Audits

If a department learns that an external audit is going to be initiated, the Billing Compliance Department and Research Administration should be notified when the scope of the audit involves billing of subjects’ services. Audits can be conducted by the Center for Medicare and Medicaid Services (CMS), Office of Inspector General (OIG), Office of Human Research Protection (OHRP), the Food and Drug Administration (FDA), the National Institute of Health (NIH) and other entities.

Billing Compliance Concerns

Federal, state, institutional and individual insurance regulations and reimbursement rules should be followed. The Billing Compliance Department may review protocol and subject billing documentation to assist in assessing the following billing compliance concerns:

- The ‘qualification’ of the study to bill Medicare, Medicaid and other third part payers for ‘routine’ services has been documented;
- Presence and sufficiency of an itemized study budget and signed study agreement(s);
- Maintenance of accurate study level billing information in the clinical trial management system (OnCore) and clinical billing system (EPIC);
- Presence of ‘pre-determination’ letter from Medicare, when applicable;
- Presence of pre-authorization for billing ‘routine costs’ to insurers, when applicable;
- Documentation supporting services invoiced to patients/insurers/sponsors;
- Maintenance of accurate subject level billing information in the clinical trial management system (OnCore) and clinical billing system (EPIC);
- Double billing services paid by sponsor to the subject/insurer(s);
- Under billing services to the sponsor or the patient/insurer(s);
- Billing subject’s/insurers for services promised free of charge in the consent form;
- Appropriateness of language used in the Informed consent economic consideration section, in case of injury section and benefits sections;
- Maintenance of invoicing and payment records for subject costs to the sponsor;
- Yale’s Human Investigation Committee (HIC) approval status at the time the service was rendered;
- Enrolling subjects meeting eligibility criteria;
- Following the HIC approved protocol procedures.

Connecticut Legislation

Below are summaries of Connecticut State Acts and regulations specific to clinical trial coverage requirements.

The Managed Care Accountability Act (CT Public Act No. 99-284) specifies that each individual health insurance policy shall define the extent to which it provides coverage for experimental treatments as of January 1, 2000. A health insurance policy may not deny a procedure, treatment or the use of any drug as experimental if such a procedure, treatment or drug, for the illness or condition being treated, or for the diagnosis for which it is being prescribed, has successfully completed a phase III clinical trial of the federal Food and Drug Administration. The Act also indicates that if coverage determinations for an otherwise covered procedure, treatment or drug has been denied on the grounds that it is experimental
and the person is diagnosed with a condition that creates a life expectancy less than 2 years; an expedited appeal may be requested. Insurers are required to respond to the expedited appeal within 48 hours of receiving the request and the necessary information on which to base a decision. This Act also mandated the creation of The Office of Managed Care Ombudsman, whose name was changed to The Office of the Healthcare Advocate in 2005. The Office of the Healthcare Advocate assists health insurance consumers understand their rights and responsibilities under managed care plans. They also analyze and monitor the development and implementation of federal, state and local laws, regulations and policies relating to health insurance consumers and recommend changes it deems necessary.

The **Act Concerning Health Insurance Coverage for Cancer Clinical Trials (CT Public Act No. 01-171)** mandates that group health insurance policies provide coverage for routine patient costs associated with most cancer clinical trials on or after January 1, 2002. Costs associated with studies of therapies, tests or other clinical interventions for purposes of treatment or palliation or therapeutic intervention for the prevention of cancer in human beings being may be covered. In order to be eligible for coverage the study must have IRB approval and reviewed and approved by (1) the NIH; (2) National Cancer Institute (NCI) affiliated cooperative group; (3) FDA investigational new drug number (IND #) or investigational device exemption number (IDE #) or exemption; or (4) Department of Defense (DOD) or Veterans Administration (VA). In addition, the person or entity seeking coverage for routine costs associated with a clinical trial need to submit a completed standardized pre-authorization form to the insurer to request coverage for the routine patient costs. Once the pre-authorization form and any other reasonable supporting materials requested by the insurer is received, the insurer has 5 business days to approve or deny coverage. If the insurer utilizes independent experts to review such coverage determination they must respond within 10 business days. Requests for coverage of phase III clinical trials for the prevention of cancer need to be approved or denied within 14 business days.

