WISCONSIN STATE LEGISLATURE COMMITTEE HEARING RECORDS

2005-06
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Committee on Insurance (AC-In)

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# Coverage Issues Manual
# Clinical Trials

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## *30-1 ROUTINE COSTS IN CLINICAL TRIALS*

*Effective for items and services furnished on or after September 19, 2000, Medicare covers the routine costs of qualifying clinical trials, as such costs are defined below, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. All other Medicare rules apply.*

*Routine costs of a clinical trial include all items and services that are otherwise generally available to Medicare beneficiaries (i.e., there exists a benefit category, it is not statutorily excluded, and there is not a national noncoverage decision) that are provided in either the experimental or the control arms of a clinical trial except:*

- *The investigational item or service, itself;*
- *Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan); and*
- *Items and services customarily provided by the research sponsors free of charge for any enrollee in the trial.*

*Routine costs in clinical trials include:*

- *Items or services that are typically provided absent a clinical trial (e.g., conventional care);*
- *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.*

*This policy does not withdraw Medicare coverage for items and services that may be covered according to local medical review policies or the regulations on category B*

*investigational device exemptions (IDE) found in 42 CFR 405.201-405.215, 411.15, and 411.406. For information about LMRPs, refer to www.lmrp.net, a searchable database of Medicare contractors' local policies.*

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*For noncovered items and services, including items and services for which Medicare payment is statutorily prohibited, Medicare only covers the treatment of complications arising from the delivery of the noncovered item or service and unrelated reasonable and necessary care. (Refer to MCM §§2300.1 and MIM 3101.) However, if the item or service is not covered by virtue of a national noncoverage policy in the Coverage Issues Manual and is the focus of a qualifying clinical trial, the routine costs of the clinical trial (as defined above) will be covered by Medicare but the noncovered item or service, itself, will not.*

A. *Requirements for Medicare Coverage of Routine Costs.--Any clinical trial receiving Medicare coverage of routine costs must meet the following three requirements:*

   1. *The subject or purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category (e.g., physicians' service, durable medical equipment, diagnostic test) and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids).*

   2. *The trial must not be designed exclusively to test toxicity or disease pathophysiology. It must have therapeutic intent.*

   3. *Trials of therapeutic interventions must enroll patients with diagnosed disease rather than healthy volunteers. Trials of diagnostic interventions may enroll healthy patients in order to have a proper control group.*

*The three requirements above are insufficient by themselves to qualify a clinical trial for Medicare coverage of routine costs. Clinical trials also should have the following desirable characteristics; however, some trials, as described below, are presumed to meet these characteristics and are automatically qualified to receive Medicare coverage:*

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.*



B. *Qualification Process for Clinical Trials.--Using the authority found in §1142 of the Act (cross-referenced in §1862(a)(1)(E) of the Act), the Agency for Healthcare Research and Quality (AHRQ) will convene a multi-agency Federal panel (the "panel") composed of representatives of the Department of Health and Human Services research agencies (National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), AHRQ, and the Office of Human Research Protection), and the research arms of the Department of Defense (DOD) and the Department of Veterans Affairs (VA) to develop qualifying criteria that will indicate a strong probability that a trial exhibits the desirable characteristics listed above. These criteria will be easily verifiable, and where possible, dichotomous. Trials that meet these qualifying criteria will receive Medicare coverage of their associated routine costs. This panel is not reviewing or approving individual trials. The multi-agency panel will meet periodically to review and evaluate the program and recommend any necessary refinements to HCFA.*

*Clinical trials that meet the qualifying criteria will receive Medicare coverage of routine costs after the trial's lead principal investigator certifies that the trial meets the criteria. This process will require the principal investigator to enroll the trial in a Medicare clinical trials registry, currently under development.*

*Some clinical trials are automatically qualified to receive Medicare coverage of their routine costs because they have been deemed by AHRQ, in consultation with the other agencies represented on the multi-agency panel to be highly likely to have the above-listed seven desirable characteristics of clinical trials. The principal investigators of these automatically qualified trials do not need to certify that the trials meet the qualifying criteria, but must enroll the trials in the Medicare clinical trials registry for administrative purposes, once the registry is established.*

*Effective September 19, 2000, clinical trials that are deemed to be automatically qualified are:*

1. *Trials funded by NIH, CDC, AHRQ, HCFA, DOD, and VA;*

2. *Trials supported by centers or cooperative groups that are funded by the NIH, CDC, AHRQ, HCFA, DOD and VA;*

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

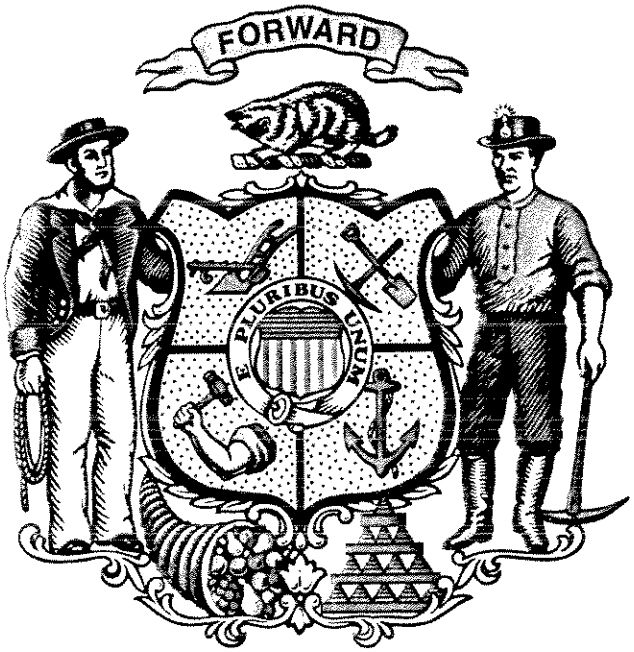
4. *Drug trials that are exempt from having an IND under 21 CFR 312.2(b)(1) will be deemed automatically qualified until the qualifying criteria are developed and the certification process is in place. At that time the principal investigators of these trials must certify that the trials meet the qualifying criteria in order to maintain Medicare coverage of routine costs. This certification process will only affect the future status of the trial and will not be used to retroactively change the earlier deemed status.*

*Medicare will cover the routine costs of qualifying trials that either have been deemed to be automatically qualified or have certified that they meet the qualifying criteria unless HCFA'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.*





*Should HCFA find that a trial's principal investigator misrepresented that the trial met the necessary qualifying criteria in order to gain Medicare coverage of routine costs, Medicare coverage of the routine costs would be denied under §1862(a)(1)(E) of the Act. In the case of such a denial, the Medicare beneficiaries enrolled in the trial would not be held liable (i.e., would be held harmless from collection) for the costs consistent with the provisions of §§1879, 1842(l), or 1834(j)(4) of the Act, as applicable.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+Choice (M+C) organizations to follow HCFA's national coverage decisions. This NCD raises special issues that require some modification of most M+C organizations' rules governing provision of items and services in and out of network. The items and services covered under this NCD are inextricably linked to the clinical trials with which they are associated and cannot be covered outside of the context of those clinical trials. M+C organizations therefore must cover these services regardless of whether they are available through in-network providers. M+C organizations 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.*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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

Press Office
Washington, DC 20201

# HCFA FACT SHEET

September 19, 2000

Contact: HCFA Press Office
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## MEDICARE COVERAGE ROUTINE COSTS OF BENEFICIARIES IN CLINICAL TRIALS

*Overview: The Health Care Financing Administration has issued a final national coverage decision to implement President Clinton's order for Medicare to cover the routine health care costs of beneficiaries in clinical trials. It not only implements the President's order to cover the "routine costs" of Medicare beneficiaries in clinical trials, but also expands the definition of such costs to include payment of most other beneficiary costs that were previously non-covered. This decision finalizes a proposed decision issued in August.*

**Reassuring Beneficiaries, Encouraging Research.** This national coverage decision is intended to encourage the greater use of clinical trials by older Americans. Clinical trials serve as the first step toward providing new clinical innovations to the forefront of medical practice. In announcing the decision to assure Medicare coverage to those in clinical trials, President Clinton noted that many seniors and people with disabilities were reluctant to participate in trials for fear they would lose their Medicare coverage. Assuring Medicare beneficiaries that their routine costs will be covered is expected to increase their participation in clinical trials. Medical researchers believe that higher participation by older Americans and those with disabilities in clinical trials could lead to faster development of therapies. The knowledge gained from clinical trials will lead to better health care for Medicare's more than 39 million beneficiaries.

**Covered Costs.** Medicare will pay most of the costs of beneficiaries in clinical trials. Payment will include costs associated with providing items and services that would otherwise be covered by Medicare if they were not provided in the context of a clinical trial. Also covered are items and services required "solely for the provision of the investigational item or service." For example, Medicare will pay for the administration of a chemotherapy drug that is being tested in a trial, including the provision of anti-nausea drugs to prevent complications from the chemotherapy drug. Medicare also will pay for monitoring and evaluation, device implantation, and other costs, such as room and board as part of a hospital stay required as part of a clinical trial, for trials of importance to Medicare beneficiaries.

- more -

**All Beneficiaries Will Be Covered.** All Medicare beneficiaries will be eligible for the coverage while in clinical trials meeting federal standards. The new policy is binding on all the private contractors that process and pay Medicare claims as well as Medicare+Choice managed care plans. The Balanced Budget Act permits Medicare to pay additional funds on behalf of Mediare+Choice organizations to compensate them for significant costs associated with national coverage decisions. Coverage becomes effective with this final national coverage decision. Coverage decisions are not retroactive.

