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# Just a Phone Call Away . . .

**Staff Supervisor Pam Redwine, R.N., draws on clinical experience to assess acuity of calls she receives on the Nurse Advice Line.**

Sometimes when a person or their loved one is hurting, they need help immediately. If that person is one of the more than 316,000 members of ***SoonerCare***, help with medical decisions, getting more information about a medical topic or condition, or finding someone who speaks their language – even if it isn't English – is just a phone call away.

Charlene Benson, Medicaid Care Management Team director, said each of the ***SoonerCare*** health plans offer a nurse advice line. Members of ***SoonerCare*** Choice have access to HealthLink's Nurse Advice Line (NAL), a telephone triage unit, 24 hours a day.

The line is staffed by resource representatives who may initially take the calls (depending on call volume) as well as one to four registered nurses. The nurses have active Oklahoma licenses and each has more than two years of clinical experience. According to Tony Waltrip, manager of nursing operations, more than 95 percent of the calls are answered within 12 seconds.

"Between 50 and 70 of the calls we receive each day are from ***SoonerCare*** Choice customers," Waltrip said.

The NAL contracts with AT&T's translator service that can accommodate more than 140 languages and dialects. Physicians with a ***SoonerCare*** Choice member in the office who does not speak English can call the Nurse Advice Line, which will connect them with an AT&T translator during the visit. The NAL can also connect with the service any time a non-English speaking customer calls.

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## Lack of Response a Main Problem in Quality Review Process

The Oklahoma Health Care Authority contracts with the Oklahoma Foundation for Medical Quality to ensure quality of care and to monitor Medicaid claims as stipulated by 42CFR (Code of Federal Register.) OFMQ randomly selects hospital cases and coordinates the denial and quality review process for OHCA.

Most case denials stem from a lack of documentation in the medical record; a physician fails to document everything done on a specific case or doesn't complete the documentation in a timely manner. Many of these might be overturned during the review process since physicians have the opportunity to appeal the decision and submit more information. Unfortunately, more than 50 percent

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of the physicians and hospitals that receive a notice that there is a concern with a case do not respond to the letter. This can potentially lose reimbursement for the responsible party or lead to more serious consequences.

"Some physicians have told the review panel that they thought the letter OFMQ sent them indicating a problem was just another letter from an insurance company or something else," said James Millar, MD, MPH, the medical director for the Oklahoma Foundation for Medical Quality. "But it is imperative to read the letter and respond in a timely manner."

### How the Medicaid review system works:

In the fee-for-service retrospective review process, cases are randomly selected for review each month from a list of Medicaid hospital paid claims. When the cases are selected, the responsible parties, usually hospitals, are notified to send the medical records to OFMQ within 30 days.

Once the medical record is received, non-physician reviewers use InterQual® criteria in order to evaluate those cases for admission necessity, length of stay, quality of care and level of care. If a case fails the InterQual® screening criteria or has a potential quality of care issue, it is sent to a physician reviewer of like specialty in a similar setting, such as urban or rural practice. Physician reviewers use their medical judgment when evaluating the medical records and are not bound by criteria.

If a physician reviewer finds a concern with a case, OFMQ sends a letter to the responsible parties, who have 30 days to exercise their appeal rights and submit additional information that might clarify the issue. If the responsible party does not respond, the judgment of the initial physician reviewer stands. If an appeal is requested or more information is submitted, the case is sent to a second physician reviewer who will evaluate the medical record with the new information. Quality of care issues range from relatively minor to gross and flagrant negligence. The level of concern is determined by the first physician reviewer, and stands if no request for reconsideration is received.

- If a responsible party does not send in the medical record at all, that case receives a technical denial and OHCA recoups money for the entire length of the patient's stay.
- If a patient was treated on an inpatient basis longer than medically necessary, OHCA could recover money for the medically unnecessary days.

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When a patient calls the NAL with a health concern, nurses assess the acuity of the situation with computerized, hierarchical protocols including the Dr. Barton Schmitt Pediatric Protocols and Centramax Plus. The protocols recommend the level of care the patient should seek. The nurse can increase the acuity level of the call if she/he believes the situation is more serious than the computerized protocols recommend.

"Nurses aren't locked into their protocols," Waltrip said. "If, based on their nursing experience, the call is more acute than the protocol recommends, they can upgrade it. That's why we use RNs with clinical experience. We want to use their experience rather than just rely on technology. Nurses here are qualified to make those decisions."

