CareSource

October 27, 2009

Greetings,

Top-quality health care and improved member safety are goals we share. To help us be successful, we're working to make it easier for you to do business with us. We're simplifying interactions and expanding our online tools so that you and your patients can make better health care decisions.

Here are a few specific examples:

- The CDC has indicated that influenza activity continues to increase in the United States. **Effective immediately, and to make it easier for you to treat your CareSource patients, we have removed the prior authorization requirement for Tamiflu and Relenza** (additional influenza season and Synagis Online Prior Authorization information can be found on pages 4 & 5 of the enclosed *ProviderSource* newsletter).
- **We've been actively involved in assessing a better way to evaluate claims that provides consistent reimbursement using Medicare and other national coding standards.** In November we plan to update our previously established claim processing edits**.** Concurrent with this update, we plan to launch enhanced claims inquiry functionality on our secure Provider Portal located on our website, www.caresource.com, that will provide more detailed claim line edit descriptions.
- **We've launched a patient-centered medical home pilot, Health Care Home Program.** The pilot promotes a collaborative approach that integrates the member, the PCP, and CareSource, giving the member better access to the care they need, satisfaction with their care and improved health overall.

Please find enclosed the fall edition of our provider communications packet. This mailing includes our *ProviderSource* newsletter, which contains articles I hope you find interesting and beneficial. In addition, we've included a handout on the Facts & Myths about Generic Drugs, a new Diabetes Checkpoints Chart Form, and a handout about Code Editing Guidelines on Professional Claims.

I also encourage you to participate in our 2009 follow-up provider satisfaction survey included in the packet. As always, your feedback is very important to help us identify areas for improvement.

Respectfully,

C Thiele MD

Craig Thiele, M.D.
Chief Medical Officer

OH-P-210

P.O. Box 8738
Dayton, OH 45401-8738
800-488-0134
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CareSource

Provider Satisfaction Survey

CareSource values feedback we receive from our providers. Your feedback helps us provide the highest quality services to you and the members we serve. We will use your feedback to identify areas for targeted improvement.

Once the surveys are completed by providers, all responses will be reviewed and results will be posted on our website. Watch for additional details in the near future.

Questions about your practice to be answered by the office manager:

1. What is the nature of your practice?
   - ☐ Primary Care Practice
   - ☐ Specialty Practice
   - ☐ Multi-Specialty Practice
   - ☐ Skilled Nursing Facility
   - ☐ Hospital

2. How many providers are in your office/care site? _____

3. How many providers are contracted with CareSource? _____

Please rate CareSource. Tell us if you strongly agree, agree, are neutral, disagree or strongly disagree with the following statements. If you have not had any experience with a particular area, please mark the questions in that area N/A.

4. PROVIDER RELATIONS STAFF

(Responsible for contracts, reimbursement issues, capitation arrangements and credentialing requirements, provider orientations and in-service and changes to provider practice information such as address or name change)

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	N/A
▪ My interactions with the Provider Relations staff are handled in a courteous and professional manner.	☐	☐	☐	☐	☐	☐
▪ The Provider Relations staff answers my questions accurately.	☐	☐	☐	☐	☐	☐
▪ The Provider Relations staff follows up on identified issues in a timely manner.	☐	☐	☐	☐	☐	☐
▪ I am satisfied with the frequency of contact with my Provider Relations Representative.	☐	☐	☐	☐	☐	☐

5. CREDENTIALING STAFF

(Responsible for verifying credentials of contracted providers)

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	N/A
▪ My interactions with the Credentialing staff are handled in a professional and courteous manner.	☐	☐	☐	☐	☐	☐
▪ The Credentialing staff is knowledgeable in answering questions and in helping resolve issues.	☐	☐	☐	☐	☐	☐
▪ I am satisfied with the amount of time it took between submitting my contract and receiving my appointment letter from the Credentialing department.	☐	☐	☐	☐	☐	☐

Please complete survey and return in the business reply envelope provided by Friday, November 20, 2009.