The **Act Concerning Health Insurance Coverage for Routine Patient Care Costs for Certain Clinical Trial Patients (CT Public Act 11-172)** expands coverage for routine care costs associated with clinical trials to patients with disabling or life-threatening chronic diseases. It became effective January 1, 2012. This Act also adds that insurers must provide coverage for certain costs associated with studies qualified to receive Medicare coverage under the Medicare Clinical Trial Policy.

**Devices**

Investigational Devices and/or the routine care associated with an investigational device study may or may not be covered by Medicare and other insurers. Chapter 14 of the Medicare Benefit Policy manual indicates that as of November 1, 1995 Medicare may cover certain investigational devices and services incident to the device.

If your study population will involve Medicare/Medicaid subjects, our local Medicare contractor, National Government Service (NGS) should be contacted following HIC approval and prior to the enrollment of the first subject to determine what costs are appropriate to bill to Medicare. The form (Investigational Device Exemption (IDE) request form) and other information required to submit to NGS (see Article for Investigational Device Exemption Requests A45910) can be found on the Compliance website at: [http://ycci.yale.edu/comply/devices/medicaredevices.aspx](http://ycci.yale.edu/comply/devices/medicaredevices.aspx).

Devices that may be covered under Medicare include the following categories:
• Devices approved by the FDA through the Pre-market Approval (PMA) process;
• Devices cleared by the FDA through the 510 process;
• FDA-approved IDE category B devices and
• Hospital Institutional Review Board (IRB) approved IDE devices.

Medicare categorizes devices differently than the FDA for purposes of determining coverage. Instead of using Class I, II and III, Medicare uses Category A and B. In general, Category A devices are Class III devices where the absolute risk of the device has not been established and the initial questions of safety and effectiveness have not been resolved. Category B devices are usually Class I or II, but may be Class III devices when the incremental risk is in question or it is known that the device type can be safe and effective because other manufacturer has obtained FDA approval of that device.

Medicare will not cover the cost of a Category A device itself, but may cover the routine costs if the Medicare Contractor determines the trial meets certain criteria: (1) the Category A IDE device, as used in the trial, must be determined to be intended for the diagnosis, monitoring, or treatment of an immediately life-threatening disease/condition; (2) providers must notify the local Medicare contractor before billing the routine costs of the Category A IDE study; (3) Practitioners must report the Category A IDE number on the claim because the contractor must validate that the IDE number is part of a current clinical trial by reviewing a monthly file provided by CMS.

Medicare may cover the cost of Category B devices and/or the routine costs associated with these types of device studies. Prior to submitting a claim associated with a Category B IDE study, the provider must notify their local Medicare contractor to clarify what costs they will cover under the trial. Once the Medicare contractor notifies the provider that all required information for the IDE had been furnished and what is eligible for coverage, the provider may release appropriate Category B IDE claims for subjects enrolled into that trial bill Medicare.

Coverage of Category B IDE devices is predicated, in part, on the device’s status with the FDA. If a sponsor loses its category B status for the device or violated relevant IDE requirements necessitating the FDA’s withdrawal of approval, all payment will cease. Providers must notify their contractor within 30 days of any change in status for an IDE.

Local Medicare Contractors are also responsible for making the coverage determination on non-significant risk device studies that do not require an IDE application with the FDA. Medicare Contractors should apply the same coverage to non-significant risk device studies that they apply to Category B devices.

It is important you known the category of the device when requesting pre-approval from Medicare. If the investigational device is billed to Medicare it must be billed using the Category B IDE HCPCS code (if applicable), the HCPCS modifier Q0 and the Category B IDE number. When billing the routine costs associated with the investigation device study the claims should include HCPCS modifier Q1 and the V70.7 diagnosis code (examination of participant in clinical trial) as the secondary diagnosis. The Medicare contractors require annual re-approval of the coverage determination.

As described above under the CT Legislation section, if the patient is insured by a carrier other than Medicare or Medicaid, the state’s pre-authorization form should be submitted to the other insurer to make a coverage determination for a subject participating in an investigational device study.
**Best Practice:** Use a log to record the device number, the date the patient received the device and the subject’s id. Enter the pre-authorization information for coverage of services/items into EPIC in the Registration section, under Referrals. Upload a copy of the Medicare’s initial coverage determination and the annual re-approval coverage determination letter into OnCore for reference by the billing staff.