**Things Not Covered.** Medicare will not pay for the investigational intervention being tested in a trial. And it will not pay for items and services provided solely to satisfy the data collection needs of the trial. It also will not pay for anything being provided free by the sponsor of the trial to any trial enrollee.

**Registry of Trials.** HCFA is developing a registry of ongoing clinical trials in which routine beneficiary costs are being reimbursed by Medicare. This registry will track Medicare expenditures associated with clinical trials. HCFA also will use the information contained in the National Institutes of Health and Food and Drug Administration clinical trial registries (www.clinicaltrials.gov) to develop a national registry of all clinical trials receiving Medicare reimbursement for their routine costs.

**Eligible Trials.** To ensure the safety of Medicare beneficiaries, the final coverage decision establishes a process to determine which clinical trials are eligible for its participants to receive payments for routine medical costs. The HCFA decision requires that clinical trials must meet specified criteria in order to be approved for Medicare coverage of their routine costs, including scientific support, credible and capable sponsorship and protection of participating patients.

Some clinical trials are "deemed" to be qualified and do not have to go through this process. These include trials that are funded by the National Institutes of Health (including those centers and cooperative groups funded by NIH), the Centers for Disease Control and Prevention, HCFA, the Agency for Healthcare Research and Quality, the Department of Defense, the Department of Veterans Affairs, and trials conducted under an Investigational New Drug application approved by the Food and Drug Administration, or those drug trials that are exempt from having an Investigational New Drug application under FDA regulations. These IND-exempt trials will have to certify that they meet the qualifying criteria once the criteria are established.

The policy is posted on HCFA's web site at http://www.hcfa.gov/quality/8d.htm.

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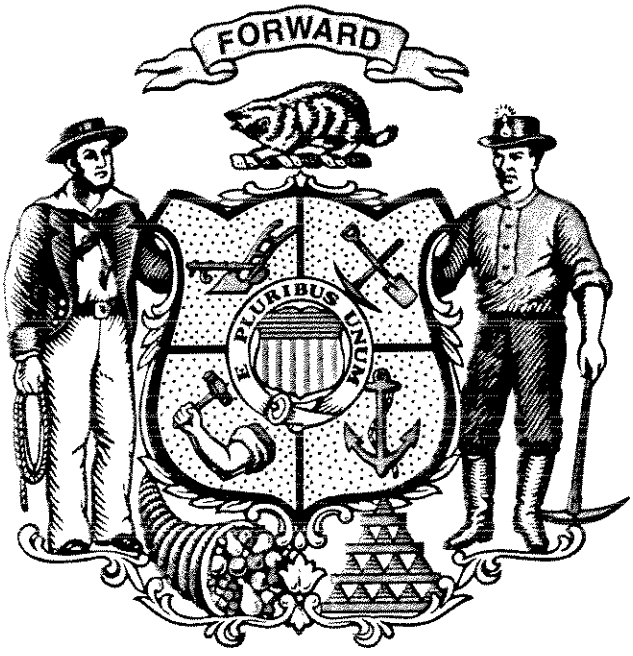
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# Clinical Trials: Are They a Good Buy?

By Charles L. Bennett, Jared R. Adams, Kirstin S. Knox, Andrew M. Kelahan, Samuel M. Silver, and Joseph S. Bailes

**Purpose:** Concern that clinical trials may be too costly has been used to justify traditionally restrictive insurer policies regarding clinical trials. Additionally, fear of insurer reimbursement denial can be a significant barrier to clinical trial participation. In this study, we reviewed the empirical data on costs of clinical trials versus standard care and summarized the current status of policy initiatives related to clinical trial insurance reimbursement.

**Methods:** Electronic and print data sources were searched for studies on the costs of oncology clinical trials. Information on policy initiatives for clinical trial reimbursement was obtained from the American Society of Clinical Oncology, the American Society of Hematology, and the Coalition of National Cancer Cooperative Groups and from searches of World Wide Web sites.

**Results:** Five pilot studies provided information for 377 patients on phase II/III clinical trials matched with controls on standard care. Cost estimates ranged from 10% lower to 23% higher costs/charges for clinical trials in comparison to standard medical care. Medicare, 14 states, and several private insurers now cover the costs of patient care in "qualifying" clinical trials.

**Conclusion:** Findings from small pilot studies suggest that phase II and III clinical trials result in at most modest increases in cost over standard treatment costs. Also, an increasing number of policy makers have decided to support clinical trial reimbursement initiatives. It is hoped that economic data from large observational studies will facilitate widespread and permanent decisions that support reimbursement for phase I, II, and III clinical trial participation.

*J Clin Oncol 19:4330-4339.* 

IT IS ESTIMATED THAT fewer than 5% of adult cancer patients participate in clinical trials.[1] In a recent Harris Interactive survey of 5,980 cancer patients, 60% of patients who were aware of clinical trials (14% of survey sample) and elected not to participate (71% of aware patients) cited concerns about insurance denial as a primary barrier to participation.[2] However, a United States General Accounting Office report found that many insurers already pay for many patients who participate in clinical trials, despite policies excluding payment for "experimental" therapies.[3] As policy makers have become aware that patient concerns over potential reimbursement denial may be a barrier to clinical trial accrual, legislators and insurers have begun to address clinical trial reimbursement policies. The Medicare Cancer Clinical Trial Coverage Act of 1997 sought to authorize a $750 million demonstration project which would reimburse routine patient care costs alongside approved clinical trials. The act also commissioned a report on the actual costs of the funded clinical trials. This legislation was not passed, primarily because of concerns over actual study costs. In 2000, the Institute of Medicine released its report, "Extending Medicare Reimbursement in Clinical Trials," which recommended that the Health Care Financing Administration (HCFA), the former administrator of the Medicare program, reimburse "routine care for patients in clinical trials in the same way it reimburses for routine care for patients not in clinical trials."[1] The report projected that the financial impact of clinical trial reimbursement would be small, based on the findings of pilot studies in 1998 and 1999 from the Group Health Cooperative of Puget Sound, the Mayo Clinic, and Kaiser Permanente.[4-6] Nonetheless, as health care costs rise, the questions related to reimbursement for clinical trials become increasingly relevant. After the favorable reports on the cost of clinical trials from pilot studies, federal policy makers, private insurers, and several state legislatures have introduced policies or laws that support reimbursement of routine medical care in clinical trials. In this article, we address the current status of reimbursement for clinical trials by reviewing the methodologies, results, and future plans for studies on the costs of clinical trials and reviewing the content of federal, state, and private sector clinical trial reimbursement initiatives.

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*Submitted December 28, 2000; accepted August 20, 2001.*

*The opinions expressed herein are solely those of the authors and are not meant to represent those of the committees and departments of the American Society of Clinical Oncology or the American Society of Hematology, where some of the background information was obtained.*

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*0732-183X/01/1923-4330/$20.00*

Table 1. Comparison of Estimates of Incremental Costs/Charges of Clinical Trials From Five Studies

| | Memorial Sloan-Kettering | AACI/ Northwestern | Kaiser Permanente | CBO/Mayo Clinic | Group Health Cooperative |
|---|---|---|---|---|---|
| Reference no. | 8 | 7 | 5 | 4 | 6 |
| Clinical trial patients | 77 | 35 | 135 | 61 | 49 breast/20 colorectal |
| Study years | 1995 | 1996-1998 | 1994-1996 | 1988-1994 | 1990-1996 |
| Phase | II/III | II | III | II/III | II/III |
| Cost Data | | | | | |
| Units used to measure costs | Costs | Charges | Costs | Costs | Costs |
| At 6 months | | | | | |
| Control patients (C) | $30,775 | $63,721 | $9,930 | $10,073 | |
| Clinical trial patients (T) | $37,055 | $57,542 | $12,242 | $12,200 | |
| % Difference (T-C) | 17 | (−10) | 23 | 21 | |
| At 12 months | | | | | |
| Control patients (C) | | | $15,516 | $14,762 | |
| Clinical trial patients (T) | | | $17,003 | $16,819 | |
| % Difference | | | 10 | 14 | |
| At 24 months | | | | | |
| Control patients (C) | | | | | $25,000* |
| Clinical trial patients (T) | | | | | $30,000 |
| % Difference | | | | | 20 |
| At 60 months | | | | | |
| Control patients (C) | | | | $26,797 | |
| Clinical trial patients (T) | | | | $27,090 | |
| % Difference | | | | 1 | |

Abbreviation: AACI, American Association of Cancer Institutes; CBO, Congressional Budget Office.

*Twenty-six closely matched breast cancer patients only; other diseases did not show a remarkable cost difference.

## METHODS

MEDLINE, EMBASE, HEALTHSTAR, and abstracts from the *Proceedings of the American Society of Clinical Oncology* from the years 1995 to 2001 were searched for reports on costs of clinical trials. Key words included cancer costs, clinical trial costs, and clinical trial participation. Leaders at the Department of Public Policy of the American Society of Clinical Oncology, the Committee on Practice of the American Society of Hematology, the Coalition of National Cancer Cooperative Groups, the Department of Defense, and the National Cancer Institute were also queried about ongoing policy initiatives related to clinical trial reimbursement. Individual bills pertaining to mandated insurance reimbursement of clinical trials were found through searches of the legislative history on the Web site of the respective legislative bodies. Web sites of health care insurers and managed care organizations operating on a national basis were reviewed to identify programs that voluntarily reimbursed medical care costs incurred on clinical trials.

