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REGULATION AND INSURANCE COVERAGE OF CLINICAL TRIALS

Statement of the Issue

Clinical trials are research studies on patients to test the safety and effectiveness of new medical treatments. Clinical research sponsors and other stakeholders in Florida have raised concerns that patients may decide not to enroll in clinical trials because of a lack of health insurance coverage for care related to the clinical trial. Over the last few years the Florida Legislature has shown some interest in requiring health insurers to provide certain coverage for their beneficiaries enrolled in clinical trials.

The regulation associated with conducting clinical trials is mostly governed by Federal law. However, health insurance coverage for routine medical care for covered beneficiaries enrolled in a clinical trial is not addressed by Federal or state law. This issue brief describes the regulation of clinical trials, discusses the insurance coverage of patient care for individuals enrolled in clinical trials, and identifies policy considerations.

Discussion

Background

Clinical trials, also known as clinical studies, research protocols or clinical research, are a type of medical research that involves human beings. Individuals volunteer to participate in carefully conducted investigations that ultimately uncover better ways to treat, prevent, diagnose and understand human disease. Some clinical trials may offer patients access to new and potentially lifesaving drugs and cures. Particularly for patients with cancer, clinical trials are often the last resort, after all other means of standard treatment have been attempted.

Clinical trials are generally biomedical or health-related research studies in human beings that follow a pre-defined research protocol. The National Institutes of Health classifies clinical trials into the following categories:

- Treatment trials – test new treatment, new combination of drugs, or other approaches to surgery or radiation therapy;
- Prevention trials – look for better ways to prevent a disease in people who have never had the disease or to prevent the disease from returning, including: medicines, vaccines, or lifestyle changes;
- Diagnostic trials – determine better tests or procedures for diagnosing a particular disease or condition;
- Screening trials – test the best way to detect certain diseases or health conditions; and
- Quality of life trials – explore and measure ways to improve the comfort and quality of life for people with a chronic illness.¹

Clinical trials that test the safety and effectiveness of new medical interventions, including drugs, medical devices or other treatments, are the most prevalent type of clinical trial.

Before a new medical device or drug is tested in a clinical trial, the drug or medical device must be extensively researched in the laboratory setting, usually involving experiments with animal and human cells. Only new treatments and medical therapies that demonstrate the most promise after laboratory and animal testing make it to a clinical trial setting. Clinical trial research is conducted according to a plan. This plan is known as the trial *protocol* that describes: the scientific rationale, objective(s), methodology, statistical considerations, and

¹ Department of Health and Human Services, Clinical Research, National Institutes of Health website, Found at: <http://clinicalresearch.nih.gov/how.html> (Last visited on September 4, 2009).

organization of the trial. The details of the clinical trial protocol help assure the safety and health of the trial subjects and provides an exact template for trial conduct by investigators. The protocol allows a clinical trial to be conducted at multiple locations and in many states.

Researchers conducting clinical trial research are required by federal law to get *informed consent*, from individuals participating in the trial. There are rigorous standards for what constitutes informed consent and how the consent is documented. The U.S. Department of Health and Human Services, Office of Human Research Protections, describes informed consent as:²

Informed consent is a process, not just a form. Information must be presented to enable persons to voluntarily decide whether or not to participate as a research subject. It is a fundamental mechanism to ensure respect for persons through provision of thoughtful consent for a voluntary act. The procedures used in obtaining informed consent should be designed to educate the subject population in terms that they can understand. Therefore, informed consent language and its documentation (especially explanation of the study's purpose, duration, experimental procedures, alternatives, risks, and benefits) must be written in "lay language," (i.e. understandable to the people being asked to participate). The written presentation of information is used to document the basis for consent and for the subjects' future reference. The consent document should be revised when deficiencies are noted or when additional information will improve the consent process.