CareSource

Provider Satisfaction Survey

6. PROVIDER SERVICES STAFF

(Responsible for answering provider inquiries regarding claims payment and claims processing, benefit eligibility, covered services and prior authorization requirements)

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	N/A
▪ My interactions with the Provider Services staff are handled in a professional manner, with a genuine concern for customer satisfaction.	☐	☐	☐	☐	☐	☐
▪ The Provider Services staff is knowledgeable about Ohio Medicaid and the CareSource plan; they answer my question(s) regarding benefits and/or prior authorization requirements.	☐	☐	☐	☐	☐	☐
▪ The Provider Services staff is an experienced team of claims representatives; I am confident they will meet my needs when I need to call them for assistance.	☐	☐	☐	☐	☐	☐
▪ If the Provider Services Representative cannot answer my inquiry without additional research, I am confident that I will be immediately connected with the appropriate representative, or I will be called back as promised.	☐	☐	☐	☐	☐	☐

7. CLAIMS PAYMENT/PROCESSING STAFF

(Responsible for processing and payment of claims)

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	N/A
▪ I am satisfied with the timeliness of CareSource claims payments when compared to other Medicaid payers.	☐	☐	☐	☐	☐	☐
▪ I am satisfied with the accuracy of CareSource claims payments when compared to other Medicaid payers.	☐	☐	☐	☐	☐	☐
▪ I am satisfied with the way that CareSource handles my outstanding claims issues when compared to other Medicaid payers.	☐	☐	☐	☐	☐	☐

8. CLINICAL APPEALS PROCESS

(Responsible for clinical appeals review, quality issues involving providers)

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	N/A
▪ Clinical appeals for service that have been denied for lack of medical necessity have been resolved in a timely manner.	☐	☐	☐	☐	☐	☐
▪ My interactions with Clinical Appeals Department staff are handled in a professional and courteous manner.	☐	☐	☐	☐	☐	☐
▪ My interactions with the Medical Directors are handled in a professional and courteous manner.	☐	☐	☐	☐	☐	☐
▪ My interactions with the Clinical Appeals Department are handled in a timely manner.	☐	☐	☐	☐	☐	☐

CareSource

Provider Satisfaction Survey

9. MEDICAL MANAGEMENT/ UTILIZATION REVIEW STAFF

(Responsible for requests for prior authorization of medical and dental services and Durable Medical Equipment, authorization of in-patient hospital admissions, Bridge to Home services)

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	N/A
▪ The prior authorization process at CareSource is clearly defined.	☐	☐	☐	☐	☐	☐
▪ CareSource provides information that is helpful in explaining the preauthorization process.	☐	☐	☐	☐	☐	☐
▪ My interactions with the Medical Management staff are handled in a professional and courteous manner.	☐	☐	☐	☐	☐	☐

10. CASE MANAGEMENT STAFF

(Responsible for outreach to members, health education, ongoing monitoring of health status, coordination of care, facilitation of needed healthcare services/ equipment, referral to appropriate community resources, providing one-on-one personal interaction and individualized education/ support)

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	N/A
▪ The Case Managers at CareSource have satisfactory knowledge of CareSource's available services and programs.	☐	☐	☐	☐	☐	☐
▪ CareSource Case Managers are easily accessible to assist in the management of chronically ill members.	☐	☐	☐	☐	☐	☐
▪ Issues raised with CareSource Case Managers are resolved within a reasonable period.	☐	☐	☐	☐	☐	☐
▪ I am satisfied with CareSource's Case Management services in the coordination of care for children with special health care needs.	☐	☐	☐	☐	☐	☐

11. PHARMACY STAFF

(Responsible for authorization of medications, answering questions about drug formulary and running medication utilization reports)

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree	N/A
▪ The CareSource preferred drug list is comparable to other Managed Care Organizations.	☐	☐	☐	☐	☐	☐
▪ The CareSource Pharmacy prior authorization process is similar to other Medicaid managed care organizations.	☐	☐	☐	☐	☐	☐
▪ My interactions with the Pharmacy Prior Authorization staff are handled in a professional and courteous manner.	☐	☐	☐	☐	☐	☐
▪ The CareSource Pharmacy prior authorization process is handled in a timely manner.	☐	☐	☐	☐	☐	☐

CareSource

Provider Satisfaction Survey

PROVIDER COMMUNICATIONS

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
12. The quarterly Provider Mail Packs (which include the *ProviderSource* newsletter, Provider Relations Representative List, etc.) provide timely and relevant information.	☐	☐	☐	☐	☐

13. Which of the following do you prefer as your method of communication with CareSource?

- ☐ Provider Portal (website)
- ☐ Quarterly Mail Pack
- ☐ Email
- ☐ Telephone
- ☐ Other

