

## EFFECTIVE COMPLIANCE PROGRAMS

Community Care developed its Compliance Program in accordance with the Office of Inspector General's Guidelines for effective Compliance Programs. Providers interested in learning more about Compliance Programs as well as obtaining assistance for developing their own programs can access this material on the web at: <http://oig.hhs.gov/fraud/complianceguidance.html>.

During the past seven years, our department has conducted trainings for Providers that outline the basic concepts of Compliance, promote awareness of initiatives that are currently being developed by the state and federal governments, and finally, provide objective information related to the regulations that must be followed by all providers in order to be reimbursed for services. This article will serve to reinforce those trainings and provide another vehicle for dissemination of the information for those who were unable to attend one of our trainings.

### *Exploding Health Care Costs*

It is estimated that the government loses between \$80-100 billion each year as a result of fraud and abuse. Our National spending on health care has risen to more than \$1 trillion each year. Of special interest to all of us working with HealthChoices is the fact that Medicaid program spending rose from \$3.9 billion in 1968 to more than \$300 billion in 2005. These staggering figures have caused the federal government to significantly increase their resources in the area of fraud and abuse investigation. In addition, the federal government has charged the individual states with developing their own fraud and abuse special investigation units.

In the state of Pennsylvania, the Bureau of Program Integrity, charged with overseeing all Compliance

activity, has mandated all managed care organizations that hold HealthChoices contracts to maintain a comprehensive compliance program. This program includes monitoring all of the providers that receive medical assistance funding in order to ensure that all regulations are being met.

### *The Federal Deficit Reduction Act of 2005*

Community Care is obligated to inform all employees of the organization as well as their contracted providers and any business associates of the requirements set forth in the Deficit Reduction Act.

This act, signed into law in February 2006, mandates states to require entities who receive at least \$5 million in annual Medicaid payments to establish specific written policies regarding the entity's procedures for detecting and preventing fraud, waste, and abuse. Section 6032 of the Act requires that as a condition of payment, each entity shall:

- Establish written policies for all employees of the entity and any contractors of the entity and provide information regarding the False Claims Act established under section 3729-3733 of Title 31
- Outline administrative remedies for false claims and statements under Chapter 38 of Title 31
- Educate employees about Whistleblower protection under such laws

The Federal False Claims Act was signed by President Lincoln in 1863 in order to make it illegal to present, or cause to be presented, a claim to the federal government for payment when the person or entity submitting a claim knows that the claim is false. In 1986, an amendment was made to the Act that included claims submitted to the government by the Healthcare industry. The False Claims Act also establishes liability

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for any person who knowingly presents or causes to be presented with a false or fraudulent claim to the U.S. government for payment. “Knowingly” is defined by the federal government as a person who:

- Has actual knowledge of falsity of information in the claim
- Acts in deliberate ignorance of the truth or falsity of the information in a claim
- Acts in reckless disregard of the truth or falsity of the information in a claim

The act does not require proof of a specific intent to defraud the U.S. government. Instead, health care providers can be prosecuted for a wide variety of conduct that leads to the submission of fraudulent claims to the government, such as knowingly making false statements, falsifying records, double-billing for items or services, submitting bills for services never performed or items never furnished, or otherwise causing false claims to be submitted.

## *False Claims Act Violations*

The False Claims Act allows for both government and individuals to file suit against the alleged wrong doer on behalf of the United States. Health care providers and suppliers who violate the False Claims Act can be subject to:

- Civil monetary penalties ranging from \$5,500 to \$11,000 for each false claim submitted
- Paying three times the amount of damages sustained by the U.S. government
- Exclusion of the provider or supplier from participation in federal health care programs
- Imprisonment from 5 to 10 years respectively.

## *Pennsylvania’s Whistle Blowers Law*

Under the law all employees and associates of Community Care have a responsibility to report in good faith any instances of wrongdoing to appropriate authorities without fear of retaliation.