Federal law requires that clinical trials be approved and monitored by an *Institutional Review Board (IRB)* to ensure that the trial risks are minimal and are worth any potential benefit. An IRB is an independent committee of experts that consists of physicians, statisticians, and members of the community who ensure that clinical trials are ethical and that the rights of the participants are protected. Periodically during the course of a clinical trial, the IRB overseeing the trial will review the research.³

Clinical trials are conducted in four *phases* ranging from the most experimental Phase I clinical trials to Phase IV clinical trials that determine long-term treatment effects of certain standard medical treatment protocols. Each trial phase has a different research objective. The National Institutes of Health describes the phases as:

- Phase I trials – test an experimental drug or treatment in a small group of people (20-80) for the first time. The purpose is to test the safety of the drug or treatment and identify side effects.
- Phase II trials – administer the experimental drug or treatment to a larger group of people (100-300) to determine its effectiveness and further evaluate its safety. Often these studies are *blinded* which means that neither the patients nor the researchers know who has received the experimental drug. This allows investigators to provide the research sponsor and the U.S. Food and Drug Administration (FDA) with comparative information about the relative safety and effectiveness of the new drug or treatment.
- Phase III trials – are randomized controlled multicenter (and multistate) trials that administer the drug or treatment to large groups of people (1,000-3,000) to confirm its effectiveness, monitor side effects, compare it with standard or equivalent treatments, and collect information that will allow the experimental drug or treatment to be used safely. Once Phase III is complete, a research sponsor can submit the drug to the FDA for approval to market the drug.
- Phase IV trials – are also known as post marketing surveillance trials. Phase IV trials are conducted after the drug or treatment is licensed by the FDA. Researchers track its safety and continue to seek more information about the drug or treatment's risks, benefits and optimal use. These trials are long-term studies involving large groups of participants in order to track any unexpected side-effects that may occur in a small percentage of individuals.⁴

Most clinical trials in the United States are sponsored by pharmaceutical companies, medical research organizations, and federal agencies, such as the National Institutes of Health, the Department of Defense, and the Department of Veterans Affairs. The clinical trial sponsor usually incurs the cost of the drug or treatment being

² Department of Health and Human Services, Office of Human Research Protections, Tips on Informed Consent, Found at: <<http://www.hhs.gov/ohrp/humansubjects/guidance/ictips.htm>> (Last visited on September 4, 2009).

³ Department of Health and Human Services, Clinical Research, National Institutes of Health website, Found at: <<http://clinicalresearch.nih.gov/how.html>> (Last visited on September 4, 2009).

⁴ Ibid.

tested in the trial and may cover other related trial diagnostic and medical treatment for the individuals participating in the trial. Additional trial costs for the sponsor may include manufacturing the drug or device being tested, salaries for the study administrators and investigators, IRB fees, and payments to the research organization.

The trial sponsor usually covers the cost of tests, procedures, and drugs for the individuals enrolled in the trial, but does not usually pay for *routine patient care*, such as doctor visits, tests, and x-rays. Some health insurance plans limit or deny coverage for trial related routine patient care if a policyholder is enrolled in a clinical trial. Several states have addressed gaps in coverage by passing legislation that requires health insurers to cover the routine patient care of policyholders enrolled in cancer clinical trials.⁵ Other states have mandated health insurance coverage for clinical trials more broadly, including clinical trials that do not provide reimbursement for trial-related medical procedures and any clinical-trial-associated routine patient care.⁶

Regulation of Clinical Trial Research

Federal Regulations

Federal law provides the regulatory framework for conducting clinical trials involving human subjects. Protection of human subjects under Title 45, Code of Federal Regulations (CFR), part 46, is the overarching Federal regulatory policy that governs research involving humans. The law requires human subjects research to be reviewed by an IRB; specifies IRB membership, functions, and review processes; and sets general informed consent standards. In addition, special regulatory protections for pregnant women, human fetuses, neonates, prisoners, and children used as research subjects are provided in law.