14. What types of information do you share with your patients? *(Please mark all that apply.)*

- ☐ Health
- ☐ Benefits
- ☐ Prescription Drugs
- ☐ Other

15. Do you use the Provider Portal available online via the CareSource website?

- ☐ Yes
- ☐ No
- ☐ Uncertain

16. What function(s) do you most often use while on our Provider Portal? *(Please mark all that apply.)*

- ☐ Member Profile
- ☐ Member Eligibility
- ☐ Claims Information
- ☐ Prior Authorization
- ☐ Prior Authorization Status
- ☐ PCP Membership List
- ☐ Coordination of Benefits (COB)
- ☐ N/A – currently not using the Provider Portal

17. What function(s) not currently available on our Provider Portal would you like to see added?

_____
_____
_____
_____

18. **GENERAL**

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
▪ I am satisfied with my overall experience with CareSource.	☐	☐	☐	☐	☐
▪ I would recommend participation in CareSource to another practice.	☐	☐	☐	☐	☐

PROVIDER INFORMATION

Name of practice or provider: _____
Name of individual completing survey: _____
Email address: _____
County of primary practice location: _____
Name of CareSource Provider Relations Rep:_____

Please complete survey and return in the business reply envelope provided by Friday, November 20, 2009.

Code Editing Guidelines on Professional Claims

As announced in our October 12, 2009 letter sent to our Provider Network, CareSource continues to be committed to industry standard claim adjudication practices. We have been actively involved in assessing a better way to evaluate claims that provides consistent reimbursement using Medicare and national coding standards. One of the key requirements in the process has been to provide you improved transparency and more detailed information regarding adjudication of your claims.

CareSource is updating its previously established claim processing edits to make it easier for you to work with us. The update is scheduled for November 2009. Concurrent with this update, we will launch enhanced claims inquiry functionality on our secure Provider Portal located on our website, **www.caresource.com.** The new functionality will provide more detailed claim line edit descriptions.

All of the edits below will be enhanced or implemented effective November 2009. These edits will apply to professional claims submitted on a CMS 1500 form.

ICD-9 codes with 4th and 5th digit specificity

These edits will identify claim lines that contain a diagnosis code, per Medicare standards, that require a 4th or 5th digit for appropriate specificity.

Inappropriate Diagnosis for Gender

CareSource will enhance this edit to include claims submitted with specific diagnosis coding that is only applicable to one gender. For example, a diagnosis of pregnancy would not be payable for a male member.

Inappropriate Modifier Combination

This edit validates the appropriateness of modifier and code combinations. When an inappropriate combination has been submitted, the claim will be denied. A corrected claim may be submitted with appropriate modifiers if within timely filing standards. Modifier relationships are based on publications from the Centers for Medicare & Medicaid (CMS) and the American Medical Association, CPT Professional and Standard Editions.

Global Days

A surgical package is defined as the period one day prior to a procedure, and a certain number of days after the procedure as defined by CMS (either 0, 10, or 90 days). Payment for surgical procedures is inclusive of any follow-up days for that procedure. If an E/M service is billed within the global surgical period, the claim line will be denied. For purposes of this edit, professional services from a physician or another physician of the same specialty who belongs to the same

group practice (by Tax Identification) that renders an E/M within the global period would also be denied.

Maximum Frequency per Day

This edit is based on CPT and HCPCS code descriptions, along with CMS standards, that define maximum billable units per procedure. If a claim line contains units that exceed these limits, CareSource will only allow the appropriate unit values associated with that code.

Unbundle

This edit compares CPT codes reported for the same date of service to find procedures that should not be submitted together. Unbundling is the act of billing CPT codes which are components of other CPT codes. Unbundling can either be incidental (procedures which are not essential to complete the procedure) or mutually exclusive (related procedures). Depending on the particular code combination, CareSource may deny one or more of the related codes.

There are 3 defined unbundling edits used by CareSource:

U = Unbundling

Unbundling is to inappropriately bill more CPT/HCPCS codes than necessary. This edit is applied when certain codes represent procedures that are basic steps necessary to accomplish the primary procedure.

For example: Laboratory should bill CPT code 80048 (basic, metabolic panel) when coding for a calcium, carbon dioxide, chloride, creatinine, glucose, potassium, sodium, and urea nitrogen performed as automated multichannel tests. It would be inappropriate to report CPT codes 82310, 82374, 82435, 82565, 82947, 84132, 84295 and/or 84520.

I = Incidental

Incidental includes procedures that can be performed along with the primary procedure, but are not essential to complete the procedure. They do not typically have a significant impact on the work and time of the primary procedure. Incidental procedures are not separately reimbursable when performed with the primary procedure.