## *Community Care’s Provider Auditing Process*

The Compliance Department is responsible for ensuring that all Providers delivering services to our HealthChoices members are adhering to federal and state regulations. When conducting an audit, the primary resource used by the auditors is the General Provisions for MA Programs, Established by Title 55 Chapter 1101 of the Pennsylvania Code. The scope is clearly defined in the language of the regulation ---“This chapter sets forth the MA regulations and policies which apply to **all providers**. Regulations specific to each type of provider are located in the separate chapters relating to each provider type.

In addition to Chapter 1101 of the PA Code, any DPW issued bulletins that apply to the program being reviewed are used during the auditing process. Contractual agreements, including fee schedules, and previously submitted corrective action plans are all a part of the audit review process.

## *What auditors look for when conducting an audit:*

- Does the documentation substantiate the claim (i.e., does the progress note clearly outline the interventions that were used during the session)?
- Did the provider bill for the time actually spent providing treatment with the member?
- Does the documentation reflect that services provided meet the service definitions, performance specifications and state and federal regulations?
- Is there missing documentation?
- Is there an inappropriate rounding-up of units?
- Is there a falsification of services/credentials?

Community Care’s Compliance Department is always available to assist providers with questions or concerns surrounding any compliance issue. In addition, trainings are offered to providers in order to ensure that all regulations are being followed and that services are being delivered appropriately.

# TAMPER-RESISTANT PRESCRIPTION PADS

**UPDATE:** *An outpouring of advocacy resulted in Congress's vote to delay the implementation of Centers for Medicare & Medicaid requirement for the use of tamper-proof prescription pads for Medicaid beneficiaries. On September 26, 2007, the House passed legislation extending several health care programs set to expire. Included in the bill is a provision that delays the tamper resistant prescription pad requirement for 6 months. The Senate passed their version and the measure now goes before President Bush, who is expected to sign the bill into law. The new implementation date would be April 1, 2008.*

Beginning October 1, 2007, handwritten prescriptions for Medicaid outpatient drugs, including over-the-counter medications, will only be reimbursable if written on a tamper-resistant prescription pad. To be considered tamper resistant on October 1, 2007, a prescription pad must contain at least one or more industry-recognized feature to prevent the following:

- 1) Unauthorized copying of a completed or blank prescription form
- 2) Erasure or modification of information written on the prescription by the provider
- 3) Use of counterfeit prescription forms

Beginning October 1, 2008, tamper-resistant pads must contain features to address all three of the above items.

## Key Items

The following are exempt from the tamper-resistant requirement:

- Prescriptions that are paid for by a managed care organization (such as UPMC for You, Gateway, Unison, etc).
- Verbal, faxed or electronic prescriptions
- Inpatient hospital services

- Refills of written prescriptions presented at a pharmacy before October 1, 2007
- Medications that are provided directly to the MA recipient by the prescriber

The following are required to adhere to the tamper-resistant guidelines:

- Handwritten outpatient prescriptions for Medicaid recipients who participate in the State Medicaid (Fee-for-Service) pharmacy program regardless of whether Medicaid is the primary or secondary payer of the prescription.
- All MA recipients handwritten outpatient prescriptions including hospital discharge, partial hospitalization, outpatient drug and alcohol clinic and independent medical clinics.

## Other Key Items:

- If the prescription does not comply with the above requirements, the pharmacist may provide the prescribed drug if the MA recipient has an immediate need for the drug. However, the pharmacist must obtain a written compliant tamper-resistant prescription, a verbal order, a facsimile or an electronic prescription within 72 hours of the drug dispense date.
- The Medical Assistance program will not pay for the tamper-resistant prescription pads. A list of approved printers/suppliers is located at: <http://www.dpw.state.pa.us/General/Bulletins/003673169.aspx?AttachmentId=4093>.
- For DPW's FAQ website regarding this information: [http://www.dpw.state.pa.us/Resources/Documents/Pdf/QAs\\_Tamper\\_Resistant\\_091707.pdf](http://www.dpw.state.pa.us/Resources/Documents/Pdf/QAs_Tamper_Resistant_091707.pdf).

We hope you find this information useful; we will keep you apprised of any changes.

