, and thus the pharmacy may bill and be paid for the drug.

Regarding NCPA's comments to the concern of CMS conducting audits and recoupment for past improper billing, the final rule states, "we do not plan to take enforcement action for incorrect billing of drugs used to refill an implanted item of DME furnished in a physician's office by pharmacies prior to January 1, 2013 if that incorrect billing stemmed directly from guidance from a Medicare contractor.

Regarding **reassignment**, the final rule states "[f]inally, we wish to clarify one other point. In the proposed rule, we stated that in the case of drugs used to refill an implantable item of DME, 'the physician must buy and bill for the drug, and a nonphysician supplier that has shipped the drug to the physician's office may not do so (except as may be permitted pursuant to a valid reassignment).' Our reference to a 'valid reassignment' was intended to refer only to the fact that in certain limited cases, as specified in section 1842(b)(6) of the Act and its implementing regulations, a physician may reassign a claim for Medicare payment. To the extent that our reference to a "valid reassignment" in the proposed rule implied that a physician could permissibly reassign a claim for a drug used to refill an implanted item of DME to a pharmacy supplier, it was in error." Therefore, while the final rule is acknowledging that assignment is a viable option in some situations, the final rule prohibits a physician from permissibly reassigning a claim for a drug used to refill an implanted item of DME to a pharmacy supplier.

II. Durable Medical Equipment Face-to-Face Encounters and Written Orders Prior to Delivery

Section 6407(b) of the Affordable Care Act amended section 1834(a)(11)(B) of the Act and requires for certain items of DME, a physician must document that a physician, a physician assistant, a nurse practitioner, or a clinical nurse specialist has had a face-to-face encounter with the beneficiary pursuant to the written order. Under section 1834(h)(3) of the Act, the items that require a written order verifying a face-to-face encounter may also include prosthetic devices, orthotics, and prosthetics.

NCPA's comments to the Proposed Rule:

The proposed rule provides a list of covered items that will be subject to the face-to-face documentation requirement. Community pharmacists provide many of the items on the list of items subject to the face-to-face requirement, including nebulizers, infusion pumps, home blood glucose monitors and oxygen supplies. The proposed rule states that, for the listed items, a physician must have documented and communicated to the DME supplier that the physician or a PA, a NP, or a CNS has had a face-to-face encounter with the beneficiary no more than 90 days before the order is written or within 30 days after the order is written.

Regarding Supplier Notification - NCPA strongly opposes the fourth option of requiring the physician to provide a copy of the face-to-face documentation to the beneficiary and disagrees with the proposed rule's reasoning that this option would, "ensure that the supplier receives the documentation of face-to- face encounter directly and limits the supplier's need to rely on the PA, NP, or CNS to receive this documentation completed by the physician." Without further clarification, this option places the burden on the pharmacy in a situation where the beneficiary does not bring the documentation of the face-to-face encounter to the pharmacy. Under this option of supplier notification, the pharmacy is placed in the position of refusing to dispense the beneficiary's DME if the beneficiary doesn't provide the documentation. In addition, a scenario could exist whereby the beneficiary may not have the face-to-face documentation available for the supplier upon processing of the order, as their face-to-face encounter occurs AFTER the order has been filled.

Regarding Expanding to Additional Products - The proposed rule provides a list of covered items that will be subject to the face-to-face documentation requirement. Community pharmacists provide many of the items on the list of items subject to the face-to-face requirements including, nebulizers, infusion pumps, home blood glucose monitors and oxygen supplies. NCPA would strongly oppose an expansion

of items that are subject to the face-to-face documentation requirement until CMS provides clear clarification that the burden of obtaining such face-to-face documentation does not fall on community pharmacists.