**Disqualification**

Clinical investigators may be disqualified from conducting clinical trials with federal agencies (such as the FDA, NIH and CDC), and/or disqualified from billing routine care services to Medicare and Medicaid if they deliberately fail to comply with applicable regulatory requirements or submit false information to a federal agency or a sponsor. In some instances the federal agency may allow the clinical investigator to enter into restricted agreements when the agency believes that lesser sanctions than disqualification would be adequate to protect the public health. Yale screens all employees against the Office of Inspector General’s excluded list on a monthly basis.

**Health Insurance and Portability Act**

Protected health information is subject to special protections the Health Insurance Portability and Accountability Act of 1996 (HIPAA). The rules under HIPAA may impact how and what data clinical researchers collect and share. Violations of HIPAA may result in sanctions. More information may be found at: [http://hipaa.yale.edu/index.html](http://hipaa.yale.edu/index.html) and [http://www.yale.edu/hipaa/](http://www.yale.edu/hipaa/).

**Hotline**

Yale University maintains a confidential hotline to help employees identify and address compliance concerns (e.g. medical billing non-compliance, conflict of interest, financial policy violation, research non-compliance, scientific misconduct, HIPAA non-compliance, fraud/theft, safety or Environmental matters, etc.). People may report either online at [www.mycompliancereport.com/yale](http://www.mycompliancereport.com/yale) or by calling **877-360-YALE (9253)** 24 hours a day, seven days a week, every day of the year. This online and telephone reporting service is not maintained on the University’s system and is not maintained by University employees. An employee may provide his or her name and contact information, or may choose to remain anonymous.

**Informed Consent to Participate in Research**

The informed consent document should contain language which is understandable to the prospective participant or his/her legally authorized representative (LAR). Language utilized within the consent document should be consistent with the protocol, federal, state and local regulations; and congruent with the terms of a clinical trial agreement/grant.

During the consent process there should be sufficient opportunity for the patient and their legally authorized representative to consider whether or not to participate during the consent process. The person obtaining the consent should be trained in the proper manner to do so and be thoroughly knowledgeable of the research protocol. It is important that the most recently IRB approved consent form be utilized.

Information contained in the informed consent form is relevant for billing in: 1) determining therapeutic intent, 2) disclosing additional costs to the participant that may result from taking part in
the research, including whether or not such costs may be billed to the third party payer and 3) disclosing what services are the responsibility of the patient after a research related injury.

Services rendered under a study that does not have therapeutic intent should not be billed to Medicare and other insurers who follow their clinical trial policy. If the study intervention may or may not benefit the participant, it is generally considered to support the idea that the study has therapeutic intent. If the study is designed so subjects “will not receive benefit from participating in the study, but it may help patients in the future”, it is generally interpreted to mean it does not have therapeutic intent.

Services or items are promised free of charge in the consent form, should not be billed to the patient and/or their insurer. Avoid using narratives such as “there will be no costs to you for participating in the research study” when routine costs required under the protocol will be billed to the patients and/or their insurers. This type of statement may be interpreted to mean the participant will not be billed for any protocol-required service. An alternative narrative such as “there will be no costs for services that are performed only because you are enrolled in this study” is considered better at conveying that the patient and/or their insurers may be billed for the routine care services that are likely to be rendered.

To be consistent with Medicare’s secondary payer rules, avoid using statements such as “these costs will be covered by the study sponsor unless not covered by your insurance or other third party coverage” within the in case of injury section of the consent form. Under Medicare’s secondary payer rules, when a sponsor agrees to cover costs of research injury, the sponsor is considered the primary (liability) insurer. If a sponsor has agreed to cover injury costs, injury costs should not be paid by Medicare when a Medicare beneficiary experiences a research injury. If Medicare is mistakenly billed for costs later determined to be part of a research injury, Medicare must also be reimbursed for their payments.

**Institutional Review Board (IRB)**

An Institutional Review Board (IRB) is a committee charged with protecting the rights and welfare of human research participants. At Yale there are 5 different IRBs under the Yale University’s Human Research Protection Program (HRRP) commonly referred to as HICs (Human Investigation Committees).