For example: CPT code 58660, Lysis of adhesions, is not to be reported separately when done in conjunction with CPT code 58661, Laparoscopy, surgical; with removal of adnexal structures (partial or total oophorectomy and/or salpingectomy).

E = Exclusive

Mutually exclusive procedures are a coding combination billed in error that follows one or both of the following criteria: Either the two services cannot reasonably be done in the same service, or the coding combination represents two methods of performing the same service.

For example: CPT code 49203, Excision or destruction by any method of intraabdominal or retro-peritoneal tumor or cysts or endometriomas, is recognized as mutually exclusive of code 47380, Ablation, open, of one or more liver tumor(s).

Not a Primary Diagnosis Code

This edit identifies ICD-9 diagnosis codes that are not allowed for reporting alone or as a primary diagnosis. Claims submitted with these ICD-9 codes will be denied and must be resubmitted with a valid Primary Diagnosis Code.

Corrected Claims

Please note that you do not need to appeal a claim denied for clinical editing if you are correcting information to make the claim coding compliant. You can resubmit the claim electronically using the appropriate EDI indicators to designate the claim as corrected or resubmit paper claims clearly marked with the word "Corrected" using the normal claim submission process.

If you have any questions about the information provided above please contact Provider Services at **1-800-488-0134** or call your CareSource Provider Relations Representative.

CareSource

REMINDER

The Bureau of Managed Care has designated November as statewide open enrollment month for both the Aged, Blind, or Disabled (ABD) and the Covered Families and Children (CFC) programs. Notices have already been sent to consumers about the open enrollment period.

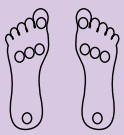
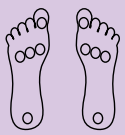
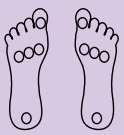
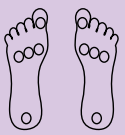
Consumers can select CareSource as their health plan by calling 1-800-605-3040 (TTY for the hearing impaired: 1-800-292-3572) or by visiting the Medicaid Managed Care Enrollment Center at www.ohiomcec.com.

ANNUAL **diabetes** CHECKPOINTS

Patient Name _____ Birth Date _____

ID/Insurance # _____ M F

Clinic/Physician _____

Treatment	D.O.S. ___/___/___	D.O.S. ___/___/___	D.O.S. ___/___/___	D.O.S. ___/___/___
A1C Goal: < 7% Every 6 months (controlled) Every 3 months (uncontrolled)				
Weight Every visit Goal: Individualize				
BMI Percentile				
BP Every visit Goal: <130/80				
Annual Lipid Panel **Total Cholesterol** Goal: <200 mg/dl				
Triglycerides Goal: <150 mg/dl				
HDL Goal: Men >40 mg/dl Women >50 mg/dl				
LDL Goal: <100 mg/dl				
Urine Microalbumin Annually Goal: <100				
ACE/ARB Therapy	☐ Rx ☐ Pt did not tolerate ☐ Pt declined	☐ Rx ☐ Pt did not tolerate ☐ Pt declined	☐ Rx ☐ Pt did not tolerate ☐ Pt declined	☐ Rx ☐ Pt did not tolerate ☐ Pt declined
Statin Therapy	☐ Rx ☐ Pt did not tolerate ☐ Pt declined	☐ Rx ☐ Pt did not tolerate ☐ Pt declined	☐ Rx ☐ Pt did not tolerate ☐ Pt declined	☐ Rx ☐ Pt did not tolerate ☐ Pt declined
Aspirin Therapy (or other antithrombolytic)	☐ Rx ☐ Contraindicated ☐ Pt declined	☐ Rx ☐ Contraindicated ☐ Pt declined	☐ Rx ☐ Contraindicated ☐ Pt declined	☐ Rx ☐ Contraindicated ☐ Pt declined
Smoking Status Document dates of counseling	☐ Nonsmoker ☐ Smoker ☐ Counseled ____ ☐ InTx	☐ Nonsmoker ☐ Smoker ☐ Counseled ____ ☐ InTx	☐ Nonsmoker ☐ Smoker ☐ Counseled ____ ☐ InTx	☐ Nonsmoker ☐ Smoker ☐ Counseled ____ ☐ InTx
DSME Once or more/yr.	**Date referred:** _____		**Documentation on chart** yes / no	
Dilated and Comprehensive Eye Exam Document date of exam yearly	**Report on chart** yes / no Eye Doctor: _____ D.O.S. ___/____/____			
Foot Exam Yearly (more frequently for those with one or more high risk foot conditions; for patients with neuropathy, each visit (-) cannot feel the monofilament (+) can feel the monofilament	R L  **Amputation R L**	R L  **Amputation R L**	R L  **Amputation R L**	R L  **Amputation R L**
Vaccinations	**Pneumonia Vaccine** Date: ___/____/____		**Influenza Vaccine** Date: ___/____/____	
Doctor must initial D.O.S.	**Initial**_____	**Initial**_____	**Initial**_____	**Initial**_____

This diabetes management guide is based on the American Diabetes Association's "Standards of Medical Care For Patients with Diabetes Mellitus".