This article addresses routine care costs in clinical trials. For most of the research articles and legislative bills, routine care costs (often referred to as patient care costs in legislation) include conventional care, items or services that are typically provided absent a clinical trial; administrative items, items or services required solely for the provision of the investigational item or service (such as the administration of a noncovered chemotherapeutic agent) and for clinically appropriate monitoring related to complications and treatment effects; and reasonable and necessary care, items or services arising from the provision of an investigational item or service, including the diagnosis or treatment of complications. Routine patient care costs do not include items and services that are customarily provided by the research sponsors free of charge for individuals participating in the trial (such as investigational drugs or items); tests or measurements conducted primarily for the purpose of the clinical trial involved; or the administrative costs associated with collecting research data.

## RESULTS

### *Pilot Studies on Costs and Charges of Clinical Trials*

Three published studies[4,5,7] and two preliminary reports[6,8] conducted an economic evaluation of the routine medical care costs of clinical trials. These studies included information on patients enrolled onto phase II (one study), phase III (one study), and phase II and III clinical trials (three studies). (Table 1) A total of 377 patients on clinical trials were included in the five studies (range, 35 to 165 patients per study). Three studies included information on patients treated in the mid-1990s, one study covered the years 1988 to 1994, and one covered the years 1990 to 1996. Two studies were for patients who received care at managed care organizations (Kaiser Permanente and Group Health Cooperative), two were single-site studies from tertiary cancer centers (Memorial Sloan-Kettering Cancer Center and the Mayo Clinic Cancer Center), and one was from five tertiary cancer centers that belong to the Association of

Table 2. Comparison of Methodologies Among the Five Economic Assessment of Clinical Trials

| Study | No. of Cancer Centers | Payment System | No. of Cancer Types | Case Selection | BMT Cases | Control Selection Matching | Excluded Resources | Costs | Analysis |
|---|---|---|---|---|---|---|---|---|---|
| CBO and Mayo Clinic | 1 | Fee-for-service | 9 | All possible cases | No | Performance status | Outpatient prescription drugs | Costs, 5 years | Paired *t* test |
| Kaiser Permanente | 17 | Managed care | 9 | All possible cases | Yes | Eligibility for trial | None | Costs, 1 year | Univariate regression |
| Memorial Sloan-Kettering | 1 | Medicare | 7 | Patients treated primarily at the cancer center | No | Survival | Resources used outside of MSKCC | Costs, 6 months | Unpaired *t* test |
| AACI/Northwestern | 5 | Fee-for-service | 5 | Patients treated primarily at the cancer center | Yes | Eligibility for trial | Resources used outside of the AACI center | Charges, 6 months | Paired *t* test |
| Group Health Cooperative | NA | Managed care | 2 | GH members on SWOG studies | Not stated | Comorbidity, (eligibility for trial: 26 breast cancer patients) | Not stated | Costs, 2 years | Not stated |

Abbreviations: BMT, bone marrow transplantation; GH, Group Health; MSKCC, Memorial Sloan-Kettering Cancer Center; NA, not applicable; SWOG, Southwest Oncology Group.

American Cancer Institutes (AACI). Control groups included patients with the same diagnosis and tumor stage and similar comorbidity levels who received similar treatments in the setting of standard cancer care.

The studies found that the differences in costs (four studies) or charges (one study) ranged from a 10% savings to a 23% increment for clinical trial participation at 6 months of follow-up, a 10% to 14% increment at 12 months' follow-up, a 20% increment at 24 months, and a 1% increment at 60 months' follow-up (Table 1). There was a wide variation in costs/charges for individual patients and controls, with some clinical trial patients differing by more than $200,000 in costs/charges from matched controls. For breast cancer patients who underwent autologous stem-cell transplantation, mean costs were 120% greater than costs for controls who received standard chemotherapy, while charge estimates were 15% lower in comparison to charge estimates for controls who received autologous stem-cell transplantation outside of a clinical trial.

In evaluating the findings of these studies, several methodologic considerations related to selection of cases and controls, identification of resources, estimation of costs, and statistical analyses should be discussed (Table 2). These areas represent the most important features of economic analyses of cancer care.[9-11]

The studies included patients with between two and nine different types of cancer diagnoses, with breast cancer being the most common diagnosis. Two studies identified cases by reviewing logs from cancer registries at the managed care organization, two studies identified patients through searches of electronic and paper files, and one study included a random sample of a specified number of clinical trial participants at each of five tertiary cancer centers. In some cases, the same patient participated in more than one clinical trial during the study period. The AACI/Northwestern University and the Memorial Sloan-Kettering Cancer Center studies included only those patients who received the majority of their care at the participating cancer center because of the operational difficulties associated with cost identification for medical care provided in multiple settings.

Identification of appropriate controls was the most challenging aspect of study design. Controls were matched for diagnosis, stage, and age in all five studies. Matching was based on eligibility for the clinical trial in two studies, on survival in one study, and on performance status or comorbidity in two studies. However, the type of comparative treatment varied and in all cases differed from that used for case patients who participated in the clinical trials. For example, three studies included breast cancer patients who received an autologous stem-cell transplant, but two of these identified controls who received standard-dose chemotherapy and one included controls who underwent transplantation outside of the clinical trial setting. For the four published studies, control patients who had similar clinical and demographic characteristics but differed with respect to the specific treatment regimen could be identified for two thirds to three quarters of the clinical trial patients.

Measurement of the resources to be included in the economic analyses varied. These data were obtained from electronic claims files in all studies, which facilitated data collection efforts. In the Kaiser Permanente and Group Health Cooperative studies, almost all of the resources associated with cancer care were captured in the electronic data files. The Mayo Clinic study excluded outpatient prescription drugs, durable medical equipment, ambulance and other transportation services, outpatient services provided by allied health professionals, and nursing home care. The other two studies excluded resource use that occurred outside of the tertiary cancer center.

The methodology for deriving economic inputs was unique to each study. The Mayo Clinic study assigned a value for each unit of service that was adjusted to national cost norms using Medicare fee-schedule rates for physician and outpatient ancillary services. Hospital charges were converted to costs by applying department-level cost-to-charge ratios obtained from Medicare reports. Unit costs were normalized to national 1995 values by use of regional hospital market-basket indexes obtained from annual Prospective Payment Assessment Commission reports. The Kaiser Permanente study used a proprietary system that assigned a value to each unit of pharmacy, laboratory, imaging, and home health services, with additional allocation of building and administrative overhead rates that were specific to the Kaiser system. Unit costs reflected average annual costs throughout Kaiser Permanente in Northern California. For out-of-network services, provider charges were used as the estimate for costs. Copayments by patients, representing out-of-pocket costs to patients, were also included. Costs in the Memorial Sloan-Kettering Cancer Center study included hospital costs and physician charges, based on estimates derived from Medicare cost-to-charge ratios for the relevant resources. The Group Health Cooperative Study is currently revising its cost estimation effort. The AACI/Northwestern University pilot study used charges, not costs, in the analyses, primarily because the five-site study would have required a different cost estimation effort for data from each tertiary cancer center. In most cases, the preferred method for economic analyses is based on estimates of costs, not charges, because of marked discrepancies that exist between billed charges and opportunity costs in health care.[12] These differences vary by type of resource, among physicians, and over time, resulting in a distorted estimate of economic differences between groups of patients treated with a variety of medical resources.

Analytic approaches also differed. The Mayo Clinic reported costs over a 5-year time period, the Group Health Cooperative reported costs over a 2-year time period, the Kaiser Permanente study reported on costs over a 1-year time period, and the Memorial Sloan-Kettering Cancer Center and the AACI/Northwestern University studies reported costs over a 6-month time period. Censoring of patients with incomplete follow-up was done only in the Mayo Clinic study because of the long follow-up period. Statistical differences were determined using paired *t* tests based on matched samples in the studies from the Mayo Clinic and the AACI/Northwestern University, a one-covariate (Charlson comorbidity score) ordinary least squares regression model in the Kaiser Permanente study, and unpaired *t* tests in the Memorial Sloan-Kettering Cancer Center study.