NAL staff doesn't provide direct intervention by calling the primary care provider or social worker, although they can activate EMS. They do NOT make diagnoses. The NAL line defers specific medication interaction questions to a pharmacist. If the protocols indicate that a person does not need to seek immediate medical care, nurses try to recommend things the patient can do at home to stay more comfortable.

"We recommend a level of care from home care to activating EMS," Waltrip said. "It assists insurance providers and health care providers by helping people get an appropriate level of care. We help people make good decisions by giving them information so they can make more informed decisions."

NAL nurses have access to a reference library and an audio library that includes more than 1100 topics for general medical questions. These include frequently asked questions about what a woman can and shouldn't do during pregnancy. HealthLink's medical director, Bruce Naylor, MD, approves all reference material and programs before use.

"We don't substitute for the provider, but we can help people make good decisions about seeking out healthcare," Waltrip said.

HealthLink is a subsidiary of the VHA Oklahoma Arkansas (formerly Voluntary Hospitals of America), a nationwide network of community-owned health care systems and their physicians.

**_SoonerCare_ plan numbers include:**
**_SoonerCare_ Choice: 1-800-530-3002**
**Heartland Health Plan: 1-800-492-7639**
**Community Care: 1-800-900-2690**
**Unicare: 1-800-700-3341**
**Prime Advantage: 1-800-559-5532**

# Generic Medications Provide Safe Alternative

Although generic medications can provide a safe, effective and less-expensive alternative for patients, health maintenance organizations and third party insurers, they continue to be underutilized in health care.

The Congressional Budget Office reported that generic drugs could save consumers an estimated $8 to $10 billion a year at outpatient pharmacies and substantially more in hospitals. In 1998, overall generic utilization was 41 percent, yet it accounted for only 8 percent of total dollars spent on prescription drugs, according to a study conducted by the National Consumer's League. [1]

Misconceptions exist about manufacturing standards, variations in the rate and extent of absorption, and differences in clinical and physiological outcomes for generic drugs relative to the innovator product. [3,4] These concerns may be preventing some providers from suggesting generic substitutions.

### The FDA Approval Process: NDA vs. ANDA

Before a pharmaceutical company can distribute and market an innovator medication, it must first file a New Drug Application (NDA) and have it approved by the FDA.

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- Services are also grouped in a hierarchy. Levels of care are paid at different rates. If a reviewer finds that the patient's illness or injury warranted a lower level of care than that indicated, OHCA can recoup funds.

In all of these cases, it is in the physician's best interest to respond to the initial letters, exercise his or her appeal rights and send in more information. Some denials can be overturned when additional information is submitted.

"Physicians need to exercise their right to appeal and send in more information," Millar said.

More than 50 percent of the quality issues and denials are automatically upheld because physicians don't respond to the initial letter that tells them the case failed review. Eighty-two quality of care issues were upheld in 2001; 45 of those were automatically upheld because the physician didn't respond. Of the cases in which the physician does respond, approximately 20 percent of the denial judgments are overturned.

It becomes even more imperative that a physician or hospital respond to the letters when the concern identified can be classified as "Substantial," "Serious Risk," or "Gross and Flagrant."

### Substantial, Serious Risk or Gross and Flagrant

If the problem identified is considered to be "Serious Risk," "Gross and Flagrant," or "Substantial," the case is referred to the medical director. The medical director re-evaluates the medical record and ensures deficiencies noted meet the criteria for substantial, gross and flagrant or serious risk. If he agrees with the decision of the physician reviewer, the case is sent to the Medical Education and Intervention Committee (MEIC), a panel of physician members from different specialties. Additional specialists are called in to sit on the committee when necessary. The committee reviews the case and decides whether to send the responsible party an educational letter, a sanctions letter or schedule a face-to-face meeting. The committee also decides if all of the physician's cases should be monitored more intensively and if a corrective action plan should be assigned.

**"Physicians need to exercise their right to appeal and send in more information."**

"The focus of this committee is really educational, not punitive," Millar said. "But by not responding, the physician may come before a peer review panel."

If a physician who has been asked to complete a corrective action plan is unwilling or unable to do so, the MEIC can send the case to the board of OFMQ and OHCA is notified. The boards then determine whether or not the case should be sent to the Office of the Inspector General (OIG). Penalties for physicians who continually fail to respond to letters, requests for face to face meetings and who do not complete corrective action plans could include the revocation of the ability to treat Medicaid patients.

"The vast majority of the physicians who have had to appear before the MEIC had let the deadline for responding pass. They then had to appear before a group of their peers to explain their care, taking the time away from patient care and personal time." Millar said.