OH-P-212 MI-P-166
September 2009

CareSource

October 14, 2009

Re: CareSource Fraud, Waste and Abuse Program

Dear CareSource Provider:

It is important for you to know that CareSource has a comprehensive program designed to detect, investigate, mitigate, prevent, prosecute, and report fraud, waste and abuse. Please pass the following information on to all your employees, contractors, and agents handling CareSource business. They must be aware of the CareSource Fraud, Waste, and Abuse Program, the False Claims Act, and how to report any concerns they may have.

Definitions

Fraud is defined as "An intentional deception or misrepresentation made by a person with the knowledge that the deception could result in some unauthorized benefit to himself or some other person. It includes any act that constitutes fraud under applicable federal or state law." (*42 CFR part 455.2*)

Abuse is defined as "Provider practices that are inconsistent with sound fiscal, business, or medical practices, and result in an unnecessary cost to the Medicaid program, or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for health care. It also includes recipient practices that result in unnecessary costs to the Medicaid program." (*42 CFR part 455.2*)

Types of Fraud, Waste, and Abuse
Fraud, waste, and abuse comes in all forms. The following are some examples:

Provider Issues:

- Billing for medically unnecessary services and prescription drugs.
- Up-coding CPT and DRG codes to obtain a higher rate of reimbursement.
- Inappropriate use of CPT codes and/or modifiers to seek higher reimbursement.
- Not checking member IDs resulting in claims submitted for non-covered persons.
- Billing for services not rendered.
- Balance billing of members for any balance owed after CareSource has paid the approved state fee for services rendered.

Member Issues:

- Inappropriate use of Medicaid/Medicare purchased narcotics.
- Forging prescriptions to obtain controlled substances.
- Sharing CareSource ID cards with nonmembers.
- Submitting fraudulent Babies First Coupons for prenatal and well-baby visits (Medicaid Only)

Company/Employee/Delegated Entities Issues:

- Embezzling CareSource funds.
- Misappropriation of CareSource assets.
- Stealing CareSource property.
- Preventing members from accessing covered services resulting in underutilization of services offered.

If, in working with CareSource, you identify fraud, waste, or abuse, please contact our Special Investigations Unit using the contact information in this letter. You may report your concern **anonymously**. All reports are **confidential** to the extent permitted by law.

The Federal and State False Claims Acts

The Federal False Claims Act
Using the False Claims Act (the Act); you can help reduce fraud against the federal government. The Act allows everyday people to bring "whistleblower" lawsuits on behalf of the government- known as "qui tam" suits- against businesses or other individuals that are defrauding the government through programs, agencies, or contracts.

As amended in 2009, the False Claims Act addresses those who:

a) Knowingly presents , or causes to be presented, a false or fraudulent claim for payment or approval;
b) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
c) Conspires to commit a violation of any other section of the False Claims Act;
d) Has possession, custody or control of property or money used , or to be used, by the Government and knowingly delivers, or causes to be delivered, less than all of that money or property;
e) Is authorized to make or deliver a document certifying receipt of property used, or to be used by the Government and, intending to defraud the Government, makes or delivers the receipt without completely knowing that the information on the receipt is true;
f) Knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the Government, or a member of the Armed Forces, who lawfully may not sell or pledge property; or
g) Knowingly makes, used, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.

Additional information on the False Claims Act and our fraud, waste, and abuse policies can be found on our website, www.caresource.com.

