

# Clinical Compliance Plan

Updated September 2009

## Section 1: Introduction

### A. Scope

This compliance plan addresses the compliance issues related to the clinical care activities at Oregon Health & Science University (OHSU). Within the context of this plan, clinical care is defined as the provision or support of patient care (including patient care provided in the context of clinical trials) provided in an inpatient or outpatient setting, for which billing of a technical and/or professional fee typically occurs.

The clinical areas covered by this plan are under the auspices of or at the locations of OHSU, including OHSU Hospital; the Schools of Medicine, Dentistry and Nursing; and the Child Development and Rehabilitation Center (CDRC).

This plan augments OHSU's institution-level compliance plan, as defined in the OHSU Integrity *Roles & Responsibilities and Program Elements* (<http://www.ohsu.edu/cc/c3randr.pdf>) and OHSU policies and procedures (<http://ozone.ohsu.edu/policy/>). Because this plan addresses the unique compliance issues related to patient care, compliance issues covered at the institutional level are not readdressed in this plan.

Throughout this document the term “We” is used to refer to employees, agents, and others who provide or support patient care in any location.

### B. Purpose

We are committed to ethical principles and institutional values and compliance with laws and regulations as they relate to patient care. We recognize the privilege and responsibilities that come with providing patient care and the importance of accurate billing for patient care services.

### C. Guidance for the Clinical Compliance Plan

This plan is based on the “Compliance Program Guidance” from the Office of Inspector General (OIG), Department of Health and Human Services (DHHS), for:

- Hospitals issued February 1998 for hospital and clinic operations, followed by supplemental guidance in January 2005;
- Clinical Laboratories issued August 1998;
- Third-Party Medical Billing Companies issued November 1998; and
- Durable Medical Equipment, Prosthetics, Orthotics and Supply Industry issued July 1999.

In addition, this plan is based upon The Deficit Reduction Act of 2005 (DRA), signed in 2006.

These guidance documents are found at:

<http://oig.hhs.gov/fraud/complianceguidance.html> and

<http://www.ncsl.org/statefed/health/ReconDocs0206.htm>

#### **D. The Seven Elements of an Effective Compliance Program**

The OIG recommends in its compliance program guidance documents that comprehensive compliance programs should include the following seven elements:

1. Written Policies and Procedures;
2. Compliance Officer and Compliance Committee;
3. Training and Education;
4. Effective Lines of Communication;
5. Enforcing Standards through Well-Published Disciplinary Guidelines;
6. Auditing and Monitoring; and
7. Responding to Detected Offenses.

#### **E. Structure of the Plan**

This plan is based on the seven elements identified above and first addresses the compliance issues that are common to all clinical areas, activities, and providers at OHSU. This plan also addresses the additional compliance issues that pertain to:

- Professional/provider services;
- Facility/hospital services; and
- Clinical laboratory services. and

Dental services

## **Section 2: Clinical Compliance Issues for All Services**

### **A. Quality Patient Care**

We provide high quality patient care that meets professionally recognized standards of health care.

We provide emergency services in accordance with Emergency Medical Treatment and Active Labor Act (EMTALA) regulations.

### **B. Licensure and Certification**

We provide services within the limits of licensure, certification, and privileges as applicable for each provider.

### **C. Privileging, Credentialing and Enrollment of Providers**

We verify credentials, evaluate applicant-specific information, and, if applicable, make recommendations to the Medical Board for appointment of medical staff membership and privileges in accordance with JCAHO standards, National Committee for Quality Assurance (NCQA) standards, and state and federal regulations.

We award clinical privileges that define the scope of practice for individual providers at OHSU in accordance with the individual's credentials, JCAHO and NCQA standards, Medical Staff policies, and state and federal requirements. We periodically reassess and reassign privileges to providers.

In order to receive reimbursement for an individual provider's clinical services, we enroll each provider with Medicare, Medicaid, and other third-party payers in accordance with applicable requirements.

### **D. HIPAA Privacy, Security, and Transactions and Code Sets**

We comply with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), American Recovery and Reinvestment Act of 2009, the Red Flag Rule, the Oregon Identity Theft Protection Act and other state and federal laws applicable to the privacy and security of individually identifiable health information.