There are two ongoing large-scale efforts designed to develop valid and reliable estimates of the incremental costs of clinical trials carried out in diverse academic and community settings. The RAND/National Cancer Institute (NCI) Costs of Clinical Trials Study is evaluating the costs of 750 individuals enrolled onto phase II/III clinical trials from multiple community and tertiary cancer centers and 750 matched controls.[10] The AACI/Northwestern University Clinical Trials Costs and Charges Project has proposed a complementary study that will evaluate and compare the costs of 100 patients enrolled onto phase I clinical trials conducted at tertiary cancer centers with those of an equal number of matched controls. These studies are warranted for several reasons. First, the five pilot studies had sample sizes that were insufficient to detect cost differences that may be important for policy purposes. Second, treatment patterns differ across institutions, and four of these studies were conducted within a single institution or health system, which makes it difficult to generalize. Third, cases and controls matched at a single institution may differ in unobserved but important ways that affect treatment costs, as a result of self-selection into trials. Fourth, the pilot studies excluded some potential important dimensions of treatment, such as clinicians outside the delivery system. Finally, single-institution studies may underestimate the financial impact of transferring care from a community setting in order to participate in some clinical trials.[10]

### *Federal, State, and Private Sector Policy Initiatives Related to Reimbursement of Clinical Trials*

*Federal efforts.* Federal policy initiatives related to clinical trial reimbursement began in 1994 when the Department of Defense (DOD) initiated a demonstration project that covered the costs of bone marrow transplantation in clinical trials (Table 3). In 1996, this demonstration project was expanded to include all phase II and III cancer treatment trials funded by the NCI. The DOD demonstration project was limited to NCI trials because the imprimatur of the NCI is only given to cancer trials that have demonstrated

Table 3. Federal Cancer Clinical Trial Legislative Efforts

| Cancer Clinical Trial Reimbursement Legislation | | | | |
|---|---|---|---|---|
| Federal Efforts | | | | |
| Federal Agency | Year | Trial Purpose | Phase | Qualified Trials |
| DOD/TRICARE | 1996,1999* | Prevention,* early detection,* screening,* treatment | II, III | DOD/NCI Cancer Clinical Trials Demonstration Project; NCI (NIH) trials only** |
| DVA | 1997 | Prevention, diagnosis, treatment | I, II, III, IV | NCI and DVA cost-sharing agreement; NCI (NIH) trials in DVA hospitals |
| Medicare/Medicaid | 2000 | Diagnosis, treatment | Any trial undertaken with therapeutic intent | All clinical trials, not just cancer, NIH, CDC, AHRQ, HCFA, DOD, DVA, FDA; other qualified trials |

Abbreviations: NIH, National Institutes of Health; DVA, Department of Veteran's Affairs; AHRQ, Agency for Healthcare Research and Quality; CDC, Centers for Disease Control; FDA, Food and Drug Administration.

*Expanded benefits added at the later date.

themselves to be addressing a critical public need with rigorous scientific methodology. In 1997, the Department of Veterans Affairs (VA) joined the federal demonstration project effort. In 1999, the DOD expanded their NCI cancer trials demonstration project to include coverage of prevention, early detection, and screening trials. Enrollment onto the program has increased three-fold since the beginning of the project in 1996. Of the approximately 11,700 patients diagnosed with cancer annually under the DOD (TRICARE) health coverage umbrella, 51 enrolled in 1996 (0.5%) and 131 enrolled in 2000 (1.5%). In 2001, an estimated 240 cancer patients (2.0%) are expected to enroll onto the DOD/NCI trial program.

Medicare policies were not supportive of clinical trials during the 1990s.[13] The HCFA excluded coverage of routine care costs associated with clinical trial participation for Medicare enrollees, on the basis that the treatment was experimental or investigational.[1] However, the United States General Accounting Office found that less than 4% of claims for clinical trial costs incurred by Medicare beneficiaries were denied.[2] Furthermore, they found that oncologists frequently submitted bills for components of complex treatments, without specifying the procedure itself. HCFA is estimated to have paid 50% to 90% of routine patient care costs in clinical trials, after taking into account both costs for which no reimbursement was sought and claims that were submitted and rejected. In 1993, the Office of the Inspector General of the Department of Health and Human Services found that Medicare was being billed millions of dollars for surgical procedures involving unapproved medical devices. Almost all of the 130 hospitals under investigation had billed for clinical trials. However, quickly passed legislation prevented HCFA from collecting from the hospitals.[1]

In addition, no federal clinical trials legislation has been passed. One 1993 bill, the Cancer Treatment Improvement Act, addressed the issue of clinical trial coverage but never made it past committee. In 1996, the Medicare Cancer Clinical Trial Coverage Act was introduced in the Senate and the Medicare Cancer Clinical Trial Demonstration Act in the House. The bill, which applied to the 44 million individuals whose coverage was regulated by Employee Retirement Security Act plans, would allocate $750 million to cover cancer clinical trials sponsored by the National Institutes of Health (NIH), DOD, and the DVA, would require development of federal regulations that would define routine patient care costs, and would study the impact of clinical trials reimbursement on group health insurance plans. The Medicare Cancer Clinical Trial Coverage Act was reintroduced in 1997, 1998, and 1999, without success. The Health Insurance Bill of Rights Act of 1997 introduced mandated coverage by all group health plans of federally funded clinical trials for "seriously ill patients with no standard treatment alternative." The language regarding clinical trials was folded verbatim in 1998 into the Patient Bill of Rights Act. The Sydney E. Salmon Access to Cancer Clinical Trials Act of 1999 was among the 90% of bills that never make it past committee. The Bipartisan Consensus Managed Care Improvement Act, introduced by Representatives Charlie Norwood (R-Georgia) and John Dingell (D-Michigan) in 1999, was passed by the House in 2000 but tabled by the Senate. The bill would have mandated group health plan coverage of all phases of federally funded prevention, early detection, and treatment trials for patients with serious or life-threatening illnesses.

In 2000, after years of lobbying of HCFA leadership by individuals, patient groups, health care workers, and organizations who were concerned about reimbursement denials of clinical trial costs and the low rates of accrual to clinical trials, former President Clinton issued a memorandum stating that HCFA was authorized to cover the costs of cancer clinical trials. This decision was supported by the

Table 4. Pending Federal Legislative Initiatives for Cancer Clinical Trials

| On the Horizon in Congress | | | | |
|---|---|---|---|---|
| Legislative Body | Year | Trial Purpose | Phase | Qualified Trials |
| House of Representatives by Pryce (R-Ohio), HR 967 | 2001 | Treatment | Not restricted | The Access to Cancer Clinical Trials Act of 2001 would mandate group health plans to cover all federally supported cancer trials (NIH, CDC, AHRQ, HCFA, DOD, DVA, DOE, NIH COOP groups, NIH-supported centers) and trials of IND-exempt drugs |
| Senate by Snowe (D-Washington), S 257 | 2001 | Treatment | Not restricted | The Improved Patient Access to Clinical Studies Act of 2001 would mandate all ERISA and group health plans to cover care received in all trials sponsored by HHS, NIH, FDA, VA, DOD, or NIH-qualified nongovernment research entity |
| Senate by McCain (R-Arizona), Edwards (D-North Carolina), Kennedy (D-Massachusetts), (S 1052) | 2001 | Not specified | Not restricted | The Bipartisan Patient Protection Act would mandate group health plans to cover trials approved and sponsored by NIH, NIH COOP group or center, FDA, DOD, or VA |
| House of Representatives by Ganske (R-Iowa), Dingell (D-Michigan), Norwood (R-Georgia), (HR 2563); Norwood (House Amendment 303) | 2001 | Not specified | Not restricted | The Bipartisan Patient Protection Act would mandate group health plans to cover trials approved and sponsored by NIH, NIH COOP group or center, FDA, DOD, VA, or NIH-qualified nongovernment entity |

Abbreviations: DOE, Department of Energy; COOP, cooperatives; ERISA, Employee Retirement Security Act; DHHS, Department of Health and Human Services.

empirical evidence on the cost of clinical trials from the Group Health, Kaiser, and Mayo Clinic studies, the Institute of Medicine's report recommending Medicare coverage of routine patient costs on clinical trials, and the growing body of state legislation and voluntary initiatives from private insurers. This benefit included a broad definition of "qualified" clinical trials. The Final National Coverage Determination issued by HCFA extended the definition of qualified clinical trials beyond those funded or conducted by government bodies to trials that satisfied qualifying criteria. Certain trials were deemed to be qualified and automatically covered: those funded by the NIH, the Centers for Disease Control and Prevention, the Agency for Health Research and Quality, HCFA, the DOD, and the DVA; trials supported by centers or cooperative groups that are funded by these organizations; and trials conducted under an investigational new drug (IND) application reviewed by the Food and Drug Administration. The Agency for Healthcare Research and Quality has, in conjunction with other federal agencies and input from interested specialty groups and other stakeholders, developed additional criteria to identify high-quality trials that would be qualified. These criteria await approval from the new administrator of the Center for Medicare and Medicaid Services (formerly the HCFA). Until these qualifying criteria are available, trials that are exempt from having an IND will be automatically considered to be qualified trials if the study evaluates an already defined Medicare benefit, is designed with a therapeutic intent (not to evaluate toxicity), and enrolls beneficiaries with a diagnosed disease if the study is for a therapeutic intervention (but it may enroll healthy beneficiaries if the trial is for a diagnostic intervention). Medicare will cover reasonable and necessary care required to diagnose and treat complications arising from participation in clinical trials, as well as items and services required for the provision of the investigational item. All clinical trials submitted for Medicare coverage will be entered onto a national registry. Medicare will cover all routine costs of automatically qualifying and investigator-certified trials. However, if the Center's chief clinical officer subsequently finds that a clinical trial was misrepresented, the provider may be held liable for the costs.