Regarding Providing Physician's with Additional Pay to Document - NCPA is concerned with CMS' proposal to compensate a physician for the "burden associated with the requirement placed on the physician to document that a face-to-face encounter has occurred between a PA, a NP, or a CNS practitioner." Community pharmacists have undergone countless burdens all the while experiencing drastic cuts within the Part B program. From face-to- face counseling to the medications they dispense, independent community pharmacists play an essential role in improving health care outcomes and decreasing long-term health care costs. As stated above, independent community pharmacists must already comply with multiple criteria in order to participate in Part B including: obtaining expensive DME accreditation; possessing a surety bond; paying to obtain the actual product; complying with extremely burdensome documentation requirements; and working with a secondary payer in order to receive payment.

The Final Rule:

The final rule makes several changes to the requirement in the proposed rule of obtaining documentation for face-to-face encounters. These changes include:

Timing

The final rule states that this face-to-face requirement is ONLY for "new orders," which are those that have been ordered on or after the effective date of the final rule. Therefore, this requirement will only apply prospectively and not retroactively.

The final rule extends the effective date of this requirement to July 1, 2013. Therefore, covered items ordered on or after July 1, 2013 will require a face-to-face encounter.

NCPA was very concerned that if face-to-face encounters were allowed to occur 30 days after the written order, patients would not possess their written order when visiting their pharmacies. As a result, the burden would be on the pharmacist to obtain the written order after already dispensing the product. To address these concerns, the option for the face-to-face encounter to occur 30 days after the written order has been removed. **Thus, the timeline has been modified to require that a face-to-face encounter occur within 6 months (this was 3 months in the proposed rule) before the written order.**

The Written Order Proposal

The proposed rule proposed requirements for "necessary and proper usage instructions" to be included on the written order. What makes and does not make a written order is proper under the final rule is important to pharmacists as a written order without the minimum elements would be considered incomplete and would not support a claim for payment. Thus, it's important for pharmacists to know what must be included on the written order in order for the pharmacists to obtain payment.

The final rule eliminates the requirement to include "necessary and proper usage instructions" and the diagnosis from the written order. Due to the large number of covered DME items and the fact that there could be many diagnoses and usage instructions for each, CMs agreed that these proposed requirements would be overly burdensome. While this information will not be required on the DME order, CMS still

expects to see related diagnoses included in the beneficiary's medical record. In addition, "necessary and proper usage instructions" must be provided to the beneficiary.

The final rule lists the following five elements as the minimum needed for CMS to consider the order valid and thus supportive of a claim for payment:

(1) The beneficiary name;
(2) The item of DME ordered;
(3) Prescribing practitioner NPI;
(4) The signature of the prescribing practitioner; and
(5) The date of the order.

Covered Products and Expanding to Additional Products

NCPA was very concerned with the expansion of this face-to-face documentation requirement to additional products and services. To address these concerns, CMS has issued a new list of products that this requirement will apply to and has asked for comments.

Specified Covered items contains items that meet at least one of the following: (1) items that currently require a written order prior to delivery per instructions in CMS' Program Integrity Manual; (2) items that cost more than $1,000; (3) items that CMS, based on experience and recommendations from the DME MACs, believe are particularly susceptible to FWA; (4) items determined by CMS as vulnerable to FWA based on reports of the HHS OIG or other oversight entities.

The new list removes items from the covered list of items where regulations explicitly state that a face-to-face encounter is not necessary such as power mobility devices (PMDs). The final rule also adds to the list any item of DME that in the future appears on the DMEPOS Fee Schedule with a price ceiling at or greater than $1,000.

The list would be updated annually to add any new items that are described by a HCPCS code for the following types of DME: (1) TENS unit; (2) rollabout chair; (3) manual wheelchair accessories; (4) oxygen and respiratory equipment; (5) hospital beds and accessories; and (6) traction-cervical

In addition, the final rule states that CMS "intends to use future rulemaking to determine which prosthetic devices, orthotics, and prosthetics, require, as a condition of payment, a written order before delivery supported by documentation of a face-to-face encounter with the beneficiary." Thus, CMS is still considering expanding this face-to-face requirement beyond to prosthetic devices, orthotics, and prosthetics.

Physician Documentation

The statute requires that a physician document that the physician or a PA, NP, or CNS has had a face-to-face encounter with the beneficiary. The proposed rule proposed two options for how this could be done.