The U.S. Department of Health and Human Services, Office for Human Research Protections, administers the law by providing leadership in the protection of the rights, welfare, and wellbeing of subjects involved in research conducted or supported by the Federal Government. In addition, the Office provides clarification and guidance, develops educational programs and materials, maintains regulatory oversight, and provides advice on ethical and regulatory issues in biomedical and behavioral research.

Clinical trials that include human subjects, and that test either a new drug or medical device are also subject to the FDA regulatory standards.⁷ Title 21, CFR, part 50, outlines protection of human subjects participating in drug and device clinical trials including: informed consent requirements and additional safeguards for clinical trials involving children. Similar to the broad federal regulations outlined above, the FDA regulations specify IRB standards, functions, record requirements, and penalties. Clinical trials investigators subject to FDA regulation are also subject to financial disclosure, new drug and device approval, and new drug manufacturing requirements.

Clinical trial sponsors and investigators are subject to other federal laws, depending on the scope of the research. For instance, all clinical trials that involve individually identifiable health information are subject to the Health Insurance Portability and Accountability Act. Clinical trial investigators must also adhere to any applicable state laws. State laws governing informed consent, age of consent, legal representatives, and government notification are applicable to most clinical trials conducted.

Florida Regulations

Current Florida law does not directly regulate the clinical-trials-research process. In the past, Florida had a state program to support pharmaceutical clinical trials. The investigational drug program and the Florida Drug Technical Review Panel were enacted in 1981 to increase the availability of life-saving investigational drugs to Florida citizens as an alternative to the FDA's, then slow, drug approval process.⁸ According to staff at the Department of Health, the last investigational drug application was submitted to the review panel in 1988 and during the intervening years the FDA drug approval process was streamlined, making the state program

⁵ Arizona, California, Connecticut, Georgia, Illinois, Louisiana, Massachusetts, Missouri, New Hampshire, New Mexico, Rhode Island, Tennessee, Vermont, Virginia, and Wisconsin.

⁶ Delaware, District of Columbia, Indiana, Maine, Maryland, Nevada, North Carolina, Ohio, Oregon, West Virginia, and Wyoming.

⁷ 21 CFR 56, 21 CFR 50.

⁸ ss. 499.018-499.022, F.S. (1999).

unnecessary. The last Florida Drug Technical Review Panel meeting was held in November of 1994. The investigational drug program and the Florida Drug Technical Review Panel were repealed from the Florida Statutes during the 2000 Legislative Session.⁹

All clinical trials conducted in Florida are subject to applicable state law including: the Florida Medical Consent Law,¹⁰ HIV testing provisions,¹¹ and health care surrogate provisions.¹² All biomedical and behavioral research on human subjects, which is funded and supported by the Department of Health, must be approved by the Department of Health IRB, pursuant to s. 381.86, F.S. However, this does not include other clinical trial research conducted in the state.

Clinical Trial Patient Care Coverage

There are two types of costs associated with a clinical trial: research costs and patient care costs. Patient care costs are usually referred to as *routine patient care* and include: health care provider visits, hospital stays, lab tests, and x-rays and scans. The research costs are related directly to the clinical trial and are usually covered by the clinical trial sponsor. Research costs include: research doctor and nurse time, analysis of trial results, and clinical tests performed purely for research purposes.¹³ When patients are injured by a clinical trial drug or device, it may be unclear who is responsible for paying for the patient care associated with the injury.¹⁴ Experimental drugs are usually covered by the clinical trial sponsor, but not in every trial. If the drug is already approved by the FDA, it is less likely that the clinical trial sponsor will cover the cost.¹⁵

Clinical Trial Coverage for Medicare and Medicaid Beneficiaries

On June 7, 2000, President Clinton issued an Executive Memorandum that directed the Medicare program to revise its payment policy and immediately begin explicitly reimbursing providers for the cost of routine patient care associated with participation in clinical trials.¹⁶ The memo directed the Medicare program to provide coverage in order to promote the participation of Medicare beneficiaries in clinical trials for all diseases, especially because the elderly are underrepresented in clinical trials. The Centers for Medicare and Medicaid Services codified the Medicare clinical trial coverage in a national coverage determination on September 19, 2000.¹⁷