Subjects receiving the statutory protections and guarantees of certain federal and state policies regarding coverage of routine costs associated with clinical trials should be enrolled into a trial that is compliance with federal regulation relating to the protection of human subjects, and meet the study’s eligibility criteria. If IRB approval lapses and subjects are actively participating in the trial, the investigator should contact their IRB immediately and indicate if any research intervention occurred during the lapsed period. It is also important to inform the IRB of any changes in the research plan (e.g. eligibility criteria, adding or deleting procedures, changes in investigators, etc.) of unanticipated problems, adverse events and protocol and consent deviations.

**Medicare Coverage**

Medicare may reimburse providers of care for certain costs associated with clinical trials. There are three general alternatives for reimbursement through Medicare: reimbursement through their investigational device coverage regulation; reimbursement available through their National Coverage Determination on clinical trials and reimbursement available through Coverage with Evidence Development. For information regarding investigational device studies please see above under **Devices**.

**Medicare’s National Coverage Determination on Clinical Trials**
Medicare extended their national coverage determination to provide coverage of certain routine costs, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in clinical trials not providing coverage under the 1995 investigational device coverage regulations as on 9/19/2000 (and amended in July 2007). The clinical trial policy noted that all other Medicare rules apply.

Under this clinical trial policy routine costs that may be considered to bill to Medicare include: (1) conventional care; (2) services or items required for the administration of the investigational item; (3) services or items to detect or prevent known complications; and (4) services or items to treat complications. Routine costs include all items and services that are otherwise generally available to Medicare beneficiaries that are provided in either the experimental or the control arms of a clinical trial except:

- The investigational item or services itself, unless otherwise covered outside the clinical trial;
- Items and services for purposes of determining eligibility for the study not related to medically necessary clinical care;
- Items and services provided solely to satisfy data collection and not necessary for clinical management; and
- Items and services customarily provided by the research sponsors free of charge to any enrollee in the trial.

To receive Medicare coverage of routine costs the trial must:

1. Investigate an item or service that Medicare pays for (falls in a benefit category);
2. The study must have therapeutic intent (not designed exclusively to test toxicity or disease pathophysiology); and
3. Enroll patients with diagnosed disease. (Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.)

In addition, the trial should have 7 desirable characteristics or have been ‘deemed’ by the Agency for Healthcare Research and Quality (AHRQ) to be highly likely to have the listed 7 desirable characteristics:

1. The principal purpose of the trial is to test whether the intervention potentially improves the participants’ health outcomes;
2. The trial is well-supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use;
3. The trial does not unjustifiably duplicate existing studies;
4. The trial design is appropriate to answer the research question being asked in the trial;
5. The trial is sponsored by a credible organization or individual capable of executing the proposed trial successfully;
6. The trial is in compliance with Federal regulations relating to the protection of human subjects; and
7. All aspects of the trial are conducted according to the appropriate standards of scientific integrity.

The following types of trials are considered ‘deemed’ to be automatically qualified to meet the 7 desirable characteristics of clinical trials and qualify to receive Medicare coverage of their routine costs:

- Trials funded by National Institute of Health (NIH), Center for Disease Control and Prevention (CDC), AHRQ, Centers for Medicare and Medicaid Services (CMS), Department of Defense (DOD), and Veterans Administration (VA);

- Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, CMS, DOD and VA;

- Trials conducted under an investigational new drug application (IND) reviewed by the FDA; and

- Drug trials that are exempt from having an IND under 21 CFR 312.2 (b)(1)

Coverage for routine costs of qualifying trials may occur if either the trial has been deemed to be qualified, if has been certified that the trial meets the qualifying criteria, or it is required through the National Coverage process. If a study is being conducted that is not automatically deemed as being approved as meeting Medicare’s requirements, the Billing Compliance Officer may assist in contacting the local Medicare contractor, National Government Services (NGS) to find out if it is approved.

When the CMS’s Chief Clinical Officer subsequently finds that a clinical trial does not meet the qualifying criteria or jeopardizes the safety or welfare of Medicare beneficiaries, Medicare’s coverage of routine costs may be denied. Where appropriate, the billing providers would be held liable for the costs and fraud investigations of the billing providers and the trial’s principal investigator may be pursued.