## **E. Marketing**

We use marketing information that is clear, correct, and non-deceptive.

## **F. Patient's Freedom of Choice**

We honor each patient's freedom of choice in selecting his/her care providers (health care professionals, nursing homes, home health agencies, and durable medical equipment suppliers) without regard to our financial relationships or our receipt or provision of anything of value. The choice of a hospital, provider, diagnostic facility, equipment supplier, or any other health care provider should be made by the patient, with guidance from his or her primary provider as to the facilities at which the provider maintains privileges and which other providers are qualified and medically appropriate, subject, of course, to the requirements of the patient's own personal circumstances and health insurance plans.

### **1. Self-Referral**

Section 1877 of the Social Security Act, also known as the "Stark law," prohibits a physician from referring a Medicare patient to an entity for certain "designated health services" if the physician has a "financial relationship" with the entity that bills Medicare, unless an exception applies. Some of the exceptions to this prohibition on referrals apply to the types of services provided pursuant to the referral, while other exceptions apply to the "financial relationship" between the physician and the entity billing Medicare.

The statute specifies two categories of "financial relationships:" (1) an ownership or investment interest in an entity and (2) a compensation arrangement, including employment compensation such as salaries and bonuses, between a physician and an entity.

Unless the OHSU Legal Department has determined that all conditions set forth in an exception to the Stark law have been met with respect to a particular arrangement between an OHSU physician (or that physician's immediate family member) and an entity, then (1) the OHSU physician (or immediate family member) who has a financial relationship with the entity may not make a referral of patients (which includes writing an order or establishing a plan of care) to that entity for the furnishing of designated health services for which payment otherwise may be made under Medicare; and (2) OHSU may not present or cause to be presented a claim to Medicare for designated health services furnished pursuant to a referral prohibited under (1). Even if the hospital-physician relationship qualifies for a Stark law exception, it will still be reviewed for compliance with the anti-kickback law.

## **2. Kickbacks**

We do not offer, pay, solicit, or receive any compensation in any form, either directly or indirectly, in return for referring or generating services or other business for which payment may be made under Medicare or other Federal Health Care Programs. OHSU employees do not accept or solicit any gift, favor, or service that might reasonably tend to influence the discharge of our official duties or that we know or should know is being offered with the intent to influence our official conduct. In certain specific and rare circumstances, vendors may pay for travel related to product or equipment use, upgrades, and training. For this situation and all others involving gifts, we comply with OHSU's policies regarding gifts: "Gifts to Individuals No. 10-01-025" and "Gifts to Institution, Schools, Units, Divisions, Departments, and Parts No. 10-01-030".

We assure that any remuneration flowing between our hospitals and physicians is consistent with fair market value for actual and appropriate items furnished or services rendered based upon arm's-length transactions without taking into account, directly or indirectly, the value or volume of any past or future referrals or other business generated between the hospitals and physicians.

## **3. Joint Ventures**

OHSU does not enter into or participate in joint ventures that are intended or designed to benefit financially from a stream of referrals from one of the joint venture parties and compensates joint venture participants for these referrals, particularly where the practical effect of the arrangement, viewed in its entirety, is to provide one party the opportunity to bill payers and patients for business otherwise provided by the other party while receiving remuneration from the venture that takes into account the value and volume of business referred by the party not otherwise in a position to bill for the identical services.

We secure prior approval by the OHSU Legal Department for joint ventures involving OHSU.

## **G. Patient/Third-party Coding and Billing**

Billing is performed by OHSU or UMG or, if by another third-party billing company, only after pre-approval of the company's compliance capabilities has been secured from the OHSU Clinical Compliance Committee (Patient Billings and Fees #09-10-005) on a case-by-case basis.

When an outside third-party billing company is used, the services will be covered in a written contract approved by the OHSU Legal Department.

## H. Billing and Coding for Clinical Services

We comply with all applicable federal and state healthcare billing laws and regulations.