In order for Medicare to provide coverage for routine patient care for beneficiaries enrolled in clinical trials, the trial must meet Medicare's standards. Medicare's standards require a clinical trial to: evaluate a current Medicare benefit category, have therapeutic intent and not just be designed to test the toxicity of a drug,¹⁸ and enroll patients with a diagnosed disease rather than healthy volunteers.¹⁹ Medicare policy defines *routine costs* of a clinical trial to include all items and services that are otherwise generally available to Medicare beneficiaries that are provided in either the experimental or the control arm of the a clinical trial except:

⁹See Chapter 2000-326, Laws of Florida.

¹⁰ s. 766.103, F.S.

¹¹ s. 381.004, F.S.

¹² Chapter 765, Part II, F.S.

¹³ U.S. National Institutes of Health, National Cancer Institute, Clinical Trials and Insurance Coverage. Found at: <http://www.cancer.gov/clinicaltrials/learning/insurance-coverage> (Last visited September 4, 2009).

¹⁴ Many clinical trial informed consent documents inform clinical trial participants that the cost of any injuries incurred during the course of the trial may be the responsibility of the participant.

¹⁵ Phase IV clinical trials test drugs that are already approved by the FDA and on the market. Rarely, Phase III trials are conducted with FDA approved drugs.

¹⁶ The White House, Office of the Press Secretary, President Clinton Takes New Action to Encourage Participation in Clinical Trials, June 7, 2000. Found at: < <http://clinton3.nara.gov/WH/New/html/20000607.html> > (Last visited September 4, 2009).

¹⁷ Centers for Medicare & Medicaid Services, National Coverage Determination for Routine Costs in Clinical Trials, Found at: < <http://www.cms.hhs.gov/clinicaltrialpolicies/> > (Last visited September 11, 2009).

¹⁸ This standard usually disqualifies all Phase I clinical trials.

¹⁹ Centers for Medicare & Medicaid Services, Medicare Coverage Clinical Trial Policy, Found at: < http://www.cms.hhs.gov/mcd/viewncd.asp?ncd_id=310.1&ncd_version=2&basket=ncd%3A310%2E1%3A2%3ARoutine+Costs+in+Clinical+Trials > (Last visited September 11, 2009).

- The investigation item or service, itself, unless otherwise covered outside the clinical trial;
- Items and services provided solely to satisfy data collection and analysis needs that are not used in the direct clinical management of the patient; and
- Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial.²⁰

Pursuant to Medicare policy, routine costs in clinical trials include:

- Items or services that are typically provided absent a clinical trial;
- Items or services required solely for the provision of the investigational item or service (e.g., administration of a noncovered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service—in particular, for the diagnosis or treatment of complications.²¹

The Centers for Medicare & Medicaid Services does not have a similar policy for Medicaid beneficiaries. Clinical trial coverage for Medicaid beneficiaries varies by individual state Medicaid program. New Mexico, Vermont, West Virginia, Indiana and California have mandated coverage for routine care in their state Medicaid programs as part of larger health insurance mandates.²² However, even without specific legislative authority some state Medicaid programs may cover routine care for Medicaid beneficiaries enrolled in clinical trials based on individual state Medicaid policies.

The Florida Medicaid program explicitly excludes experimental drugs and experimental or investigational procedures from reimbursement.²³ However, Medicaid beneficiaries, particularly beneficiaries enrolled in fee-for-service Medicaid, may be enrolled in a clinical trial, particularly if the trials are testing pharmaceutical drugs that are already approved by the FDA and on the Medicaid Preferred Drug List. The Agency for Health Care Administration does not have a mechanism to estimate the extent to which Medicaid beneficiaries in Florida participate in clinical trials.²⁴

Insurance Mandates and Compacts

There is no consensus over who is financially responsible for paying for costs associated with clinical trials. The extent to which insurers cover routine patient care for a covered beneficiary enrolled in a clinical trial varies by insurance company and the individual insurance policy. Some health plans define clinical trials as *experimental* or *investigational*, and refuse to provide coverage. Other health plans authorize reimbursement for routine patient care on a case-by-case basis or provide coverage for only Phase II-IV trials.