Efforts to pass broad clinical trial legislation have moved forward in 2001 (Table 4). The recently approved Patient Protection Act legislation led by Senators McCain (R-Arizona), Edwards (D- North Carolina), and Kennedy (D-Massachusetts) in the Senate (S. 1052) and Congressman Ganske (R-Iowa), Dingell (D-Michigan), and Norwood (R-Georgia) in the House (H.R. 2563) includes a section mandating coverage of all phases of federally funded treatment trials for the seriously ill. However, after incorporation of an amendment related to financial and administrative considerations for lawsuits by Representative Norwood (House Amendment 303) that was negotiated with President Bush, the Senate and House bills differ markedly in their language regarding other aspects of managed care and will need to be reconciled in the conference process of the Congress. A bill dealing specifically with coverage of patient care costs of cancer clinical trials was introduced in the House by Representative Deborah Pryce (R-Ohio) as the Access to Cancer Clinical Trials Act of 2001 (H.R. 967). This bill is in line with the Medicare National Coverage Decision and mandates coverage of all phases of federally funded cancer prevention, diagnostic, and treatment trials,

trials approved and funded by "qualified nongovernmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants," and IND-exempt investigator-initiated trials. During debate over the McCain-Kennedy-Edwards legislation, the Senate approved a nonbinding "Sense of the Senate" amendment on clinical trials by an 89 to 1 vote. The amendment, offered by Senator McCain, expresses the sense of the Senate that individuals with life-threatening diseases should have the opportunity to participate in federally approved or funded clinical trials. All versions of the proposed legislations state that qualified individuals have life-threatening or serious illnesses "for which no standard treatment is effective" and that participation in the trial offers "meaningful potential for significant clinical benefit." This language raises concern that patients might be excluded from clinical trials if the standard therapies are a reasonable option. Attempts to clarify this language are ongoing. President Bush has also voiced support for coverage of patient care costs for treatment in qualified clinical trials in a February 2001 statement sent to Congress related to "principles" for a patient's bill of rights. Thus, the prospects for passage of comprehensive federal legislation supporting clinical trial reimbursement are good, although the exact details remain uncertain.

*State legislative efforts.* As of August 2001, 14 states have passed laws mandating coverage of patient care costs associated with treatment provided on specified categories of cancer clinical trials (Table 5). The question put before state legislatures has been whether the insurance barrier to clinical research is best removed through the voluntary action of health insurers or if formal legislation is needed. Rhode Island was the first state to legislate insurance coverage for clinical trials in 1995. The bill originally supported coverage of phase III and IV cancer treatment trials but was amended in 1997 to cover phase II, prevention, screening, and phase III trials. Qualifying trials were those that were funded by the NIH, DVA, or DOD or conducted in an NCI-affiliated cancer center. Georgia mandated insurance for selected pediatric cancer trials in 1998. Maryland and Virginia expanded on the idea in 1999, mandating insurance for cancer trials conducted in in-state academic institutions. Also in 1999, Maine passed a law requiring coverage of NIH-sponsored trials in cooperative groups or NCI-designated cancer centers. The same year, Louisiana passed a law including these trials as well as trials sponsored by the Food and Drug Administration, DOD, DVA, and the Coalition of National Cancer Cooperative Groups. Several other states followed suit in 2000 and 2001. Illinois extended its guarantee of coverage to all "seriously ill patients for which no standard therapy is available." This ambiguous clause defined the qualified patient as necessarily lacking "standard care," phrasing echoed in the Patient Bill of Rights. Furthermore, it only required that insurers had to offer this as an option, not that employers had to buy the benefit as part of their employee health coverage package. Most of the state-level legislation does not define a qualified patient but instead defines qualified trials. Similar legislation is pending in a number of other states. Many of the current coverage initiatives exclude phase I trials partly because no data exist on costs, little data exist on the investigative treatment, and the treatments have little chance of being therapeutic. Other initiatives limit their scope to trials with a therapeutic intent. Most initiatives limit coverage to cancer clinical trials, in part because the national infrastructure surrounding cancer trials is the most established and comprehensive of all diseases and cancer clinical trials are subject to high levels of controls, monitoring, and oversight. State legislative efforts do not pertain to employees of self-insured corporations as defined under the Employee Retirement Security Act of 1974. Lastly, concern over variable scientific quality has led many state legislatures to limit reimbursement to trials funded by federal agencies. Although institutional review boards ensure that a trial is designed and conducted ethically, they do not assess scientific validity. However, this policy excludes a great many high-quality clinical trials that are funded by sources other than the federal government.

*Private insurer efforts.* Private insurers may be concerned that clinical trial costs are excessive, primarily as a result of extensive observation and testing periods. Uncertainty over reimbursement, rather than actual denial of reimbursement, may adversely affect participation in clinical trials. Furthermore, some clinical trials, such as trials of bone marrow transplantation for breast cancer, were undoubtedly expensive. In the early 1990s, private insurers who refused reimbursement for bone marrow transplants for breast cancer paid large jury awards and settlements to families of the affected individuals. Subsequently, many states and private insurers adopted policies to reimburse for the procedure. In 1999, findings of an absence of clinical benefit with bone marrow transplantation for breast cancer were reported. The reports had been delayed by several years because poor clinical trial accrual had led to an extended study period.

At the end of the prior decade, several large private health insurers agreed to reimburse for medical care that occurs with clinical trials. These insurers included the New Jersey Association of Health Plans, OhioMed, United Healthcare, and the Mayo Health Plan[14] (Table 6). The New Jersey Association of Health Plans agreement is unique in that it represents the first instance for which all private insurers in a single state have voluntarily agreed to provide cancer

**Table 5. State Legislative Efforts for Cancer Clinical Reimbursement**

| State | Cancer Clinical Trial Reimbursement Legislation | | | |
|---|---|---|---|---|
| | State Legislation | | | |
| | Year | Trial Purpose | Phase | Qualified Trials and Pending Initiatives |
| Alabama | | | | None |
| Alaska | | | | None |
| Arizona | 2000 | Prevention, palliation, treatment | I, II, III, IV | NIH, NIH COOP group, DVA, FDA, entity meeting NIH grant criteria, academic institutions in Arizona |
| Arkansas | | | | None |
| California | 2001 | | I, II, III, IV | NIH, FDA, DOD, DVA, trials of IND exempt drugs |
| Colorado | | | | None |
| Connecticut | 2001 | Prevention, treatment | III (prevention); I, II, III, IV (treatment) | NIH, COOP groups, FDA, DOD, DVA |
| Delaware | 2001 | Treatment | Not specified | NIH, COOP group, cancer center, CCOP, DOD, DVA; part of state patients' bill of rights |
| District of Columbia | | | | None |
| Florida | | | | Bill introduced in 2001; did not progress through committee |
| Georgia | 2000 | Treatment | II, III, IV | Bill introduced to amend current law to include adults in NIH, COOP group trials; did not progress through committee |
| | 1998 | Treatment | II, III | Pediatric trials only, NIH, FDA, meets COG standards |
| Hawaii | | | | None |
| Idaho | | | | None |
| Illinois | 2000 | Treatment | II, III, IV | Terminally ill patients with no standard treatment, NIH, DHHS, FDA*; benefit must be offered but employer not required to purchase |
| Indiana | 2001 | Detection, prevention, treatment | I, II, III, IV (detection, prevention); II, III, IV (treatment) | Bill introduced, referred to committee; NIH trials |
| Iowa | 1998 | | | Health Insurance Consumers' Bill of Rights introduced but did not come out of committee |
| Kansas | | | | None |
| Kentucky | | | | None |
| Louisiana | 2000 | Detection, prevention, treatment | II, III, IV | NIH, COOP group, cancer center, FDA, DOD, DVA, Coalition of National Cancer Cooperative Groups |
| Maine | 1999 | Treatment | Not specified | DHHS, NIH, COOP group, cancer center |
| Maryland | 1999 | Prevention, early detection, treatment | I, II, III, IV | NIH, NIH COOP group, DVA, FDA, academic center in Maryland, IRB-approved trials at institution with MPA from OHRP |
| Massachusetts | | | | Bills introduced in House and Senate, referred to committee |
| Michigan | | | | Voluntary agreement, pending final sign-off |
| Minnesota | | | | Voluntary agreement, pending final sign-off |
| Mississippi | | | | None |
| Missouri | | | | Bill introduced in 2001, referred to committee |
| Montana | | | | None |
| Nebraska | | | | None |
| Nevada | | | | None |
| New Hampshire | 2001 | Treatment | IV | NCI (COOP groups, centers, CCOPs), FDA, DOD, DVA, IRB-approved trials at institutions that have MPA from OHRP |
| New Jersey | 1999, 2000† | Prevention, early detection, treatment | II†, III†, III | Voluntary agreement covering NIH, FDA, DOD, DVA* |
| New Mexico | 2001 | Prevention, detection, treatment | I, II, III, IV | NIH, COOP group, cancer center, DOD, DVA, NIH-qualified nongovernment agency |
| New York | 2001 | | | Bill introduced for coverage of "experimental drugs" for breast cancer; referred to committee |
| North Carolina | 2001 | | | Two bills introduced, still in committee |
| North Dakota | | | | None |
| Ohio | | | | Coverage of trials on individual case basis |
| Oklahoma | 2001 | | | Bill introduced, but clinical trial clause removed in conference committee |
| Oregon | | | | None |
| Pennsylvania | 2001 | | | Bill reintroduced, still in committee |
| Rhode Island | 1995, 1997† | Treatment | II†, III, IV | NIH, NCI, COOPs, DVA, FDA, NIH-qualified institute following NCI guidelines |
| South Carolina | | | | None |
| South Dakota | | | | Possible coverage through off-label drug provision |
| Tennessee | | | | Possible coverage through off-label drug provision |
| Texas | | | | None |
| Utah | | | | None |
| Vermont | 2001 | Prevention, early detection, treatment | I, II, III, IV | Cancer trials at Norris Cotton Cancer Center and Vermont hospitals |
| Virginia | 1999 | Treatment | II, III, IV | NIH, VA, FDA, academic center in Virginia |
| Washington | | | | Two bills did not progress through committee in 1999 and 2000; not yet reintroduced |
| West Virginia | | | | None |
| Wisconsin | 1999 | | | Voluntary agreements by selected payers associated with UWCCC |
| Wyoming | | | | None |

Abbreviations: CCOP, Community Clinical Oncology Program; COG, Children's Oncology Group; IRB, institutional review board; MPA, Multiple Project Assurance; OHRP, Office of Human Research Protection; UWCCC, University of Wisconsin Comprehensive Cancer Center.