Medicare regulations require Medicare Part C (Medicare Advantage Plans) to follow CMS’s national coverage decision. Medicare Advantage Plans may have reporting requirements when enrollees participate in clinical trials, in order to track and coordinate their members’ care, but cannot require prior authorization or approval.

When standard of care services are rendered to a subject and associated with a Medicare approved clinical trial, the Modifier Q1 (routine clinical service provided in a clinical research study that is an approved clinical research study) must be added to the CPT code on the claim form. When an investigational clinical service is rendered to a subject and is part of a Medicare approved clinical trial, the Modifier Q0 (investigational clinical service provided in a clinical research study that is in an approved clinical research study) must be added to the CPT code on the claim form. In addition, the claim must include the ICD.9 V70.7 (examination of participant in clinical trial) as a diagnosis. (Note: under ICD.10 the Z00.6 diagnosis code should be listed instead of ICD.9 V70.7; ICD.10 Z00.6 denotes encounter for examination for normal comparison and control in clinical research program.)

Medicare’s Coverage with Evidence Development (CED)

Certain items or services may be covered by the Centers for Medicare and Medicaid Services’ (CMS) Coverage with Evidence Development (CED) policies. When a CED exists for a certain item or service, Medicare’s coverage of those costs may be contingent upon the beneficiary being denoted as enrolled into registry and/or clinical trial. CEDs provide conditional coverage for new technologies while collecting additional evidence on the technology’s effectiveness. The principal function of CEDs is to
gather additional information to make a determination if the item or service is reasonable and necessary. In general, a CED allows for coverage of FDA-approved medical technologies and services when improvements in health outcomes have not been conclusively demonstrated, although there is evidence suggesting it is of benefit.

Determination of what services or items need a CED is handled on a case-by-case basis, depending on the nature of the item or service, available alternatives, and other factors with respect to the needs and priorities of the Medicare program. CMS, the Agency for Healthcare Research and Quality (AHRQ) and other agencies may work together to develop and conduct research described under a CED. A CED cycle is considered completed when CMS removes a requirement for study participation as a condition of coverage for one or more indications of an item or service.

CED cases active in 2012 included:

- Trials for Positron emission tomography (FDG-PET) for suspected dementia (patients with mild cognitive impairment) and early dementia (2004 – ongoing)
- Registry and Trials for Positron emission tomography (PET) for cancers (2005 – ongoing)
- Registry for Implantable cardioverter defibrillators (ICDs) (2005 – ongoing)
- Trials for artificial hearts (2008 – ongoing)
- Registry for Positron Emission Tomography (FDG-PET) for solid tumors (2009 – ongoing)
- Trials for Pharmacogenomic Testing of CYP2C9 or VKORC1 alleles to predict Warfarin responsiveness (2009 – ongoing)
- Registry for Positron Emission Tomography (NaF-18 PET) to Identify Bone Metastasis of Cancer after completion of initial treatment (2010 – ongoing)
- Trial for Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) for Myelodysplastic Syndrome (2010 – ongoing)
- Trial for Magnetic Resonance Imaging (MRI) with implanted pacemakers (PMs) or implantable cardiac defibrillators (2011 – ongoing)

**Best Practice:** The research team, billers, and administrative staff need to ensure that charges are billed to the appropriate entity, coded appropriately when billed to insurers, not double billed or under billed. All studies should undergo a Medicare Coverage Analysis to ensure the proposed or current budgets are sufficient, assist in understanding what costs are appropriate to bill subjects/insurers and assist in understanding what language is appropriate to use in the consent form. If the study is being performed at Yale-New Haven Hospital and/or by Yale Medical Group providers, a protocol billing calendar may need to be built in OnCore. The trial’s approval status for billing Medicare for routine costs should be documented in OnCore. The party designated as responsible for each subject’s costs in OnCore should be consistent with the federal/state/local regulations, terms of the clinical trial agreement/grant, language in the consent form, and medical needs of the individual subject. Information regarding the subject’s enrollment status, study visit encounters, study-related procedures and items must be entered appropriately into OnCore and EPIC in a timely manner to ensure billing compliance.
Off-label Drug Usage Studies