In order to ensure coverage of routine patient care for individuals enrolled in clinical trials, several legislative mandates and other coverage requirements have been proposed and successfully implemented. There is currently legislation filed in the U.S. Senate and the U.S. House of Representatives that would require all health insurers to provide coverage for individuals participating in approved cancer trials.²⁵ Over the last few years, bills with similar mandates have been filed in Congress, but the bills have not passed. Almost half of all states have passed legislation or instituted special agreements requiring health plans to pay the cost of routine medical care for beneficiaries enrolled in a clinical trial.²⁶

²⁰ Ibid.

²¹ Ibid.

²² National Conference of State Legislatures, Clinical Trials: What are States Doing? August, 2009. Found at: <http://www.ncsl.org/default.aspx?tabid=14331> (Last visited: September 4, 2009).

²³ 2008-2009 Florida Medicaid Summary of Services, pages 77, 79, 81 and 93, Found at: http://www.fdhc.state.fl.us/Medicaid/pdf/files/SS_08_080701_SOS.pdf (Last visited: September 4, 2009).

²⁴ Consultation with Agency for Health Care Administration staff, August, 2009.

²⁵ See S. 488 and H.R. 716: Access to Cancer Clinical Trials Act of 2009.

²⁶ National Conference of State Legislatures, Clinical Trials: What are States Doing? August, 2009. Found at: <http://www.ncsl.org/default.aspx?tabid=14331> (Last visited: September 4, 2009).

Twenty-three states have enacted health insurance mandates for the coverage of routine patient care for beneficiaries enrolled in clinical trials.²⁷ The nature of the routine patient care insurance mandate varies by: who is required to reimburse for routine patient care, clinical trial phase or disease state covered by the mandate, and other criteria, such as the type of clinical trial (treatment vs. preventative). Many state mandates only cover cancer clinical trials, and some states further limit the mandate to only children enrolled in cancer clinical trials.²⁸

Georgia, Michigan, New Jersey, and Ohio have signed special agreements, or compacts, with the insurers in each state, to voluntarily provide coverage for routine patient care for covered beneficiaries enrolled in clinical trials. Ohio and Georgia also have a legislative mandate to cover some clinical trial routine patient care. Enacted in 1998, Georgia state law requires all insurers operating in the state and the state health plan to provide routine patient costs incurred in Phase II and III of prescription drug clinical trial programs for the treatment of children's cancer, that generally first manifests itself in children under the age of 19.²⁹ The Georgia Clinical Trials agreement broadens coverage by requiring all parties³⁰ that sign onto the compact to provide coverage for routine patient care costs associated with Phase I – Phase IV cancer clinical trials.³¹

Advocates for clinical trial coverage insurance mandates and insurance compact agreements to provide coverage for routine patient care for individuals enrolled in clinical trials have pushed for legislation in other states to address the denial of coverage for routine care for patients enrolled in clinical trials.³² In some instances, the lack of coverage is a real risk and in others it is only a perceived risk.³³ Another reason supporters have pushed for coverage requirements is that the lack of health insurance coverage for routine patient care treatment has been identified by major cancer centers as a barrier to enrolling patients in clinical trials.³⁴

Additional insurance mandates can increase the cost of providing health care and calculating the cost of an additional insurance mandate usually is part of the insurance mandate policy discussion. Studies have shown that the treatment costs of individuals enrolled in some clinical trials is slightly higher than individuals not enrolled in clinical trials. A study that compared the treatment costs of adults enrolled in cancer clinical trials was generally 6.5 percent higher (\$35,418 vs. \$33,248) over a 2.5-year period than if the patients did not enroll.³⁵