We are committed to preventing fraud and abuse in billing and are responsible to submit only charges that are truthful and accurate, that reflect medically necessary or appropriate services, and that are fully supported by health care record documentation. Attention is given to submitting a correct claim for payment the first time.

We submit charges only when all of the following information is known to be correct: the identity of the patient, the date of service, the place of service, the service provided, the charge, and, if applicable, the name and identification of the individual who performed the service. We submit claims only for services actually performed.

We submit charges for payment only under the correct provider's name and do not give out or allow anyone else to use a provider's name to submit charges. We comply with applicable federal and state rules relating to reassignment of the right to receive reimbursement for health care services provided.

We code based on the documentation in the health care record, accurate narratives of codes (i.e. ICD-9, CPT, CDT, and HCPCS) and appropriate coding guidelines and requirements.

We obtain additional information needed from the provider to clarify an order or if we are unsure of the correct code to use.

We follow the medical necessity billing rules when billing Medicare.

We comply with Medicare's National Coverage Decisions and Local Coverage Decisions when billing for clinical services or clinical research services.

When a student is involved with patient care we assure both that the student's involvement is appropriate for the student's level of education, knowledge, and skills, and that the patient care given is appropriately supervised. In addition, if patient/third-party payer charges are submitted, we comply with applicable federal, state, and third-party payer requirements.

We do not charge more than once for the same service, inappropriately unbundle charges by submitting them in fragmented fashion to maximize reimbursement, or re-bill accounts automatically when payment is not received.

For clinical trials, we bill Medicare and/or other third-party payers for the medical care that would have been received regardless of the study ("standard of care") in accordance with Medicare and other third-party requirements. We bill the research sponsor for the medical care given because of the study ("study related care").

We do not provide financial incentives or encourage employees or third-party billing companies or other agents to either inflate the value of submitted claims or encourage a reduction in services provided to patients who participate in managed care programs.

We retain medical and other records as required.

We report any alleged violation of law, regulation or OHSU policy that affects the billing of clinical services promptly to appropriate management and/or an OHSU compliance officer.

OHSU management and its compliance officers assure that appropriate and expeditious remedial action is taken to correct bills when we become aware of inaccuracies or errors in bills that have been submitted for payment.

## **I. Federal False Claims Act**

The False Claims Act (FCA) is a federal statute that covers fraud involving any federally funded contract or program, including Medicare and Medicaid. The act establishes liability for any person who knowingly presents or causes to be presented a false or fraudulent claim to the government for payment. The act does not require proof of a specific intent to defraud the government.

The FCA permits a person with knowledge of fraud against the US Government, referred to as the "qui tam plaintiff," (whistleblower) to file a lawsuit on behalf of the government against the person or business that committed the fraud. If the action is successful the qui tam plaintiff is rewarded with a percentage (15-30%) of the recovery. Such persons filing a lawsuit are referred to as relators.

In addition to a financial reward, the FCA entitles whistleblowers to additional relief, including employment reinstatement, back pay, and any other compensation arising from retaliatory conduct against the whistleblower for filing an action under the FCA or committing other lawful acts, such as, investigating a false claim, providing testimony, or assisting in a FCA action.

OHSU has policies and information that discuss the detecting and preventing of fraud, waste, and abuse as well as the rights of employees to be protected as whistleblowers. This information can be found in various places including:

The OHSU Code of Conduct

Clinical Compliance Plan

Regulatory Compliance (#01-05-004)

CMS Medical Necessity (# ADM 1.62)

## **J. Waivers of Co-payments and Professional Courtesy or Other Discounts**

We do not waive patient co-payments or deductibles. We do not offer or allow professional courtesy. Discounts based on patient status are not permitted except as outlined for employees and immediate family members in the policy "Employee Discounts and Personal Use of Institutional Resources, No. 03-25-080." Instead, we give patients the opportunity to receive financial screening and decreased financial responsibility if financial need criteria are met.

## **K. Credit Balances**

We track credit balances in accordance with Medicare and other third-party payer requirements and we refund patients and/or third-party payers in a timely manner.