The Deficit Reduction Act of 2005
The Deficit Reduction Act of 2005 (DRA) contains many provisions reforming Medicare and Medicaid that are designed to reduce program spending. As an entity that offers Medicaid and Medicare coverage, CareSource is required to comply with certain provisions of the DRA. One such provision prompted this communication, as it requires us to provide you with information about the Federal False Claims Act, state False Claims Acts, and other state laws regarding Medicare and Medicaid Fraud. **In addition, the DRA requires you and your contractors and agents to adopt our policy on fraud, waste, and abuse when handling CareSource business.**

Ohio Law
While Ohio has not passed its own false claims statute, there may nevertheless be liability under various Ohio laws regarding false or fraudulent claims with respect to Medicaid program expenditures, including:

- Medicaid Fraud, Ohio Revised Code Sec. 2913.40
- Medicaid Eligibility Fraud, Ohio Revised Code Sec. 2913.401
- Falsification, Ohio Revised Code Sec. 2921.13
- Offenses by Medicaid Providers, Ohio Revised Code Sec. 5111.03

Other Fraud, Waste, and Abuse Laws
- Under the **Federal Anti-Kickback Statute**, and subject to certain exceptions, it is a crime for anyone to knowingly and willfully solicit or receive, or pay anything of value, including a kickback, bribe, or rebate in return for referring an individual to a person for any item or service for which payment may be made in whole or in part under a Federal health care program. 42 U.S.C. §1320a-7b.

- Under the **Federal Stark Law**, and subject to certain exceptions, physicians are prohibited from referring federal health care program patients for certain designated health services to an entity with which the physician or an immediate family member has a financial relationship. The Stark Law imposes specific reporting requirements on entities that receive payment for services covered by Federal health care programs. 42 U.S.C. §1395(a) and §1903(s).

- As part of the **Health Insurance Portability and Accountability Act (HIPAA)**, the U.S. Criminal Code was amended, and it is a crime to knowingly and willfully execute, or attempt to execute a scheme or artifice to defraud any Federal health care program or obtain by means of false or fraudulent pretenses, representations or promises, any money or property owned by or under the custody or control of any Federal health care program. 18 U.S.C. §1347.

Prohibited Affiliations
CareSource is prohibited by federal and/or provider agreements (with the state) from knowingly having relationships with persons who are debarred, suspended, or otherwise excluded from participating in federal procurement and non-procurement activities. Relationships must be terminated with any trustee, officer, employee, provider or vendor who is identified to be debarred, suspended, or otherwise excluded from participation in federal or state health care programs. If you become aware that you are a prohibited affiliation, you need to notify us immediately.

Protections for Reporters of Fraud, Waste, or Abuse
In addition, federal and state law and CareSource's policy prohibit any retaliation or retribution against persons who report suspected violations of these laws to law enforcement officials or who file "whistleblower" lawsuits on behalf of the government. Anyone who believes that he or she has been subject to any such retribution or retaliation should also report this to the Special Investigations Unit.

Fraud, Waste, or Abuse Reporting Process
It is CareSource's policy to detect and prevent any activity that may constitute fraud, waste, or abuse, including violations of the federal False Claims Act or any state Medicaid fraud laws. If you have knowledge or information that any such activity may be or has taken place, please contact our Special Investigations Unit using the contact information in this letter. Information may be reported anonymously.

CareSource Special Investigations Unit Contact Information

Anonymously:

- **Fraud Hotline**: 800-488-0134 and follow the prompts for reporting Fraud
- **Fraud Fax:** 800-418-0248
- **Written Report:** Use the Fraud, Waste, and Abuse Reporting Form on the Website at www.caresource.com

  Send to: CareSource
  Attn: Special Investigations Unit
  P.O. Box 1940
  Dayton, OH 45401-1940

Another way to report fraud, waste, and abuse that is not anonymous:

- **Fraud E-Mail**: fraud@caresource.com

All reports are **confidential** to the extent permitted by law.

Thank you for your help in the fight against health care fraud, waste, and abuse.

Drugs

Fact and Myths about Generic Drugs

Today, 7 in 10 prescriptions filled in the United States are for generic drugs. This fact sheet explains how generic drugs are made and approved and debunks some common myths about these products.

FACT: FDA requires generic drugs to have the same quality and performance as the brand name drugs.

