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FDA Taking Steps to Promote Generic Drug Competition

By Eileen Koutnik-Fotopoulos

The FDA is taking new steps to promote generic drug competition as part of its ongoing implementation of the Drug Competition Action Plan, according to a statement released by FDA Commissioner Scott Gottlieb, MD, on January 3, 2018. The Drug Competition Action Plan comprises 3 main

Continued on page 8

"Incident to" Billing and Nonphysician Practitioners

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Rheumatologists have been billing under the Centers for Medicare & Medicaid Services (CMS) "incident to" benefit for years; that is how they have been reimbursed for nurse-administrated methotrexate injections, infusion services, and other

Continued on page 5

New Hampshire's Enforcement of USP 797 Pharmacy Standards in the Physician Office

By Brian Nyquist, MPH
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The US Pharmacopeial Convention is an independent, nonprofit organization founded by pharmacists to develop pharmacy standards. US Pharmacopeia (USP) Chapter 797 specifically relates to standards for compounding sterile products. These

Continued on page 6

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"Incident to" Billing and Nonphysician... *Continued from the cover*

physician services personally provided by a clinical staff member. The claim goes out as if the supervising physician personally provided the service, and this is appropriate as the medical assistant or registered nurse is not considered a qualified healthcare professional who can bill on his or her own. As nonphysician practitioners (NPPs), such as physician assistants (PAs) and advanced registered nurse practitioners (ARNPs), have started to work in rheumatology practices with greater frequency, it has become increasingly important to understand "incident to" requirements.

This importance can primarily be attributed to 2 factors. First, the NPP can and must enroll in the Medicare program,[1] and consequently has his or her own Medicare number with which to bill the program directly. Second, the Medicare reimbursement for an NPP is 85% of the physician's payment; therefore, physicians understandably want to bill the NPP's services as incident to their own so as not to lose 15% of their charges. However, if the "incident to" billing requirements are not met or well-documented, the physician could end up in the unpleasant situation of having an overpayment assessed.

"INCIDENT TO" REQUIREMENTS

To qualify as "incident to," services must be part of the patient's normal course of treatment, during which a physician in the practice personally performed an initial service, and remains actively involved in the course of treatment.[2] The physician does not have to be physically present in the patient's treatment room while these services are provided, but must provide direct supervision; that is, a physician in the group must be present in the office suite to render assistance, if necessary. The patient record should document the essential requirements for an "incident to" service, including that the services and supplies are:

- An integral, although incidental, part of the physician's professional services and established treatment plan
- Of a type that are commonly furnished in a physician's office or clinic
- Furnished under the physician's direct personal supervision
- Furnished by an individual who qualifies as an employee (ie, with a W-2 or 1099) of the physician's practice.

If the "incident to" billing requirements are not met or well-documented, the physician could end up in the unpleasant situation of having an overpayment assessed.

THE CONFUSION

Anecdotally, it appears that confusion and misunderstanding as to when it is permissible to bill ARNP or PA services as if the physician personally provided the service stems from the disconnect between the NPP's scope of practice, which may require just general supervision, and that of "incident to" billing, which requires direct supervision (ie, a billing physician in the office suite). It is common for a PA or ARNP to say "When I'm seeing a patient I don't need a physician in the office to supervise me." From their licensure perspective, that is accurate, and CMS would agree, but CMS would also add that, when no physician is in the office suite, the services provided by an NPP must be billed under the NPP's name and National Provider Identifier (NPI).

When CMS says services must be "part of the physician's professional service," that means there must have been a direct, personal, professional service furnished by the physician to initiate the course of treatment—of which the service being performed by the NPP is an incidental part—and that there must be subsequent services by the physician of a frequency that reflects the physician's continuing active participation in, and management of, the course of treatment.[3]

A PA or ARNP can create his or her own plan of treatment, change the dose of a medication started by the physician, order an x-ray, and so forth—however, the moment NPPs make independent treatment decisions, they are no longer just following the physician's plan of treatment, and services must now be billed to Medicare under the NPP's name and NPI.

FINAL THOUGHTS

It must be noted that this article only discusses the CMS requirements for "incident to" billing. As more NPPs begin working in rheumatology practices, it is imperative that other payer policies be checked. Some insurers, such as Florida Blue, do not allow any NPP "incident to" billing. The SA Modifier must be added to Evaluation & Management services on claims provided by an ARNP or PA and billed via the supervising physician to UnitedHealthcare. Physicians billing com-

Continued on page 6

"Incident to" Billing and Nonphysician... *Continued from page 5*

mercial plans must therefore review their provider contracts and health plan rules to determine whether billing the services of one provider under the name and NPI of another is allowed (and if so, under what circumstances).

There is a very real compliance risk if a physician bills under their own NPI as if all "incident to" billing requirements were met when they were not. Although we no longer see a CMS1500 claim form, the physician's signature on a claim still attests that he or she personally provided or personally supervised the services, and that all of the information on the claim is accurate and correct.

In 2017 there were several cases of physicians being charged with false claims. These claims were allegedly submitted to Medicare or other payers with the physician's name and NPI listed as the rendering provider when the services were personally performed by an NPP when the physician was not in the office or had not previously seen the patient, or when the NPP changed the physician's treatment plan. One such example is a family practice physician who paid a fine of $133,880.50 under the Civil Monetary Penalties Law for submitting claims to Medicare for nurse practitioner services as if he had personally performed the services himself, when all of the "incident to" requirements had not been met.

NPPs can be a great asset to rheumatologists; they increase access to care, and allow the rheumatologist to see new patients and provide consultations while the NPP provides routine follow-ups. Just like any other new venture, however, the physician and practice manager must take the time to research the criteria for incorporating NPPs into their practice the right way. In the case of NPPs and "incident to" billing, that means checking state regulations for the scope of practice of ARNPs or PAs, as well as the billing rules for Medicare[4] and other payers. ■

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New Hampshire's Enforcement of USP... *Continued from the cover*

standards are not enforceable unless they are adopted into state law. As of December 2017, 32 states and the District of Columbia have adopted USP 797 into law, including New Hampshire. Once adopted, a state agency, which is typically the state's Board of Pharmacy, must be appointed to oversee and enforce these standards. Because boards of medicine have jurisdiction over the practice of medicine in the physician-office setting, boards of pharmacy have not had much traction to enforce these USP 797 standards in nonpharmacy settings.

In late 2017, the National Infusion Center Association (NICA) began receiving reports that the New Hampshire Board of Pharmacy was sending inspectors into physician offices that were known or suspected to deliver in-office infusions. These inspectors wanted to observe the preparation of intravenous (IV) or injectable medications, mainly biologics, in the office setting to monitor compliance with state regulation (ie, USP 797).

In November 2017, 14 organizations were issued citations involving monetary fines and/or a letter mandating the cease and desist of compounding practices. Soon after this, the New Hampshire Board of Pharmacy issued a statement indicating the Board's awareness "that some entities or individuals may not be complying with USP 797 standards when compounding CSPs [sterile products] such as Remicade in either clinics or in patients' homes." The statement closed with a directive to comply with USP 797 standards or cease and desist in-office prepara-