## **L. Compliance Officers and Compliance Committees**

We have dedicated clinical compliance officers in OHSU Healthcare and FPP. In addition, we have clinical compliance committees:

### **Clinical Compliance Committee**

The Clinical Compliance Committee meets quarterly (or more frequently, if needed) to address clinical compliance topics. The Chair of the committee is selected consistent with the Clinical Compliance Committee Charter. The Clinical Compliance officers of the Integrity Office staff the committee. Members include representatives from the Schools of Medicine, Nursing, and Dentistry; Hospital Administration; CDRC; and OHSU Legal Counsel (ex-officio). This committee is advisory to the Chief Integrity Officer.

### **Hospital Clinical Compliance Committee**

This subcommittee meets regularly to address hospital documentation, coding, billing, and education compliance issues that are of concern to OHSU Healthcare. The committee includes the Hospital Clinical Compliance Officer, Assistant Integrity Officers for Healthcare, Director of PBS, Director of the Clinical Research programs, Director HIM, Reimbursement Manager for HFS, Senior Manager for Clinical Research Billing, and the Manager of Medicare and Medicaid PBS. Legal counsel is ex-officio.

### **Faculty Practice Plan Clinical Compliance Committee**

The Faculty Practice Plan Clinical Compliance Committee is an oversight group for clinical compliance issues related to OHSU professional services. The Committee is advisory to both the Clinical Compliance Officer for Professional Services and to

the OHSU Clinical Compliance Committee. The committee meets quarterly and addresses issues related to professional services in regards to documentation, coding, and billing accurately for services performed and billed by OHSU clinicians. The Committee also provides oversight to the development and implementation of an educational program.

## **M. Training and Education**

New Healthcare employees are required to complete training for Compliance, HIPAA, and Respect in the Workplace.

New clinically active physicians, house officers, and other practitioners who are eligible to bill for their services as independent practitioners are required to complete Fraud Awareness Training, HIPAA compliance training that is applicable to their roles, and Respect in the Workplace. Employees may also be required to complete compliance education that is specific to their roles, such as for billing and coding.

All required initial and periodic ongoing compliance training is a condition of employment.

## **N. Compliance Program Updates and Effectiveness Reviews**

We stay current with changes in laws, rules, and third-party requirements and modify the compliance program as needed to conform to changing requirements.

We periodically measure and report on the effectiveness of the compliance program and develop enhancements to the compliance program.

## **Section 3: Additional Clinical Compliance Issues**

In addition to the above common compliance issues, professional services, facility/hospital, clinical laboratory services, and dental services have additional compliance issues:

### **A. Professional Services**

We know and follow Medicare and Medicaid's "Teaching Physician Rules" for charges submitted for services rendered by physicians when they are supervising or working in conjunction with residents and fellows. As physicians, we document in the medical record our presence or participation in the key portion of any service or procedure for which payment is sought. (Medicare Claims Processing Manual, 100-04, Chapter 12, Physician/Practitioner Billing, Section 100 - Teaching

Physician Services, <http://www.cms.hhs.gov/manuals/downloads/clm104c12.pdf>)

We follow published Centers for Medicare & Medicaid Services (CMS) guidelines for medical record documentation when providing evaluation and management (E&M) services.

We follow applicable billing requirements when we submit charges for other services provided by other practitioners such as nurse practitioners (NPs), physician assistants (PAs), and certified nurse specialists (CNSs), including, but not limited to, rules governing the reimbursement of services provided “incident to” physician services.

In addition to the corrective and disciplinary actions described in the OHSU Integrity ***Roles & Responsibilities and Program Elements***, corrective action may also include the following: a requirement that billing be handled in a designated way or that billing responsibility be reassigned; a requirement that restrictions be imposed on billing by particular care providers; and/or a requirement that repayment be made and that the matter be disclosed externally.