The final rule adds to this by stating that "the submission of the pertinent portion of the medical record documented by the physician is sufficient to document that the face-to-face encounter has occurred, when the physician conducts the face-to-face encounter." The final rule clarifies that the documentation of a face-to-face encounter must include an evaluation of the beneficiary, needs assessment for the beneficiary, or treatment of the beneficiary for the medical condition that supports the need for each covered item of DME. In addition, pharmacists should note that a written order is still required for these

covered items of DME. **See above for the required information that must be included on a written order in order to submit a claim for payment.**

When a Physician Assistant (PA), Nurse Practitioner (NP), or Clinical Nurse Specialist (CNS) conducts the face-to-face encounter, the final rule requires that the physician document the face-to-face encounter was performed by a NP, PA, or CNS by signing or cosigning the pertinent portion of the medical record indicating the occurrence of a face-to-face encounter for the beneficiary for the date of the face-to-face encounter, thereby documenting that the beneficiary was evaluated or treated for a condition relevant to an item of DME on that date of service.

Supplier Notification

Regarding supplier notification, NCPA expressed grave concerns with the methods that the proposed rule set forth and stressed that undue burden should not be placed upon pharmacists to obtain this face-to-face documentation. NCPA strongly opposed the requirement that the physician provide the documentation to the beneficiary. NCPA stressed that the burden would be on the pharmacist to obtain such documentation from the beneficiary instead of transmitted such documentation from one provider to another. The final rule does not require a particular method of transmission for supplier notification that the face-to-face encounter has occurred. Practitioners and suppliers can communicate the information and requirements through existing business processes for transmitting this information. Pharmacists must note that completion of the face-to-face requirement is a condition of payment and therefore, suppliers must make this documentation available to CMS upon request.

The final rule states that since the supplier submits the claim for the covered items of DME, the supplier **must** have access to the documentation of the face-to-face encounter. All documentation to support the appropriateness of the item of DME ordered, including documentation of the face-to-face encounter **must** be available to the supplier. The pharmacy submitting the claim must maintain access to the written order and supporting documentation relating to written orders for covered items of DME and provide them to CMS upon request.

While the proposed rule set forth four options for comment for the supplier notification of the face-to-face encounter, the final rule does not require a particular method of transmission for supplier notification that the face-to-face encounter has occurred. The final rule states that, "practitioners and suppliers can communicate the information and requirements through existing business processes for transmitting this information." In addition, "CMS will monitor the effects of this provision on beneficiaries' access to medically necessary DME." The final rule does reiterate several times that "this documentation must be made available to supplier to allow them to ensure all requirements are met." Thus, CMS is declining to define how supplier notification must occur and who is responsible for transmitted the written order.

To NCPA's concern that the proposed rules does not make clear that the burden to obtain documentation of face-to-face encounters will not be placed on pharmacies, the final rule states that CMS does not believe that is appropriate to carve out an exception for pharmacies. It goes on to states that if a pharmacy bills Medicare for one of these covered items, that this documentation must be available upon request.

This could be a problem for pharmacists as many different scenarios could arise where the pharmacist would have the burden of obtaining the documentation from either the physician or the beneficiary. For example, as the fourth option in the proposed rule allowed the physician to give the written order to the beneficiary. In this scenario, the pharmacist would bear the burden of obtaining the written order from the beneficiary, who is likely not to bring the written order with

them to the pharmacy. In that instance, the pharmacist would be placed in the position of denying beneficiaries DME supplies. The final rule does note that it removes the ability for the face-to-face encounter to occur 30 days after the written order so that suppliers will have more protection as all documentation will be available at the time of order. However, the final rule also emphasizes that completion of the face-to-face requirement is a condition of payment and could be subject to audit.

Providing Physician's with Additional Pay to Document

The proposed rule proposed giving physician's additional pay in the amount of $15 in order to supplement what CMS said was the additional burden associated with the requirement placed on a physician to document that a face-to-face encounter occurred between a PA, a NP, or a CNS and the beneficiary.