*These projects will include an analysis of the economic impact of clinical trial reimbursement.

†Expanded benefits added at the later date.

Table 6. Private Insurance Plan Agreements for Cancer Clinical Trial Reimbursement

| Private Insurance Plan Agreements | | | | |
|---|---|---|---|---|
| Organization | Year | Trial Purpose | Phase | Qualified Trials |
| New Jersey Association of Health Plans | 1999, 2000* | Prevention, early detection, treatment | I*, II*, III | NIH, FDA, DOD, DVA† |
| Ohio Med | 2000 | Treatment | II, III | NCI (NIH) trials only† |
| United Healthcare | 2000 | Prevention, diagnosis, treatment | I, II, III, IV | Trials of COOP groups participating in Coalition of National Cancer Cooperative Groups and trials of the Coalition† |
| Aetna US Healthcare | 2000 | Not specified | Not specified | FDA, NCI, or similar national cooperative body |

*Expanded benefits added at the later date.
†These projects will include an analysis of the economic impact of clinical trial reimbursement.

clinical trial coverage. The agreement was the result of a collaborative effort of a working group consisting of insurers, consumers, and physicians. In the face of recent expansion in state legislation on health insurance, Michigan and Minnesota have recently followed the New Jersey example by encouraging collaborative task forces to work with private insurers to voluntarily pursue clinical trial coverage. Policy makers in Minnesota felt that a voluntary agreement among insurers avoided the antagonistic nature of mandated health coverage and would more likely lead to a broader definition of qualified clinical trials than piecemeal legislation. Voluntary initiatives might also foster cooperation. However, the task force from New Jersey also warned that oversight of the insurance agencies was still warranted.

## DISCUSSION

A paradox exists in reimbursement policies in which insurers may refuse to cover a promising new therapy because it is available only through clinical trials while covering what is considered standard treatment even though it may often be ineffective and sometimes more expensive. Pilot studies have found that the incremental costs and charges of clinical trial participants are similar or only slightly greater than those incurred by patients not enrolled onto clinical trials. It is expected that the large RAND/NCI Costs of Clinical Trials Study, which addresses phase II and phase III studies, the AACI/Northwestern University Clinical Trials Costs and Charges Project, which addresses phase I studies, and the economic projects built into several of the health policy initiatives will provide empirical data that allow for derivation of generalizable estimates of the costs of clinical trials. The small cost increment observed in pilot studies to date is justified by the additional benefits that clinical trials bring to all patients. If increased clinical trial enrollment could facilitate the completion of a trial that demonstrates an innovative therapy to be effective or a current therapy to be ineffective even a year earlier, thousands of lives could potentially be saved. Moreover, clinical trials remain our best source of information on drug safety. During phase I, II, and III clinical trials, reporting of adverse events is virtually complete, with comprehensive reports of these events as well as assessments of possible or definite causality. Identification of rare but potentially fatal side effects is facilitated in the clinical trial setting.

There are three strategic options for addressing clinical trial reimbursement: litigation, legislation, and voluntary cooperation. Litigation, as might be suggested by the bone marrow transplant studies in breast cancer, may be unlikely to lead to the most coherent, egalitarian, and entirely scientific reimbursement policy. Legislation and voluntary industry initiatives are the most probable paths to rational health policy decisions about clinical trial reimbursement. Initiatives such as the DOD/NCI cancer clinical trials demonstration project have started slowly, but the numbers of participants in the DOD demonstration in 2000 almost doubled from the year before and will most likely double again this year. Several states, several large private insurers, and Medicare have agreed to reimburse for medical care that occurs in the setting of certain clinical trials, although phase I clinical trials are frequently excluded. Medicare has made the largest leap in extending coverage to all clinical trials and drafting criteria to extend the range of qualified clinical trials beyond those sponsored by the NIH, DVA, or DOD. The New Jersey Working Group expects that their health insurance cooperative agreement, which covers 98% of insured patients in New Jersey, will increase the 3.3% rate of New Jersey cancer patients currently on clinical trials to 15% in 3 years.

Most major improvements in cancer treatment have been accomplished through controlled clinical trials. While a Harris Interactive survey found that both the general public as well as persons who participated in cancer trials had a favorable impression of clinical trials,[2] only 4% of cancer patients participate in these studies. If recruitment to clinical

trials continues to be poor, then the generalizability and timeliness of clinical trial findings will be jeopardized. Enrolling large numbers of patients onto clinical trials facilitates translational efforts to identify the most effective medical treatments, enhances comprehensive assessments of drug safety, and helps identify therapies that are likely to be ineffective. Finally, if empirical data continue to show that clinical trials result in only modest increases in costs, and if broad-based policy initiatives continue to occur, then there is no reason that clinical trial coverage should not ultimately be a permanent benefit that is supported by federal, state, and private sector policies.

## ACKNOWLEDGMENT

We thank Deborah Kamin, PhD, of the Department of Public Policy, American Society of Clinical Oncology, Alexandria, VA, for helpful comments.

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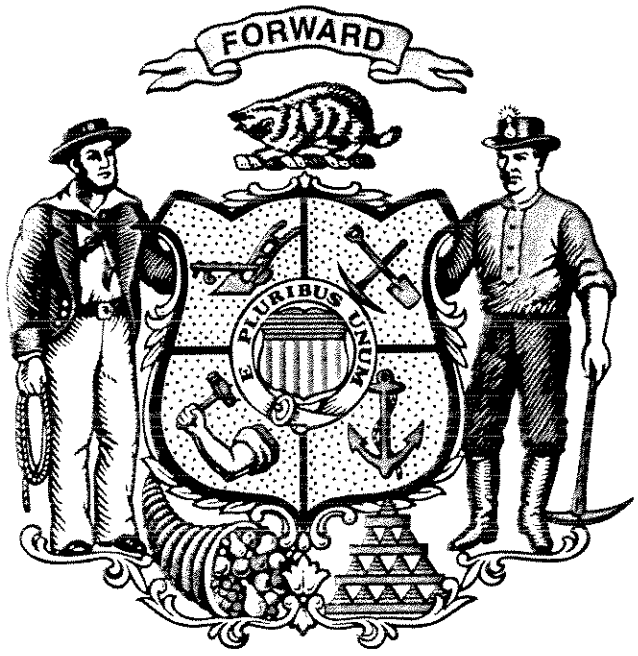
FORWARD
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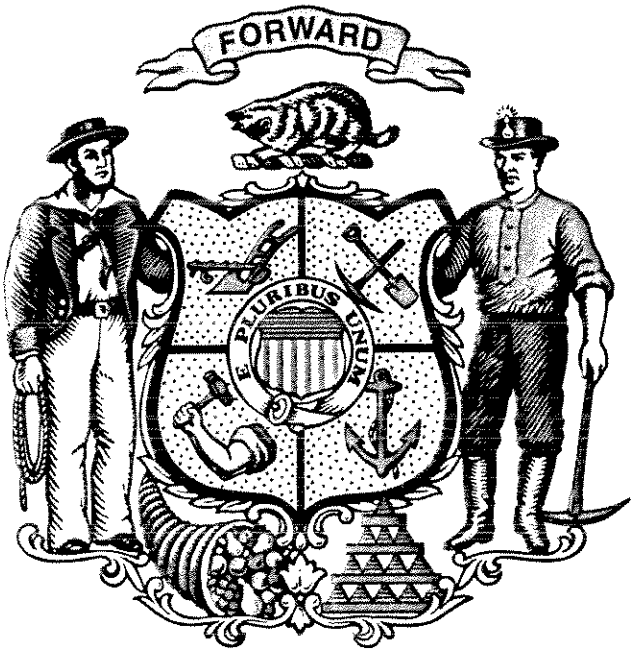
## Summary of Clinical Trail Experience
## Unity Members in Dane County
## Jan, 2004 - February, 2005

| | Members | % of Total |
|---|---|---|
| Total members with chemotherapy | 137 | |
| Members on Phase III clinical trial | 6 | 4.4% |

| | Total Charges | | | | |
|---|---|---|---|---|---|
| | Clinical Trial | | Standard chemotherapy | | |
| Type of Cancer | | Patients | Lowest | Highest | Patients |
| Lymphoma & Sarcoma | $137,928 | 1 | $23,841 | $142,943 | 4 |
| Lung | $81,644 | 1 | $89,425 | $140,057 | 4 |
| Pancreas | $124,603 | 1 | $32,700 | $244,435 | 4 |
| Uterine | $64,368 | 1 | $32,979 | $51,419 | 3 |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## CANCER PATIENT PROTECTION BILL - List of Supporters 7/8/05