## **B. Facility/Hospital**

We recognize and address the unique billing compliance risks that are associated with hospital care in all patient care settings, including inpatient, outpatient, day patient, observation, and emergency room. For example:

- We follow the Medicare requirements regarding the inpatient prospective payment system (IPPS). We appropriately bill for discharge in lieu of transfer, observation, same day discharges and readmissions, and outpatient services rendered in conjunction with an inpatient stay.
- We follow the Medicare requirements for the outpatient prospective payment system (OPPS). For example, we bill appropriately for pass-through drugs and supplies; we do not bill on an outpatient basis for “inpatient only” procedures; we use appropriate modifiers for multiple procedures; and we conform to the “same day” rules to include on the same claim all outpatient services provided to the same patient on the same day.

We comply with Medicare and Medicaid cost reports requirements. For example, we provide accurate and auditable data to support the reimbursement components of bad debt, direct medical education (DME), indirect medical education (IME), disproportionate share hospital (DSH), and organ acquisition. In addition, we follow Medicare cost finding principles to accumulate and report patient care costs.

We keep the Charge Description Master (EAP) up-to-date and accurate. We maintain accurate service descriptions matched to correct CPT, HCPCS, and revenue codes. Before adding new services to the EAP we determine if the service is part of the facility charge, is billable and is appropriately bundled, and is in accordance with Medicare and other third-party payer requirements.

We report bad debts to Medicare in conformance with federal regulations and guidelines.

We follow Medicare guidelines regarding the write off of small balances for Medicare patients and we follow other third-party payer requirements and our internal policies for small balances.

We include compliance as an element of employee position descriptions and performance appraisals for Hospital employees.

### **C. Clinical Laboratories**

Laboratory services for OHSU patients are provided by OHSU laboratories and by outside laboratories through contracts and referral arrangements pre-approved by the medical director of the OHSU Pathology Department or the Division of Laboratory Medicine. When OHSU obtains laboratory services from a laboratory outside OHSU, we assure that the outside laboratory is certified at the appropriate level of complexity in compliance with the Clinical Laboratory Improvement Amendment (CLIA) regulations.

We recognize and address the unique compliance issues of clinical laboratories:

- We identify for ordering physicians situations where reflex or confirmatory testing might be performed.
- We follow the policy “Standing Orders, Clin. 01.33” of the Clinical Policy Manual.
- We adhere to the OIG Compliance Guidance for Clinical Laboratories of 1998.

### **D. Dental Services**

We follow applicable billing requirements when submitting charges to third-party payers for services provided by faculty practitioners, residents, and predoctoral dental students. We bill third-party payers utilizing the American Dental Association (ADA) Code on Dental Procedures and Terminology and the ADA dental claim form format. We meet all the standards of and maintain full accreditation by the ADA Commission on Dental Accreditation.

## **Section 4: Reporting of Regulatory and External Reviews**

It is the obligation of all OHSU employees to report to the OHSU Integrity Office any regulatory or external reviews that occur as soon as the employee becomes aware of the review. The OHSU Integrity Office will then work with the necessary departments and individuals to handle and respond to the review appropriately and timely.

## **Section 5: Compliance Certification and Reporting Compliance Concerns**

Employees report any suspected or known non-compliance to a manager, supervisor, department head, or the OHSU Integrity Office. Managers, supervisors, or department heads who receive such reports notify the OHSU Integrity Office. Employees may report non-compliance concerns anonymously via a toll-free Hotline. Retaliation are not acceptable behavior against individuals for the reporting of a concern made in good faith. Upon request of the Integrity Office, Department Directors and other key individuals certify that they have addressed and/or resolved known compliance concerns.

## **Section 6: Employee Corrective Action**

Instances of non-compliance are evaluated on a case-by-case basis and progressive, appropriate, and consistent corrective action is based on the facts and circumstances surrounding the conduct. Corrective action for noncompliance may result in education, loss of privileges, termination of relationships with OHSU, or other administrative, judicial, contractual, managerial, or other mechanism available to OHSU to secure compliance.

## **Section 7: Updates and Questions**

The OHSU Clinical Compliance Plan is designed to provide an overview of the clinical compliance program at OHSU. It is updated periodically to reflect updates or changes to our clinical compliance program. If you have any questions or comments regarding this document, please contact the OHSU Integrity Office at 503-494-2133 or toll free at 1-877-733-8313.