Investigators conducting studies on drugs that have FDA-approval for other indications may be able to bill the costs of the investigational drug to the subject or their insurer. If the sponsor has not agreed to provide the drug free-of-charge and the drug is not being promised free in the consent form, the costs of a drugs being studied for a non-FDA approved indication may be covered by Medicare and other insurers. The investigator should not bill Medicare for a drug being used for non-FDA approved indication until the local Medicare Contractor determines if it is appropriate. Further information regarding coverage for drugs given off-label may be found in the Billing Compliance website at: http://ycci.yale.edu/comply/offlabel/offlabeldrugs.aspx.

Investigators conducting Off-label Drug Usage studies must also consider if the routine care costs associated with the study are eligible for coverage through Medicare’s National Coverage Determination on Clinical Trials.

For patients insured by private insurers, the pre-authorization for the costs of the drug may be considered by the insurer when they evaluate if routine costs will be covered. See Private Insurers below for more information.

Office of Inspector General

The Billing Compliance Office considers areas under the current Office of Inspector General’s (OIG) Work Plan when determining what areas to focus on for Yale internal audits. The OIG’s Work Plan sets forth various projects to be addressed by the Office of Audit Services, Office of Evaluation and Inspections, Office of Investigations, and Office of Counsel to the Inspector General. The projects are performed in part to detect and prevent fraud, waste and abuse of programs and operations under the U.S. Department of Health and Human Services (HHS). The projects monitor activities under agencies such as the Centers for Medicare & Medicaid Services (CMS), National Institute of Health (NIH), Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC) and Administration on Aging. The 2013 OIG Work Plan may be viewed at https://oig.hhs.gov/reports-and-publications/workplan/index.asp.

Patient Protection and Affordable Care Act (PPACA)

Starting in January 2014, Statute U.S.C. A § 300gg-8 of the Affordable Care Act (ACA) (section 2709) makes it mandatory for routine patient costs to be covered for “qualified” subjects participating in an “approved” clinical trial. This is the first federal law mandating group health plans (including new self-funded arrangements) and state-licensed health issuers to cover the standard of care costs associated with participation in clinical laws. (Grandfathered plans are exempt from this provision.) Medicare coverage will not be impacted by this statute. Further information regarding the coverage under the ACA may be found on the Billing Compliance website.

Private Insurers

Under CT Public Act 11-172 and Statute U.S.C. A § 300gg-8 of the Affordable Care Act (ACA) private insurers in CT are required to provide coverage for ‘qualified’ subjects participating in ‘approved clinical trials’. In CT, providers need to submit a completed standardized pre-authorization form to the subject’s private insurance plan prior to submission of routine costs claims. This information will be
used by the private carrier to make the coverage determination. A copy of this form may be obtained at: http://ycci.yale.edu/comply/insurance/policies.aspx under Insurance Policies, Pre-Authorization.

**Principal Investigator Responsibilities**

Principal investigators (PI) are responsible for conducting research in accordance with the federal, state and local regulations. The PI should ensure the study is conducted according to the IRB approved protocol, terms of the clinical trial agreement/grant, investigator statement and other applicable regulations. The PI must supervise a clinical study in which some study tasks are delegated to employees or colleagues of the investigator or other third parties; and protect the rights, safety and welfare of subjects. The PI should track the dispensing and disposal of investigational products. The PI may work with their department administrator to ensure it is identified who is responsible for costs of tests, treatment, procedures and services that are study-related upon rendering or requesting such a service. If a patient or insurer is inappropriately billed for costs of study-related tests, treatment, procedures and/or services, the PI should ensure those payments are refunded and billed to the appropriate entity.

**Studies Comparing Different Standards of Care**

It is generally appropriate to bill the costs of a study comparing different standard of care regimens as they would be billed outside of a study. Extra (non-standard) office visits and/or procedures performed only for data collection purposes and not medically necessary, should not be billed to the subjects or their insurers. Services and/or items being paid for by a sponsor and/or promised free of charge in the consent form must not be billed to the subject or their insurer. Studies comparing standard of care regimens may need to utilize the OnCore clinical trial management system feature to ensure billing compliance, particularly when non-standard care or free care is part of the protocol.