All Saints Healthcare

American Cancer Society-Midwest Division

American Lung Association of Wisconsin

Aurora Health Care

Children's Hospital of Wisconsin

Columbia St. Mary's

Covenant Healthcare

Froedtert and Community Health

Green Bay Oncology

Gundersen Lutheran Medical Center

Leukemia & Lymphoma Society-WI Chapter

Marshfield Clinic

Medical College of Wisconsin

Oncology Nursing Society-WI Chapters

ProHealth Care

St. Vincent Regional Cancer Center

UW Cancer Center Aspirus Wausau Hospital

UW Center for Patient Partnerships

UW Center for Tobacco Research and Intervention

UW Comprehensive Cancer Center

UW Department of Surgery

UW Health - UW Hospital & Clinics

UW Health - UW Medical Foundation

UW Health - UW Medical School

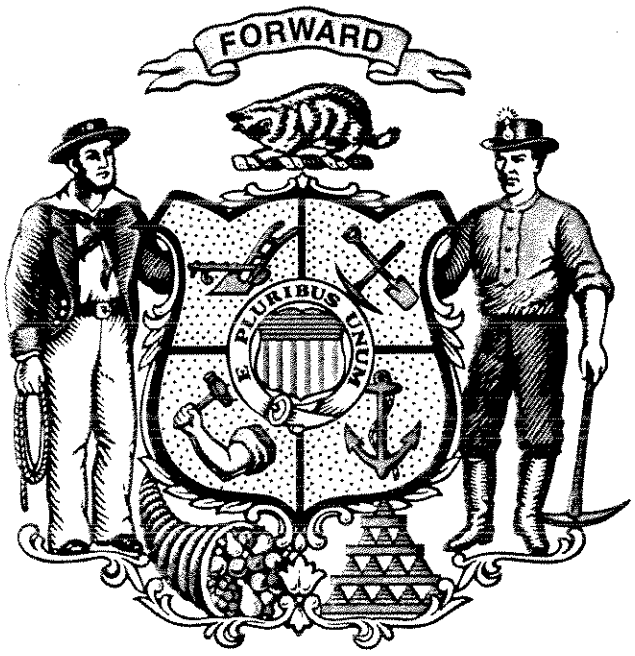
Wisconsin Breast Cancer Coalition

Wisconsin Cancer Council

Wisconsin Medical Society

Wisconsin Oncology Network

Wisconsin Women's Health Foundation, Inc.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**Rosenak, Mary Jan**

| | |
|---|---|
| **Subject:** | Mjr Senate Committee on Health, Children, Families, Aging and Long Term Care Public Hearing Notice |
| **Location:** | 201 SE |
| **Start:** | Wed 08/31/2005 1:00 PM |
| **End:** | Wed 08/31/2005 1:30 PM |
| **Recurrence:** | (none) |
| **Meeting Status:** | Meeting organizer |
| **Required Attendees:** | Mary Jan Rosenak (Mary Jan Rosenak) |

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| | |
|---|---|
| **From:** | Stegall, Jennifer |
| **Sent:** | Monday, August 22, 2005 10:10 AM |
| **To:** | *Legislative All Senate; *Legislative All Assembly |
| **Cc:** | Rose, Laura; Alice O'Connor; Alison Prange; Cathleen Dettmann; Klein, Christopher; Cory Mason; Dan Schwartzer; Deb Anderson; Eric Borgerding; Greg Aronin (Johnson and Johnson); Guarasci, Patrick - Office of Governor Jim Doyle; Hermes, Ron; Hillary Conley; Huffer, Linda; J. D Chris Taylor (chris.taylor@ppwi.org); Jack; Jason Helgerson; Jason Westphal; Jeff Ranous; Jeremy Levin; Jim Hemes; Jodi Bloch; Jodie Tierney ; Julie Swiderski; Karla (Ministry Health Care); Kate Venne; Katie Walby; Kelly Eakin Christianson Assoc. ; Laurie Kuiper; Linda Klein-Schmidt; Lisa Macaulay; Lisa Maroney; Lisa Roys; Little, Kevin; Liz Schumacher Meriter; Louie Schubert; Mara Brooks (mbrooks@wda.org); Mark Grapentine; Mark Reihl (carpenters union); Martin, Larry - DRL; Mary Klaver RTL; Maureen McNally; Michael Heifetz; Michael Welch; Michele Mettner; Moyer, Andrew - Office of Governor Jim Doyle; Nancy Wenzel; Paul Merline; Paul Westrick; Peter Christianson; Peter Theo; Plona, Katie - Office of Governor Jim Doyle; Robert Phillips; Sandy Lonergan; Snyder, MaryAnne; Tom Engels; Tom Fonfara; Tom Moore; Tony Driessen; Vaughn Vance |
| **Subject:** | Revised: Senate Committee on Health, Children, Families, Aging and Long Term Care Public Hearing Notice |

# REVISED

*Senate*

# PUBLIC HEARING

## Committee on Health, Children, Families, Aging and Long Term Care

The committee will hold a public hearing on the following items at the time specified below:

Wednesday, August 31, 2005
1:00 PM
201 Southeast
State Capitol

**Allen, Okie**

Of Eau Claire, as a member of the Hearing and Speech Examining Board, to serve for the term ending July 1, 2009.

**Dickinson, Loreli**

Of Oconto, as a member of the Nursing Home Administrator Examining Board, to serve for the term ending July 1, 2007.

**Kinast-Porter, Susan**

Of Albany, as a member of the Nursing Home Administrator Examining Board to serve for the term ending July 1, 2009.

**Korabic, Edward**

Of Shorewood, as a member of the Hearing and Speech Examining Board, to serve for the term ending July 1, 2009.

**Nosse, Larry**

Of Wauwatosa, as a member of the Physical Therapists Affiliated Credentialing Board to serve for the term ending July 1, 2009.

**Shropshire, Mark**

Of Appleton, as a member of the Physical Therapists Affiliated Credentialing Board to serve for the term ending July 1, 2008.

**Senate Bill 284**

Relating to: the investigation of child abuse or neglect reports in which a person who is not a caregiver of the child is suspected of the abuse or neglect of the child; defining the persons who are considered to be relatives of a child or juvenile for purposes of the Children's Code and the Juvenile Justice Code; extending the time for which a child may be held in custody when additional time is required to determine whether the filing of a petition initiating proceedings under the Children's Code is necessary; and the transfer of guardianship and custody of a child to a county department of human services or social services in a county other than Milwaukee County for the placement of a child for adoption in the home of the child's foster or treatment foster parents.

By Senators Roessler, Olsen and A. Lasee; cosponsored by Representatives Kestell, Townsend, Ott, Jeskewitz and Musser.

**Senate Bill 285**

Relating to: granting the juvenile court child in need of protection or services jurisdiction over a child 6 years of age or over who is or should be enrolled in grades kindergarten to 5 and who is truant from school as a result of the person having control of the child not causing the child to attend school regularly.

By Senators Roessler and Olsen; cosponsored by Representatives Kestell, Townsend and Ott.

**Senate Bill 244**

Relating to: granting a parent electronic communication with a child.

By Senators Stepp, Grothman and Darling; cosponsored by Representatives Vos, J. Fitzgerald, Gronemus, LeMahieu, Nass, Strachota, McCormick, Ballweg, Ainsworth, Hahn, Nischke, Sheridan, Lehman and Musser.

**Senate Bill 288**

Relating to: coverage of certain health care costs in cancer clinical trials.

By Senators Stepp, Roessler, Brown, Darling, Erpenbach, Hansen, Kanavas, A. Lasee, Lassa, Olsen, Risser, Wirch and Zien; cosponsored by Representatives Gunderson, Davis, Wasserman, Albers, Ballweg, Benedict, Berceau, Bies, Boyle, Fields, Gronemus, Hahn, Hines, Kaufert, Krawczyk, Kreibich, Kreuser, Lehman, Lothian, Molepske, Montgomery, Musser, Nelson, Ott, Pettis, Sheridan, Steinbrink, Townsend, Turner, Van Akkeren, Van Roy, Vos and Vruwink.