Another study that examined the direct cost of medical care for patients enrolled in cancer clinical trials for patients enrolled in the Kaiser HMO found that participation in cancer clinical trials is not associated with a large increase in the cost of medical care.³⁶ The cost of medical care for cancer patients enrolled in clinical trials

²⁷ Arizona, California, Connecticut, Delaware, District of Columbia, Georgia, Illinois, Indiana, Louisiana, Maine, Maryland, Massachusetts, Missouri, New Hampshire, Nevada, New Mexico, North Carolina, Ohio, Oregon, Rhode Island, Tennessee, Vermont, Virginia, West Virginia, Wisconsin, and Wyoming.

²⁸ National Conference of State Legislatures, Clinical Trials: What are States Doing? August, 2009. Found at: <http://www.ncsl.org/default.aspx?tabid=14331> (Last visited: September 4, 2009).

²⁹ Ibid.

³⁰ As of August 31, 2009, Aetna, Blue Cross/Blue Shield, CIGNA, Coventry, Humana, Kaiser, OneHealth, and United HealthCare have all signed the Georgia Clinical Trials Agreement.

³¹ Georgia Cancer Coalition, Georgia Clinical Trials Agreement. Found at: < <http://www.georgiacancer.org/treat-trials.php> > (Last visited: September 4, 2009).

³² National Conference of State Legislatures, Clinical Trials: What are States Doing? August, 2009. Found at: <http://www.ncsl.org/default.aspx?tabid=14331> (Last visited: September 4, 2009).

³³ Barriers to Clinical Trial Enrollment: Are State Mandates the Solution? Journal of the National Cancer Institute, Vol. 96, No. 14, July 14, 2004. Found at: <http://jnci.oxfordjournals.org/cgi/reprint/96/14/1048?maxtoshow=&HITS=10&hits=10&RESULTFORMAT=&fulltext=barriers+to+clinical+trial+enrollment%3A+are+state+mandates+the+solution&searchid=1&FIRSTINDEX=0&resourcetype=HWCIT> (Last visited: September 4, 2009).

³⁴ The EDICT Project: Policy Recommendations to Eliminate Disparities in Clinical Trials, Version 2, October, 2008. Found at: <http://www.bcm.edu/edict/PDF/EDICT_Project_Booklet.pdf> (Last visited: September 4, 2009).

³⁵ Incremental Treatment Costs in National Cancer Institute-Sponsored Clinical Trials, JAMA, July 11, 2003—Vol 289, No. 22. Found at: <<http://jama.ama-assn.org/cgi/content/full/289/22/2970>> (Last visited: September 4, 2009).

³⁶ Cost of Care for Patients in Cancer Clinical Trials, Journal of the National Cancer Institute, Vol. 92, No. 2, January 19, 2000. Found at: <<http://jnci.oxfordjournals.org/cgi/reprint/92/2/136?maxtoshow=&HITS=10&hits=10&RESULTFORMAT=&fulltext=cost+of+care+for+patients+in+cancer+clinical+trials&searchid=1&FIRSTINDEX=0&resourcetype=HWCIT>> (Last visited: September 4, 2009).

exceeded patients with cancer not enrolled in a trial by an average of 10 percent or \$1,487 per person. However, the study determined that the cost of trial enrollees that included bone marrow transplantation explains the higher costs. Cancer patients enrolled in a clinical trial without bone marrow transplantation treatment had no higher patient costs than similarly diagnosed patients not in a trial.³⁷

Clinical Trial Patient Care Coverage in Florida

The extent to which patients enrolled in clinical trials in Florida are eligible for health insurance coverage for routine patient care is hard to determine. Similar to the Florida Medicaid program policy, many health insurance policies include general language that excludes investigational and experimental treatment expenses.³⁸ However, no carrier has the same exclusion policy and the nature of coverage varies greatly. Some carriers broadly exclude all experimental treatment costs, while others authorize limited coverage under certain circumstances, and others provide coverage but require prior authorization.³⁹ During meetings with Senate professional staff several stakeholders expressed concerns over lack of health insurance coverage for routine patient care for patients enrolled in clinical trials.