# Vision Screening Essential for Infants and Children

Just like the rest of his body, a baby's eyes are still developing at birth. Parents breathe a sigh of relief when they hear their baby cry, rush to count fingers and toes and happily take him/her home with a clean bill of health. Physicians need to remember that even a small vision problem at birth can lead to permanent vision loss and improper development of visual centers in the brain if not detected and treated early. Good vision is essential for the proper physical, neurological and educational development of a child. The American Academy for Ophthalmology has published guidelines for the timing and extent of regularly scheduled examinations for children. Those guidelines can be found at http://med-aapos.bu.edu/AAPOS/Screening.html.

The newborn's eyes should always be examined in the nursery by a physician. An ophthalmologist should examine all high-risk infants, such as those subject to the development of retinopathy of prematurity. Infants 6 to 12 months old should be screened during well baby checks. Look for opacities in the pupil, an abnormal red reflex or one eye turned in or out. Visual acuity testing should begin as soon as the child is cooperative, usually around 2 ½ to 3 years of age. The box letter E turned in different directions or picture cards are valuable tools. Regular assessment of the child's eyes should continue and be a part of the school examinations, beginning at age 5.

## Normal growth and development

The eye at birth of a normal full-term infant is two-thirds the size of the adult eye and the visual system is not mature. Rapid growth occurs in the first three years, especially in the first year. The posterior chamber increases in relative volume more than the anterior chamber, with the eye becoming more spherical in shape. At birth many normal infants may have eye movement and alignment coordination problems. Proper coordination should occur soon after birth and certainly should be achieved by 6 months of age. Evaluation is needed of any persistent deviation of an infant's eye. The consensus recommendation is for all children to have monocular visual acuity tested before the age of four years.

## Amblyopia

Amblyopia is a condition of the brain that results from Strabismus (misalignment) or unclear images due to refractive error. Early detection is critical. If amblyopia is untreated or detection and treatment are delayed, visual loss will be permanent. The visual outcome can range from 20/25 to 20/200. Amblyopia is defined as the reduction in the best-corrected central acuity not directly attributable to an abnormality of the visual pathway or visible organic lesion of the eye. Early detection and treatment can prevent most vision loss connected with this condition. Children with a family history of amblyopia are at increased risk. The best time for treatment is the preschool years, with limited effectiveness after the age of eight. Amblyopia due to strabismus is the most common form, and is caused by the suppression of the signal from the deviating eye to the brain, preventing double vision. The affected eye may lose its visual potential with prolonged suppression. When the angle of the strabismus is small, detection may be difficult therefore acuity testing early in life is critical.

"Deprivation" amblyopia results from the retina not receiving a clear image. The most common cause is cataracts. The opacity in the lens, either bilateral or unilateral, is detected by looking for distortion or absence of the red reflex at well baby checks.

The most difficult form of amblyopia to detect is due to refraction problems. When the eyes have markedly asymmetric refraction, the eye with the better refraction is used, and the other is suppressed. This suppression can result in loss of the visual potential, similar to the problems with strabismic amblyopia. Treatment is specific for the cause. Correction of the refractive errors will correct the amblyopia, if there is no strabismus. Occlusion of the better eye with patching or other techniques is the typical therapy if strabismus is also a factor.

## Strabismus

Strabismus is defined as the misalignment of the eyes. Mild degrees of change can be treated with glasses, and surgery is required for others. Patching of the "good' eye is usually required. Initially this occlusion is full-time, and then is adjusted according to the patient's age and

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response to therapy. An alternate therapy is to blur the dominant eye with atropine drops, a process referred to as penalization.

### Ocular Inflammation

Conjunctival inflammation can be a result of toxins, irritants, allergens, and viral or bacterial agents. Conjunctivitis is common in childhood, and is broadly classified as infectious and non-infectious. Uveitis (inflammation of the choroid, ciliary body, or iris) can cause symptoms of vision loss, pain, and light sensitivity. The most common cause of iritis is juvenile rheumatoid arthritis. All patients with Juvenile Rheumatoid Arthrititis should be screened under the slit lamp by an ophthalmologist. Physicians using eye drop combinations with steroids without the benefit of a slit lamp should remember that this could lead to or aggravate herpes simplex corneal infections.

### Eye Trauma

Blunt trauma can cause swelling and bruising of the eyelids and periorbital regions. In the case of extensive injuries be sure to consider the possibility of an orbital fracture. Extensive flushing is the treatment of choice for chemical injuries with either an acid or alkali solution. The flushing is recommended for at least thirty minutes or until a neutral pH is obtained. Saline or Ringer's lactate are preferred solutions, however, water is an acceptable alternative.