- When a generic drug product is approved, it has met rigorous standards established by the FDA with respect to identity, strength, quality, purity and potency. Some variability can and does occur during manufacturing, for both brand name and generic drugs. When a drug, generic or brand name, is mass produced, very small variations in purity, size, strength and other parameters are permitted. FDA puts limits on how much variability in composition or performance of a drug is acceptable.
- Generic drugs are required to have the same active ingredient, strength, dosage form, and route of administration as the brand name (or reference) product. Generic drugs do not need to contain the same inactive ingredients as the brand product.
- Through review of bioequivalence data, FDA assures that the generic product will perform the same as its respective brand name (or reference) product. This standard applies to all generic drugs, whether immediate or controlled release.
- A generic drug must be shown to be bioequivalent to the reference drug; that is, it must be shown to give blood levels that are very similar to those of the reference product. If blood levels are the same, the therapeutic effect will be the same. In that case, there is no need to carry out a clinical effectiveness study and they are not required.
- All generic manufacturing, packaging and testing sites must pass the same quality standards as those of brand name drugs and the generic products must meet the same exacting specifications as any innovator brand name product. In fact, many generic drugs are made in the same plants as innovator brand name drug products.
- If an innovator of a brand name drug switches drug production to an alternative manufacturing site, or they change formulation of their brand name drug, these companies are held to the same rigorous manufacturing requirements as those that apply to generic drug companies.

FACT: Research shows that generics work just as well as brand name drugs.

- A recent study evaluated the results of 38 published clinical trials that compared cardiovascular generic drugs to their brand-name counterparts. There was no evidence that brand-name heart drugs worked any better than generic heart drugs. [Kesselheim et al. Clinical equivalence of generic and brand-name drugs used in cardiovascular disease: a systematic review and meta-analysis. JAMA. 2008;300(21)2514-2526].

FACT: When it comes to price, there is a big difference between generic and brand name drugs. On average, the cost of a generic drug is 80 to 85% lower than the brand name product.

- An IMS National Prescription Audit shows that a typical formulary now charges $6 for generic

medications, $29 for preferred branded drugs, and $40 or more for non-preferred branded drugs. [Aitken et al. Prescription drug spending trends in the United States: looking beyond the turning point. Health Aff (Millwood). 2009;28(1):w151-60].

- Independent research has shown that total prescription drug expenditures in the United States only increased by 4.0% from 2006 to 2007, with total spending rising from $276 billion to $287 billion. This is a sharp decrease from the 8.9% growth rate observed in prescription drug expenditures in 2006. One factor cited as a reason for the slowdown is an increase in availability and use of generic drugs [Hoffman et al. Projecting future drug expenditures--2009. Am J Health Syst Pharm. 2009;66(3):237-57].

Recently, misinformation in the media has raised concerns over generic drugs. Below are some common myths in circulation.

MYTH: FDA lets generic drugs differ from the brand name counterpart by up to 45 percent.

FACT: This claim is false. Anyone who repeats this myth does not understand how FDA reviews and approves generic drugs.

- FDA recently evaluated 2,070 human studies conducted between 1996 and 2007. These studies compared the absorption of brand name and generic drugs into a person's body. These studies were submitted to FDA to support approval of generics. The average difference in absorption into the body between the generic and the brand name was **only 2.3 percent.** Some generics were absorbed slightly more, some slightly less. This amount of difference would be expected and acceptable, whether for one batch of brand name drug tested against another batch of the same brand, or for a generic tested against a brand name. In fact, there have been studies in which branded drugs were compared with themselves as well as with a generic. As a rule, the difference for the generic-to-brand comparison was about the same as the brand-to-brand comparison.
- Any generic drug modeled after a single, brand name drug (the reference) must perform approximately the same in the body as the brand name drug. There will always be a slight, but not medically important, level of natural variability – just as there is for one batch of brand name drug to the next.

MYTH: People who are switched to a generic drug are risking treatment failure.

FACT: There is no evidence for this claim. Treatment failures can and do occur when taking generic or brand name drugs. If someone is switched to a generic drug around the time they are relapsing, they may attribute the problem to the switch.

- Many people who have recovered from major depression have a relapse despite continued treatment. These relapses have been shown in trials of long-term therapy. [Byrne and Rothschild. Loss of antidepressant efficacy during maintenance therapy: possible mechanisms and treatments. J Clin Psychiatry. 1998;59(6):279-88].
- Many people who are on a seizure medications will re-experience a seizure despite continued treatment on a single drug. The likelihood of re-experiencing a seizure, despite staying with the same drug product, goes up with time. [Brodie et al. Comparison of levetiracetam and controlled-release

carbamazepine in newly diagnosed epilepsy. Neurology. 2007;68(6):402-8].

- A percentage of people will re-experience gastric ulcers, despite an initial, positive response to and continued treatment with prescription strength antacids (cimetidine tablets; http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?id=8131#nlm34067-9).

MYTH: Generic drugs cost less because they are inferior to brand name drugs.

