

Common Misperceptions of Third Party Payors

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Member pharmacists have reported that third party insurers say they require, for reimbursement purposes, a pharmacist to report the original manufacturer's "National Drug Code (NDC) number" of the main bulk drug in the compounded product. Third party insurers sometimes will incorrectly say that federal law is the basis for requiring NDC numbers on claim forms. (Please note that if you have a contract with a third party provider, you should check the contract for any requirements for report claims and whether there is a contractual requirement for an NDC number.) Below are some of these misconceptions and our responses.

MYTH #1: An NDC number indicates FDA approval.

An NDC number does not indicate that a drug is FDA approved. FDA's regulation at C.F.R. 207.39 specifically proves that: "[r]egistration of a drug establishment or drug wholesaler, or assignment of a registration number, or assignment of an NDC number does not in any way denote approval of the firm or its products. Any representation that creates an impression of official approval because of registration or possession of registration number of NDC number is misleading and constitutes misbranding."

Instead, drug approval involves a completely different process, which includes the submission by a manufacturer of a new drug application (ANDA), which FDA then may approve.

MYTH #2: The absence of an NDC number on the drug labeling indicates a failure to comply with FDA regulations.

FDA's own regulations do not require that the NDC number appear on the drug's label or labeling. Specially, the relevant regulation, 21 C.F.R. 201.2, says that "[t]he National Drug Code (NDC) number is requested but not required to appear on all drug labels and in all drug labeling,

including the label of any prescription drug container furnished to a consumer." A manufacturer that omits an NDC number from a drug's label or labeling has not violated FDA's regulations.

MYTH #3: The lack of an NDC number indicates that a compounded drug is not of high quality.

The presence or absence of an NDC number on a label is unrelated to product quality or to approval. Bulk drugs used in compounding typically do not have NDC numbers. FDA and every state recognizes that compounding is a traditional part of the pharmacy, and that one of the principal sources of ingredients for compounding is bulk chemicals. Bulk drugs have been distributed in the United States for use in compounding since passage of the FDC Act in 1938 and do not need to be "approved" by FDA. Thus, bulk drugs used in compounding, unlike drugs sold in finished dosage form, may be legally sold without FDA approval. The sale of such drugs has long been accepted by FDA and the state boards of pharmacy, even though these products do not have NDC numbers on their labels.

The two national organizations that have set standards for compounding practice, the National Association of Boards of Pharmacy (NABP) and the United States Pharmacopeia (U.S.P.), also recognize the use of bulk chemicals for compounding, but do not require that they be "approved" or have NDC numbers. The quality of a compounded drug is unrelated to whether the bulk chemical has an NDC number on its label.

MYTH #4: The absence of an NDC number means that the product is not a "federal legend drug."

The appearance of an NDC number bears no relationship to a drug's prescription status. Both OTC and prescription drugs have NDC numbers.

We must make third party insurers aware that bulk chemicals are vital to compounding practice so that a patient gets the medication that the physician believes is the safest and most effective for that patient. Compounding with these ingredients provides patients with much needed alternatives to commercially available medications. Restricting reimbursement to bulk chemicals labeled with NDC numbers have the negative effect of preventing patients from getting the most appropriate medication.

THIRD PARTY ALERT

Several pharmacists have recently been advised by third party claims desk personnel to submit compounded prescriptions using the NDC of the highest priced brand alternative in order to "simplify the submission process."

This is an illegal process and subject to penalties upon audits. Auditors frequently cite this practice as an example of fraudulent billing. When a third party plan offers this type of advice, request the information in writing.

Because of the dilemma posed by limitations on electronic claims and even paper submission systems, many members are finding the simplest method of payment for services is to have the patient submit directly for reimbursement from the insurance company.

IACP has a Universal Claim Form for Compounded Medications that can be used for this purpose. Call the IACP office at (800) 927-4227 and request a copy of this claim form.