Corneal abrasions and foreign bodies are also common forms of eye trauma. Treatment will depend on the nature of the injury, whether the foreign body is on the cornea or if there is a penetrating wound of the globe.

### Examination

Visual acuity can begin with the E test. Parents should be instructed to play the E game at home and teach the child to turn their fingers in the same direction as the E. Up or down presentations are less confusing for children than left or right. If the child knows letters, than the Snellen acuity chart can be used. An acuity of 20/20 is expected by age five or six, with 20/30 the typical at age four, and 20/40 acceptable for age three. Visual field assessment must be adjusted to the patient's abilities and age. In many younger children, gross estimates by peripheral testing of the four quadrants is the extent of the testing that can be accomplished. Color vision testing can be performed whenever the patient can trace or name the test symbols (numbers, triangles, X's, O's, etc.).

Pupillary examination is the evaluation of the size and symmetry of the pupils under reduced illumination, reaction to near gaze, and consensual and direct reactions to light. Ocular motility tests for the range of motion while the eyes follow an object. The examiner is testing for both completeness of the motion and symmetry. Deviations from a conjugate gaze are called esotropia (turning in), exotropia (turning out), hypertropia (turning up), and hypotropia (turning down). The cover test of the motility is performed by covering and uncovering each eye as they are focused on a detailed object straight ahead. Binocular vision testing requires cooperation by the patient, and is usually done by an ophthalmologist using the Titmus test or other similar process.

External examination evaluates the symmetry, shape, and size of the orbits, movement and position of the lids, as well as symmetry and position of the globes. Checking for the red reflex is part of the newborn examination. This is usually done from a distance of one to two feet, using the ophthalmoscope. Abnormalities in the red reflex need further immediate evaluation. If the reflected light appears white, the abnormality is referred to as leukocoria. The central retina can be seen without dilation in newborns but may be easier with the pupils dilated, if there are no contraindications.

Refraction will be done under cycloplegia in young patients who are unable to state preferences between a choice of different lenses. Subjective refinement of the refraction can be accomplished with many school-aged patients who can choose between different lenses. Tonometry may require sedation in young children or the uncooperative patient. Palpating the globe with the index fingers placed side-by-side above the tarsal plate on the upper lid will only identify particularly high pressure in most hands. Slit-lamp examination is often required in the evaluation of trauma to the eye.

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# Customer Service: Keeping You Informed

Last quarter, we answered questions concerning the Health Insurance Portability and Accountability Act (HIPAA) and how it will affect our customers. In this issue, we continue with more information about how this law will affect you.

**Q** *What do I need to do when the Electronic Data Interchange standards portion of HIPAA goes into affect?*

**A** If you already file claims electronically, check with your vendor to ensure they are in the process of becoming HIPAA compliant. If you are investigating the possibility of electronic claims filing, be sure to question your prospective vendors about HIPAA compliance.

**Q** *What if I currently file paper claims?*

**A** You may continue to file paper claims. You will be notified of any required procedure code or format changes.

**Q** *Is the HIPAA implementation date still set for October 16, 2002?*

**A** Yes, HIPAA legislation was passed in 1996, and the first set of rules and regulations for the Administrative Simplification portion of the law will be in effect nationwide on October 16, 2002. OHCA will be HIPAA compliant October 16, 2002. It is imperative that your billing software vendor or billing agent is aware of this implementation.

To follow HIPAA implementation activities and find further information, go to the OHCA website at ohca.state.ok.us and select the Provider Home Page. In the last paragraph, you should see the link to HIPAA information.

# Generic Medications Provide Safe Alternative (continued from page 3)

The NDA documents the safety and efficacy of the medication and the manufacturing control procedures to be used in the production of the medication. [2,5,6] The research and development (R&D) process necessary for approval of a new drug is extremely costly and may take years. The majority of a medication's patent life will elapse during the testing and evaluation period, leaving the manufacturer a limited amount of time to recover their R&D costs. [7]

In contrast, generic drug companies must only file an Abbreviated New Drug Application (ANDA). To gain FDA approval of an ANDA, a generic drug must:

- contain the same active ingredients as the innovator drug (inactive components may vary)
- be identical in strength, dosage form and route of administration
- have the same use indications
- be bioequivalent
- meet the same batch requirements for identity, strength, purity and quality
- be manufactured under the same strict standards of the FDA's good manufacturing practice regulations required for innovator products [2,6]

Both brand and generic drug entities must meet the same developmental, manufacturing and clinical quality standards. However, generic products do not have to duplicate animal or human research data obtained in clinical trials. Since generic manufacturers are not required to provide such data, they are financially able to offer patients the same drug at a much lower cost. Because both brand and generic drugs must successfully complete this rigorous approval process, patients and providers can fully expect that the generic product will produce the same clinical effect and safety profile as the innovator drug.