Some consumers have filed complaints or grievances regarding the denial of claims related to routine patient care while that consumer was enrolled in a clinical trial. In the last two years, the Division of Consumer Services of the Florida Department of Financial Services and the Florida State Group Plan have received only two clinical trial coverage complaints.⁴⁰ The Agency for Health Care Administration, Subscriber Assistance Program, has received more grievances. The program reviews grievances filed by managed care subscribers that have not been resolved by the managed care entity⁴¹ to the satisfaction of the subscriber.⁴² In the last three fiscal years the Subscriber Assistance Program received 52 clinical trial coverage related grievances out of a total of 1,486 filed grievances.⁴³ Of the 52 filed cases, 19 were either resolved before the panel heard the case or the panel ruled in favor of the beneficiary. According to the Agency for Health Care Administration, generally 49 percent of the grievances filed with the Subscriber Assistance Program are found or resolved in the subscriber's favor.⁴⁴

During the last two regular legislative sessions there were some discussions regarding coverage for routine patient care for patients enrolled in clinical trials. During the 2008 Session, language in CS/SB 2618, directed the Department of Health to convene a workgroup of all insurers licensed under chapter 627, F.S., to develop a compact to provide minimum industry standards for patients enrolled in cancer clinical trials.⁴⁵ The language required insurers to negotiate an agreement to provide cancer clinical trial coverage to beneficiaries. Committee substitute for SB 2618 died in messages.

During the 2009 Session, the Florida House of Representatives, Health Care Regulation Policy Committee, had a presentation on clinical trials by the Leukemia and Lymphoma Society at the March 10, 2009, committee meeting. In addition, there was an amendment filed to CS/CS/CS/SB 1986 during the 2009 Regular Session, that would have required health insurers that deny coverage of routine patient care costs associated with Phase I – Phase IV clinical trials to annually submit to the Office of Insurance Regulation a detailed year-cost differential report that included a comparison of the cost of treatment for patients enrolled in clinical trials with those not enrolled.⁴⁶ The amendment was withdrawn from consideration.

September 4, 2009).

³⁷ Ibid.

³⁸ Office of Insurance Regulation telephone correspondence, August, 2009.

³⁹ Select health insurer policies on file with the Office of Insurance Regulation, 2009.

⁴⁰ The Department of Financial Services does not collect information directly related to clinical trial coverage.

⁴¹ HMOs and prepaid health clinics certified under chapter 641, F.S.; prepaid health plans authorized under s. 409.912, F.S.; and exclusive provider organizations certified under s. 627.6472, F.S.

⁴² See s. 408.7056, F.S.

⁴³ 18 of the 408 grievances filed in FY 06/07 were related to clinic trial coverage; 21 of the 526 grievances filed in FY 07/08 were related to clinical trial coverage; and 13 of the 552 grievances filed in FY 08/09 were related to clinical trial coverage.

⁴⁴ Agency for Health Care Administration email correspondence, August, 2009.

⁴⁵ See Amendment barcode #843570, filed to CS/SB 2618, 2008 Legislative Session.

⁴⁶ See Amendment barcode #953014 filed to CS/CS/CS/SB 1986, 2009 Legislative Session.

Policy Considerations

In summary, the outstanding policy issues related to the regulation and insurance coverage of clinical trials are:

1. What role, if any should the state have in providing incentives for people to enroll in clinical trials or in removing obstacles to people enrolling in clinical trials?
2. Who should be financially responsible for paying for routine patient costs for patients enrolled in a clinical trial, and who should be responsible for paying for injuries that result from clinical trial participation?