

Clinical Compliance Plan

updated Dec 2006

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 and OHSU Medical Group (OHSUMG), including OHSU Hospitals and Clinics (H&C); 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,
- Durable Medical Equipment, Prosthetics, Orthotics and Supply Industry issued July 1999
- 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 services,
- facility/hospital services,
- 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 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 for medical staff membership and privileges in accordance with JCAHO standards, National Committee for Quality Assurance (NCQA) standards, 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, 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) and other state and federal law 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 (physicians, 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, physician, diagnostic facility, equipment supplier, or any other health care provider should be made by the patient, with guidance from his or her physician as to which facilities the physician maintains privileges and which 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) that 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, OHSUMG or, if by another third-party billing company, only after pre-approval of the companies 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 medical 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 charge for outpatient services using the correct place of service as either outpatient hospital setting or office setting.

We code based on the documentation in the medical record, accurate narratives of codes (i.e. ICD-9, CPT 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 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 patients or their third-party payers for free samples of drugs.

We do not charge more than once for the same service, inappropriately unbundle charges by submitting them in fragmented fashion to maximize reimbursement or rebill 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/OHSUMG compliance officer.

OHSU/OHSUMG 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/OHSUMG 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

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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 Hospitals & Clinics and OHSUMG. 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 director, or his/her designee, of the OHSU Integrity Office chairs the committee. Members include representatives from OHSUMG; the Schools of Medicine, Nursing and Dentistry; Hospital Administration; CDRC; OHSU Associate Integrity Officers and OHSU Legal Counsel (ex-officio).

Clinical Laboratories Subcommittee

This committee meets regularly to assist the Clinical Laboratory compliance officers in addressing and implementing compliance issues in the Clinical Laboratories. The committee is composed of the Administrative Department Director (who acts as a Clinical Laboratories co-compliance officer), the department chair, the Vice Chair for Laboratory Medicine (who also acts as a Clinical Laboratories co-compliance officer), the Vice Chair for Anatomic Pathology and the Departmental Business Manager.

Billing Compliance Subcommittee

This subcommittee meets regularly to address professional and facility billing compliance issues that are of common interest and concern to OHSU Hospitals and Clinics (H&C) and OHSUMG. The committee includes the Associate Integrity Officer for H&C, OHSUMG Integrity Officer, Assistant Integrity Officers for H&C, Director of PBS, Director of the Clinical Research program, Director HIS, Reimbursement Manager for HFS and the Manager of Medicare and Medicaid PBS. Legal counsel is ex-officio.

General & Education Compliance Subcommittee

This subcommittee meets regularly to address non-billing and training and education compliance issues that are of common interest and concern to OHSU Hospitals and Clinics (H&C) and OHSUMG. The committee includes the Associate Integrity Officer for H&C, OHSUMG Integrity Officer, Assistant Integrity Officers for

H&C, Risk Management, H&C Quality Management, H&C VP Finance, H&C VP Ambulatory Care, CDRC, and the School of Nursing, Director of the Clinical Research program, Human Resources, School of informatics, H&C Clinical education and H&C HIPAA. Legal counsel is ex-officio.

M. Training and Education

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

New physicians, house officers and other practitioners are required to complete training for Compliance (that is applicable to their roles), HIPAA compliance training that is applicable to their roles and Respect in the Workplace. All providers are required to complete Fraud Awareness Training as well.

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 perform enhancements of 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 house officers 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 (CDM) up-to-date and accurate. We maintain accurate service descriptions matched to correct CPT, HCPCS and revenue codes. Before adding new services to the CDM we determine if the service is part of the facility charge, is billable and is appropriately bundled and 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 H&C 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 OHSU Pathology Department, Division of Laboratory Medicine or OHSU. When OHSU obtains laboratory services from a laboratory outside OHSU, we assure that the outside laboratory is certified at the appropriate level of complexity.

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.

We use the billing and billing compliance oversight services of OHSUMG for dental and medical services provided in the Hatfield Oral and Maxillofacial Surgery facility.

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 with subjects in Sections 2 and 3 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. We do not retaliate 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

We evaluate instances of non-compliance on a case-by-case basis and apply progressive, appropriate, and consistent corrective action 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 compliance program at OHSU. It is updated periodically to reflect updates or changes to our 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.