### Determination of Bioequivalence

In order to be labeled therapeutically equivalent ("A"-rated) by the FDA, a drug must be both *pharmaceutically equivalent* and *bioequivalent*. A pharmaceutically equivalent generic drug has the same active ingredient, strength, dosage and route of administration, and comparable labeling as the innovator product. A bioequivalent generic drug must demonstrate "the absence of a significant difference in the rate and extent to which the active ingredient or active moiety is absorbed from a pharmaceutically equivalent drug product and becomes available at the site of action." [5,6] The rate of absorption is usually expressed as area under the plasma drug concentration-time curve (AUC) and extent of absorption refers to maximum drug concentration (Cmax).

### Allowable Range of Variation for Generic Drugs

Based on FDA criteria, the 90

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percent confidence interval for a generic product's AUC or Cmax must lie entirely within a range of 80 percent to 125 percent of the innovator's value.[8] Many have argued that the 80 percent to 125 percent range creates such a large variance that generic drug products could be less efficacious. Statistically, if the confidence interval (CI) of the generic's value must lie ***entirely*** within 80 percent to 125 percent, the lowest mark that it could have is 87 percent to 88 percent. Therefore, any generic product with a value below 87 percent would fail to meet FDA standards because the CI would fall below the lower limit of 80 percent. The use of the 90 percent CI is much stricter than many may realize.

One of the most compelling misconceptions is that FDA-approved generic drugs do not produce similar physiological responses and therapeutic outcomes. To dispel such concerns, in 1997 the FDA reviewed several previous studies to determine if non-bioequivalent medications had slipped through the cracks. No significant differences between the generic entity and the reference product were found. [8,10] The mean AUC difference between the generic and brand products was 3.47 percent and the difference in mean Cmax was 4.29 percent.[10] More importantly, an FDA official noted that these small differences between generic and the innovator products were no different than if one lot of the innovator product was compared to another.[8]

## Substitution of Narrow Therapeutic Index (NTI) Drugs

The term "narrow therapeutic index" has been used to define a number of drugs that have a specific

therapeutic range in which slight deviations could result in subtherpeutic or toxic levels. Although the FDA has never formally designated or classified any drugs as NTIs, over the years popular opinions have identified drugs such as warfarin, phenytoin, carbamazepine, digoxin and theophylline as NTIs. The terminology used by FDA is "narrow therapeutic ratio." According to federal regulations, a drug has a narrow therapeutic ratio if:

1. There is less than a two-fold difference in the median lethal dose (LD50) and effective dose (ED50) values, or
2. There is less than a two-fold difference in the minimum toxic concentrations and minimum effective concentrations in the blood, and
3. Safe and effective use of the drug requires careful titration and patient monitoring.

Debate has occurred over the safety and appropriateness of generic substitution of NTI drugs. Many anecdotal reports of adverse events have been published in medical literature. A recent review of several reports identified gaps in information and methodological oversights that left the author of that review unconvinced that a sound case could be made that harm actually occurred because of switching.[4]

The FDA has also addressed these concerns in two separate letters. In an April 1997 response to the National Association of Boards of Pharmacy, Dr. Roger Williams of the FDA's Center of Drug Evaluation and Research (CDER) stated: "Because of the FDA's strict bioequivalence criteria, we believe that drugs do not fall into discrete groups that would allow one to consider NTI drugs as being clearly different from other drugs for purposes of substitution."[8]

Dr. Williams went on to conclude that "if one therapeutically equivalent drug is substituted for another, the physician, pharmacist and patient have the FDA's assurance that the physician should see the same clinical results and safety profile. Any differences that could exist should be no greater than one would expect if one lot of the innovator's products was substituted with another."[8]

In a subsequent letter dated January 6, 1998 sent to health practitioners, Dr. Stuart Nightingale of the FDA stated: "It is not necessary for the health care provider to approach any one therapeutic class of drug products differently from any other class, when there has been a determination of therapeutic equivalence by FDA for the drug products under consideration."

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*References available on request*


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