# IMPROVING SERVICES

Every county served by Community Care has a consumer and family satisfaction team that works to find ways to improve services for behavioral health consumers. The teams, which consist of people in recovery or family members of someone in recovery, conduct confidential interviews with consumers about their mental health and/or drug and alcohol treatment services. Using feedback from these interviews, Community Care works with providers to improve consumer satisfaction. **Providers are asked to encourage members to consent to being interviewed.**

## LABEL UPDATES

On October 5, 2007, Eli Lilly sent a letter to Health Care Professionals informing them of important information being added to the Zyprexa and Symbyax labels. These updates include new warnings for weight gain and hyperlipidemia and an updated warning for hyperglycemia. Significantly greater increases in cholesterol and triglycerides have been observed with olanzapine use and weight gain may continue in olanzapine-treated patients for over two years. Olanzapine also appears to have a greater association with increased glucose levels than some other atypical antipsychotics. Monitoring of glucose, weight, and lipids is recommended during treatment. For more information on the recommended guidelines, physicians can refer to the Consensus Development Conference on Antipsychotic Drugs and Obesity and Diabetes cited below.

### References:

October 2007 Important Zyprexa Labeling Changes. Zyprexa for Healthcare Professionals web site. Available at: [http://www.insidezyprexa.com/pdf/Dear\\_HCP\\_Letter.pdf](http://www.insidezyprexa.com/pdf/Dear_HCP_Letter.pdf).

Consensus Development Conference on Antipsychotic Drugs and Obesity and Diabetes. *Diabetes Care*. 2004; 27:596-601. Available at: <http://care.diabetesjournals.org/cgi/content/full/27/2/596>.

## ANTI-DEPRESSANTS AND GASTROINTESTINAL BLEEDS

New research published in October's issue of *Alimentary Pharmacology and Therapeutics* shows that selective serotonin reuptake inhibitors (SSRIs) may double the risk of gastrointestinal bleeding. When these drugs are taken with aspirin and other similar pain medications, the risk is more than 600 percent higher.

The researchers pooled data from four studies involving 153,000 patients, which allowed them to detect effects that might not show up in the individual studies. They found patients taking SSRIs were nearly twice as likely to develop upper GI bleeding than patients not taking the drugs. When the patients also took nonsteroidal anti-inflammatory drugs (NSAIDs), the risk of upper gastrointestinal bleeding was six times higher than in patients taking neither medication. The authors said the combined use of NSAIDs and SSRIs may have a synergistic effect, which results in the elevated risk of bleeding beyond that seen with each agent alone. NSAIDs include prescription medications such as Celebrex® and over-the-counter drugs such as aspirin and Aleve.

Based on their findings, the authors estimate that for every 411 patients over age 50 taking SSRIs, one is likely to develop upper GI bleeding requiring hospital admission. In patients taking both SSRIs and NSAIDs, one out of 82 would be expected to develop the problem. Particularly vulnerable are older adults because they are most likely to have conditions such as osteoarthritis that require the use of NSAIDs. The research did not distinguish between specific drugs and whether one was associated with more bleeding than another. However, previous studies have shown that paroxetine (Paxil®), sertraline (Zoloft®) and fluoxetine (Prozac®) are most often associated with abnormal bleeding.

Providers and their patients should be aware of the potential risk with these medications and should consider alternatives when appropriate. These findings emphasize the importance of providers taking a detailed gastrointestinal history from patients and targeting the use of SSRIs to patients who are at relatively low risk for upper GI bleeding.

FIRST SIGNS, a national non-profit organization dedicated to educating parents and pediatric professionals about the early warning signs of autism and other developmental disorders, is pleased to announce the launch of the ASD Video Glossary. Developed in collaboration with Autism Speaks and Florida State University's FIRST WORDS Project, the glossary helps parents of children recently diagnosed with autism better understand some of the words and terms used in association with autism. A useful resource for providers, the ASD Video Glossary can be accessed at [www.autismspeaks.org](http://www.autismspeaks.org), [www.firstsigns.org](http://www.firstsigns.org), or <http://firstwords.fsu.edu>. We hope you will recommend the site to HealthChoices members and your colleagues.