FACT: Generic manufacturers are able to sell their products for lower prices, not because the products are of lesser quality, but because generic manufacturers generally do not engage in costly advertising, marketing and promotion, or significant research and development.

- When a brand name drug comes off patent and generic drugs are permitted to compete with the brand name drug, the generic products compete by offering lower prices. Unlike the manufacturers of brand name drugs, generic drug companies do not have significant expenses to recoup for advertising, marketing and promotion, or research and development activities.

MYTH: There are quality problems with generic drug manufacturing. A recent recall of generic digoxin (called Digitek) shows that generic drugs put patients at risk.

FACT: FDA's aggressive action in this case demonstrates the high standards to which all prescription drugs – generic and brand name – are held.

- In March 2008, FDA performed a scheduled inspection of the Actavis production facility and identified products that were not manufactured to required specifications over a period of time extending back to the year 2006. Included in this list of products was one particular lot of Digitek.
- Actavis detected a very small number of oversized tablets in this lot (specifically, 20 double-sized tablets in a sample of approximately 4.8 million tablets).
- Although Actavis attempted to remove the affected Digitek tablets through visual inspection, FDA determined that this method of removal was inadequate to assure the product's quality and consistency in accordance with the current Good Manufacturing Practice (cGMP) regulations.
- Since the detection of the manufacturing problem, FDA has been actively engaged with this company to ensure that **ALL** potentially affected lots of Digitek tablets have been recalled. In our best judgment, given the very small number of defective tablets that may have reached the market and the lack of reported adverse events before the recall, harm to patients was very unlikely.
- FDA takes action whenever we find that a drug manufacturer is not following cGMPs. Over the last ten years, FDA has taken enforcement action against many brand name and generic firms for failing to meet FDA manufacturing quality standards.

MYTH: FDA's enforcement action against the generic drug company Ranbaxy demonstrates quality problems with imported generic drugs.

FACT: FDA's action demonstrates FDA's commitment to safe generic drugs.

- FDA has taken several regulatory actions against the generic drug manufacturer Ranbaxy, on the basis of problems at two of Ranbaxy's manufacturing facilities. Ranbaxy is one of many non-U.S. based generic and brand drug manufacturers.

- On Sept. 2008, the FDA issued two warning letters and instituted an Import Alert barring the entry of all finished drug products and active pharmaceutical ingredients from Ranbaxy's Dewas, Paonta Sahib and Batamandi Unit facilities due to violations of U.S. cGMP requirements. That action barred the commercial importation of 30 different generic drugs into the United States and remains in effect today (http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm149
- Subsequent FDA investigations also revealed a pattern of questionable data raising significant questions regarding the reliability of certain generic drug applications from Ranbaxy.
- To address the allegedly falsified data, the FDA has invoked its Application Integrity Policy (AIP) against the Paonta Sahib facility. When the AIP is implemented, the FDA stops all substantive scientific review of any new or pending drug approval applications that contain data generated by the Paonta Sahib facility. This AIP covers applications that rely on data generated by the Paonta Sahib facility only.
- In the fiscal year 2008, FDA performed 2,221 drug-related inspections. FDA takes many different enforcement actions, not just against generic drug manufacturers. For a list of enforcement actions in the fiscal year 2008, see http://www.fda.gov/downloads/ICECI/EnforcementActions/EnforcementStory It is FDA's responsibility to ensure that the drugs people use, generic or brand name, are safe and effective.

MYTH: Brand name drugs are safer than generic drugs.

FACT: FDA receives very few reports of adverse events about specific generic drugs. Most reports of adverse events are related to side effects of the drug ingredient itself.

- The monitoring of postmarket adverse events for all drug products, including generic drugs, is one aspect of the overall FDA effort to evaluate the safety of drugs after approval. In most cases, reports of adverse events generally describe a **known reaction** to the active drug ingredient.

MYTH: FDA does not care about concerns over generic drugs.

FACT: FDA is actively engaged in making all regulated products – including generic drugs – safer.

- We are aware that there are reports noting that some people may experience an undesired effect when switching from brand name drug to a generic formulation or from one generic drug to another generic drug. Evidence indicates that if problems with interchangeability of drug formulations occur, they occur only for a very small subset of people.
- FDA is encouraging the generic industry to investigate whether, and under what circumstances, such problems occur. The Agency does not have the resources to perform independent clinical studies, and lacks the regulatory authority to require industry to conduct such studies. FDA will continue to investigate these reports to ensure that it has all the facts about these treatment failures and will make recommendations to healthcare professionals and the public if the need arises.