The Need for Compounded Medications and the Problem of Reimbursement

The International Academy of Compounding Pharmacists

Introduction

Over the last 50 years pharmaceutical manufacturers have played a significant role in advancing health care. Nevertheless, although mass-marketed and mass-produced prescription drugs meet the needs of the majority of patients, there are still a number of patients who require pharmacists to customize medication to meet their unique medical needs. This practice of individualizing or customizing medication is called "compounding". Many pharmacists and physicians are rediscovering the benefits of compounding to improve patient care. However, reimbursement policies and processes, designed for manufactured prescription products, often do not enable the reimbursement of a prescribed compounded medication. The lack of policies and processes for the reimbursement of compounded medications has caused serious administrative problems for providers and has kept patients from receiving the proper therapeutic care prescribed for them by their physicians.

Compounding—The need and benefit

The practice of preparing medications dates back to the origins of pharmacy, yet the pharmacy profession has changed over the years. As late as the 1930's, approximately half of all medications were compounded. During the 1950's and 1960's, with the advent of pharmaceutical manufacturers, the practice of compounding greatly declined. Today, however, there is still a compelling and vital need for compounded medications. One study suggests that approximately 5% of prescribed proprietary drugs do not meet the true medical needs of the patient, and that a compounded medication may be more appropriate.[i]

Manufacturers must be assured there will be a return on their investment when entering the market place with a drug product. It literally costs millions of dollars to get a single drug approved. Therefore, there are limited chemical forms, dosage forms, strengths, flavors, and packaging that are available for physicians to prescribe. Compounding allows the physician to prescribe a custom-tailored medication that is not available commercially.

One of the most important reasons to use a compounded medication is patient non-tolerance of a manufactured product. Many patients are allergic to preservatives or dyes, or are sensitive to standard drug therapies. Physicians also prescribe compounded medications to change the strength, alter its form to make it easier for the patient to ingest, and/or to change the flavor to make it more palatable. The pharmacist can also prepare the medication using several unique delivery systems, such as a sublingual lozenge, a lollipop, or transdermal gel. Thus, compounding can substantially improve patient compliance.

Compounded medications are also used to help patients who are experiencing chronic pain. For example, topical, transdermal ointments can be applied locally allowing a patient to avoid nausea and other adverse gastrointestinal side effects. The ultimate goal of compounded medications is to help the physician and patient achieve a more positive and cost-effective therapeutic outcome.

Compounding—Legal Parameters

In 1997, national pharmacy organizations became united in their efforts to ensure that pharmacists could continue to meet the unique needs of patients through compounding and to create standards for the practice of compounding. The National Association of Boards of Pharmacy formulated Good

Compounding Practices that have been utilized by many states. The U.S. Pharmacopoeia Convention prepared a chapter for the USP/NF and established monographs for the compendia for compounding. Finally, compounding pharmacists, professionals, and pharmaceutical organizations supported compounding legislation as part of the Food and Drug Administration Modernization Act (FDAMA) of 1997[ii]. The legislation exempts compounded medication from FDA's new drug application (NDA) process and good manufacturing practices (GMPs)[iii]. Congress passed this law in recognition of the important role pharmacy compounding plays in promoting patient care. In addition, the legislation sets forth legal parameters of compounded medication—including the requirement for a pharmacist-patient-physician relationship, specific guidelines for drugs that may be used for compounding, those that may not be used for compounding, and parameters for anticipatory compounding. Together, these laws and guidelines establish defined standards over the compounding of medications.

Compounding—The Problem of Reimbursement

However, patients and pharmacists face problems when seeking reimbursement for compounded medications. The first problem for getting reimbursement for compounded medications relates to the use of NDC numbers. Some providers refuse to reimburse or allow on-line billing of prescribed compounded medications because of policies stating that all medications must have an NDC number.

NDC numbers are identifier numbers for manufactured drug products. The Food and Drug Administration (FDA) assigns a five-digit number to identify a manufacturer that is registered with the agency. The manufacturer then assigns a four-digit product identification number and a two-digit size number to the product.

NDC numbers do not apply to compounded medications—medications prescribed by a physician that are specially altered to meet a unique patient need. The FDA iterated this in a letter to Senator Thad Cochran:

> A compounded drug, i.e., a drug compounded by a pharmacist on order of a licensed practitioner, is not subject to these regulations [applicable to NDC numbers] and does not receive an NDC number. Such compounding of drugs is considered the practice of pharmacy/medicine.

Since NDC numbers are often required for on-line billing, many pharmacists are asked to provide the NDC number of the most expensive product in the compounded medication. However, even if it contains the same active ingredients, the compounded medication does not represent the manufactured product. The result is a compounded medication misbranded with an incorrect NDC number.

It is also important to note that an NDC number does not indicate FDA approval. A drug product is assigned an NDC number by the drug's manufacturer or distributor, and by FDA[iv]. An NDC number can be assigned even though there is no FDA approval. FDA's regulations specifically provide 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 or NDC number is misleading and constitutes misbranding.[v]

Therefore, assignment of an NDC number does not mean that a drug is FDA-approved. While companies can obtain an NDC number for their approved drugs, they are not obliged to do so. A manufacturer that omits an NDC number on a drug's label or labeling has not violated FDA's regulations. Furthermore, the appearance of an NDC number bears no relationship to whether the drug is a legend drug or one sold over-the-counter.

The requirement for NDC numbers has prohibited pharmacists from billing compounded prescriptions online. This has had a negative impact on patient care by the inability to be reimbursed for compounded medications—medications that are prescribed by their physician. These patients should be reimbursed. The International Academy of Compounding Pharmacists (IACP) has developed a Universal Claim Form for compounded medications that can be used by patients to seek reimbursement from the provider, yet even these claim forms are often denied.

Furthermore, there has been an increased use of formularies that prohibit—often unintentionally- the reimbursement of compounded medications. Formulary limitations that restrict compounded medications may lead to higher costs through non-compliance, non-tolerance of manufactured products, and/or restrictions on clearly prescribed beneficial therapies.

To ensure that patients continue to receive prescribed compounded medication that is best suited for their unique needs (e.g., an allergic reaction to a dye in a manufactured product), employers and providers must ensure that those responsible for their benefit plans allow for the reimbursement of compounded medication. They must also ensure that any formulary restrictions do not limit prescriptions to medications that are FDA-approved. Further, providers must develop standards that allow for pharmacists to bill on-line prescribed compounded medications without the use of NDC numbers or reimburse compounded medications via a written claim form such as IACP's Universal Claim Form for Compounded Medications.

The International Academy of Compounding Pharmacists (IACP) is a non-profit organization that represents over 1300 compounding pharmacists in the U.S. and Canada. IACP would be happy to provide more extensive information regarding this subject. If you have any questions or comments, please call 281-933-8400.

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[i] Riley, Rebecca J. and Curtis D. Black. "The Need and Utilization of Pharmaceutical Compounding". Unpublished Data, 1999. University of Toledo.
[ii] Food and Drug Cosmetic Act § 503A
[iii] Id. § 503A (a)
[iv] Food and Drug Cosmetic Act 21 C.F.R. § 207.35
[v] Id. C.F.R. § 207.39.

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