NCPA expressed strong concern that CMS is proposing to grant physicians an additional fee for documenting something that occurred in their own facility while at the same time cutting pharmacists' reimbursement under Part B via competitive bidding and/or inherent reasonableness.

The final rule imposes the new G-code in order to compensate a physician who documented that a PA, NP, or a CNS practitioner has performed a face-to-face encounter for the list of Specified Covered Items.

III. Expanding Coverage of Hepatitis B Vaccination and its Administration to Individuals Diagnosed with Diabetes Mellitus

NCPA's comments to the Proposed Rule

NCPA strongly supports the propose rule's efforts to expand coverage for Hepatitis B vaccine and its administration to all individuals diagnosed with diabetes mellitus, not just those individuals with diabetes that are receiving glucose monitoring in facilities. This would allow community pharmacists to continue to offer a complete spectrum of care to beneficiaries.

Final Rule

The final rule with comment expands coverage of Hepatitis B vaccination to individuals diagnosed with diabetes mellitus, not just those individuals with diabetes that are receiving glucose monitoring in facilities, for example, in nursing homes.

IV. Updating Existing Standards for E-prescribing under Medicare Part D and Lifting the LTC

NCPA's comments to the Proposed Rule

NCPA supported CMS' proposal to retire SCRIPT version 8.1 on October 31, 2013 and adopt SCRIPT version 10.6 as the official Part D e-prescribing standard effective on November 1, 2013. Furthermore, NCPA supported lifting the Long-Term Care exemption. However, NCPA agreed with concerns expressed by NCPDP that the effective date of lifting the Long-Term Care exemption should be set at November 1, 2014, which is one year later than was expressed in the proposed rule. NCPA also reiterated that these provisions in no way mandate e-prescribing.

Final Rule

The final rule addresses NCPA's concerns. It clarifies that while PDP sponsors and MA organizations offering MA prescription drug plans are required to establish electronic prescription drug programs, there is no requirement that prescribers or dispensers implement e-prescribing. The final rule also retires SCRIPT version 8.1 and adopts SCRIPT 10.6 as the official Part D e-prescribing Standard effective November 1, 2013. In terms of eliminating the Long-Term Care e-prescribing exemption, the final rule delays this until November 1, 2014.

V. Care Coordination

NCPA's comments to the Proposed Rule

Under the proposed rule, CMS proposed creating a HCPCS G-Code for all non-face-to-face services related to the transitional care management furnished by the community physician or qualified nonphysician practitioner within 30 calendar days following the date of discharge from an inpatient acute care hospital, psychiatric hospital, long-term care hospital, skilled nursing facility, and inpatient rehabilitation facility; hospital outpatient for observation services or partial hospitalization services, and partial hospitalization program at a CMHC to community-based care. NCPA expressed concern that pharmacies are performing many of these transitions of care related activities and should be compensated for them, specifically medication reconciliation. NCPA asked CMS to allow pharmacies who participate in Part B to bill for transitional care management services that involve medication therapy.

Final Rule

CMS is proceeding with the proposal in a modified form by accepting the recommendation to adopt the AMA's CPT TCM codes in place of the proposed TCM G-code. The final rule will pay for the new CPT TCM codes 99495 and 99496. The AMA's CPT TCM code requires a face-to-face visit within 7 to 14 days of discharge. The final rule does amend a requirement in the AMA's CPT TCM code that requires the physician to have an established relationship with the patient in order to allow a physician to bill these codes for new patients.

The final rule clarifies that CMS believes that NPs, Pas, CNSs, and certified nurse midwives can furnish the full range of E/M services and complete medical management of a patient under their Medicare benefit to the limit of their state scope of practice. The final rule states that "other nonphysician practitioners or limited-licensure practitioners are limited by the scope of their state licensing or their statutory Medicare benefit to furnish comprehensive medical evaluation and management services, and thus there is no Medicare benefit category that allows explicit payment to some of the other health professionals (such as pharmacists and care coordinators) seeking to bill TCM services." As such, the final does not adopt requests of other health care professionals to bill the CPT TCM codes.