*The committee will hold an executive session on the following:*
*AB 385*

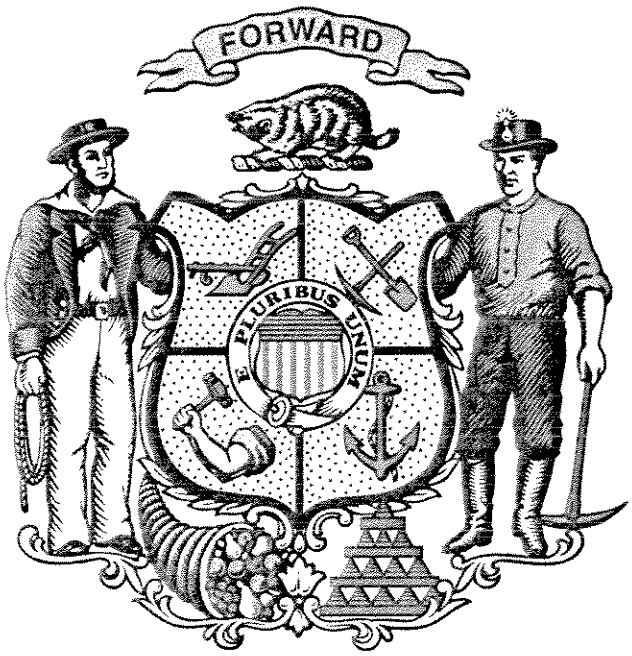
*Appointment of Steven Conway, of Athens, as a member of the Chiropractic Examining Board, to serve for the term ending July 1, 2009.*

*The appointment of Gerald Wilkie, of Eau Claire, as a member of the Council on Domestic Abuse, to serve for the term ending July 1, 2008.*

*The committee may hold an executive session on any of the other items before the committee.*

*08/22/2005: Senate Bill 288 was added to the list of items to be heard.*

Senator Carol Roessler
Chair


FORWARD
E PLURIBUS UNUM

Hearing Procedures
Committee on Insurance
November 3, 2005

Call to Order:

> ***"The Assembly Committee on Insurance will come to order. Will members and visitors please take their seats."***
> [Use gavel, if necessary]

Call of the Roll:

> ***"The clerk will call the roll."***
>
> [Clerk calls the roll.]
>
> ***"Representatives X, Y, and Z are excused. We will hold the roll open for members that may be joining us later."***

Welcome:

> ***"Welcome and thank you for being here. Today we are holding a public hearing on Assembly Bills 553 and Assembly Bill 617. As some members and citizens wishing to testify have time constraints, I ask that the committee and visitors remain flexible so that we may accommodate everyone here today.***
>
> ***Please note the memorandum on Clearinghouse Rule 05-059 (INS 9) and the action taken by the Senate Committee on Agriculture and Insurance.***
>
> ***Please also note there is an updated copy of Clearinghouse Rule 05-066, which is also available online through Folio."***

Committee Operations:

> *"If you are here to testify before the committee, please fill out a hearing slip and return it to a messenger. If you do not want to speak, but want to register your position, you may do so on the same slips. Anyone with time constraints should indicate that on the hearing slips. We will do our best to accommodate you.*
>
> *Written testimony is highly encouraged. Please give it to the messenger when you are called to speak.*
>
> *Speakers are encouraged to summarize their remarks rather than reading verbatim, and avoid repeating previous speakers. Questions from members will follow testimony.*
>
> *To the extent possible, we will alternate between speakers with different points of view on the subjects before the committee.*
>
> *It is our hope that we will be able to adjourn at a reasonable hour so your brevity is appreciated.*
>
> *Today's proceedings will be recorded but not broadcasted. Audio links and committee documents and written testimony can be found online at (www.RepNischke.com).*
>
> *Are there any questions from members?"*

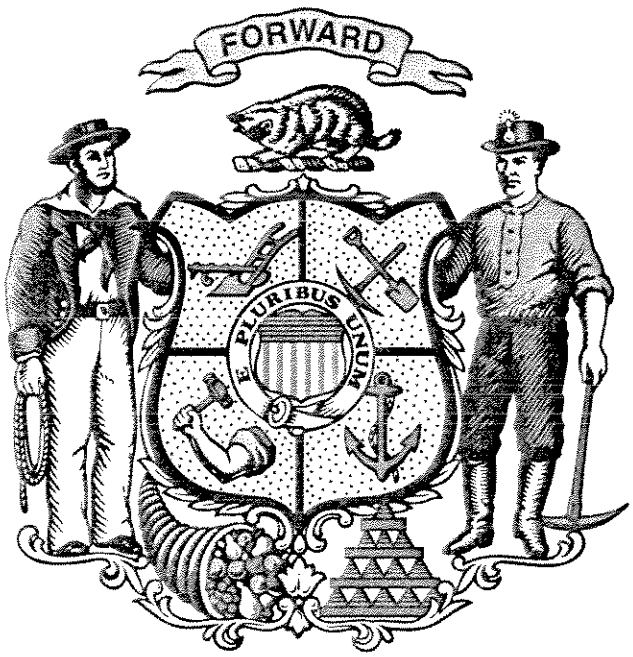
Next to last person to testify:

> *"This is the last person to register on this topic. If anyone else wants to speak, please complete a hearing slip and give it to the messenger at this time."*

Adjournment:

*"Thank you everyone who came today and sharing us with your perspective. Thank you for those who stayed until the end for your patience."*

*With no other business before the committee, this hearing is adjourned."*


FORWARD
E PLURIBUS UNUM

Hearing Procedures
Committee on Insurance
November 29, 2005

Call to Order:

> ***"The Assembly Committee on Insurance will come to order. Will members and visitors please take their seats?"***
> [Use gavel, if necessary]

Call of the Roll:

> ***"The clerk will call the roll."***
>
> [Clerk calls the roll.]
>
> ***"We will hold the roll open for members that may be joining us later."***

Welcome:

> ***"Welcome and thank you for being here. Today we are holding an executive session on Assembly Bill 553, 617, 844 and Senate Bill 288.***
>
> ***If there is no objection, we will consider Senate Bill 288 after Assembly Bill 617 since they are companion bills.***
>
> ***As some members have time constraints, I also ask that the committee hold the roll open for members joining us later.***
>
> ***Additionally, because of the short notice of our meetings, yesterday I asked that members allow bill amendments during our executive session in the morning.***

***Please note that to report our bills out, an LRB number is required. If you have an amendment in the process of being drafted, I ask that you at least provide the committee clerk with a full LRB number including the version (slash-number).***

***As a courtesy to amendment authors, I ask, if there is no objection, that amendments be introduced by unanimous consent, so that we will consider only adoption of amendments."***

"W***ritten testimony as well as a draft committee report was emailed and hand-delivered to your offices last night for your review.***

***Are there any questions from members?"***

Committee Operations:

Assembly Bill 533: 553

1. Explanation of ***bill and amendment*** by Legislative Council.
2. Substitute Amendment LRBs03162

3.) Bill as amended

Assembly Bill 617 and Senate Bill 288

1. Explanation of both ***bills and amendment*** by Legislative Council
2. Consideration of ASA 1 (LRBs0287) to AB 617.
3. Consideration of Assembly Bill 617 as amended.
4. Unanimous consent that the roll for Assembly Bill 617 apply to Senate Bill 288.

Assembly Bill 844

Tyler

1. Explanation of both ***bill and amendments*** by Legislative Council
2. Consideration of LRBa~~XXXX~~. 1580

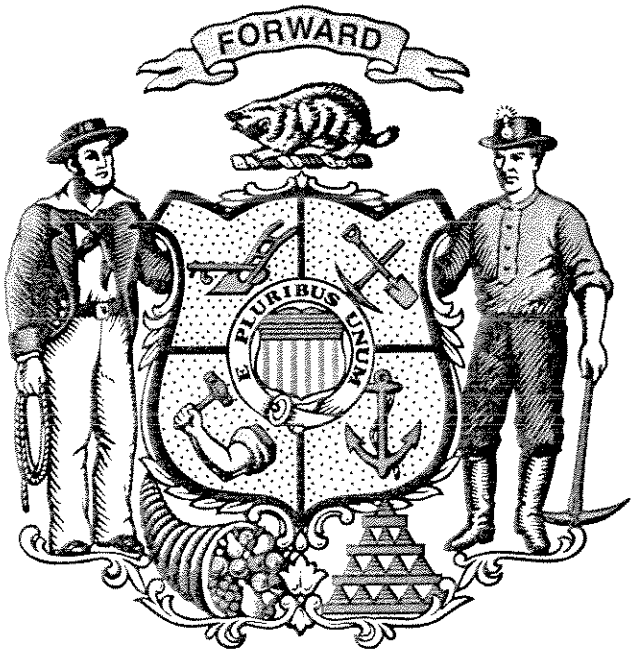
3. Consideration of LRBa~~XXXX~~ 1578
4. Consideration of LRBa~~XXXX~~ 1579
5. Consideration of LRBa~~XXXX~~ ~~1560~~ 1560
6. Consideration of ASA 1 (LRBs0319) to AB 844
7. Consideration of Assembly Bill 844 as amended.

Adjournment:

***"Thank you everyone who came and engaged in the discussion today. I will remind those present that committee documents including a draft committee report will be available online at (www.RepNischke.com)."***

***With no other business before the committee, this executive session is adjourned."***

Debb Moore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# CANCER PATIENT PROTECTION LEGISLATIVE PROPOSAL

## GOAL

The goal is to provide the most appropriate and cost effective treatment with the highest likelihood of success for each individual cancer patient in Wisconsin. The legislation simply states that the routine tests for cancer treatment covered under an individual's health plan would also have to be provided if the individual enrolls in a clinical trial.

## JUSTIFICATION

Cancer can be financially devastating in addition to the toll it takes on body and psyche. The high cost of cancer care is related to the cost of therapy, especially expensive chemotherapeutic agents. Often such drugs are administered in the context of clinical trials, studies aimed at continuously refining our understanding of the best therapy for a specific cancer. These trials are where the newest drugs and combinations of drugs are studied, often giving patients the best chance for a response to treatment. This is also the way we discover what drugs are not useful, thereby sparing patients the burden and expense of therapy that is not helpful. For these reasons, many in the cancer care community believe that care delivered in a clinical trial setting often represents the best treatment option for cancer patients. However, because such trials may be considered "research", the routine care costs incurred by patients enrolled in these trials are often not covered by insurers. Lack of coverage, in turn, limits the access of some patients to this "state of the art" care. Many in the cancer care community think that coverage of the routine care costs of clinical trials participation will actually decrease health care costs by finding new treatments that are more effective with better long term outcomes. For these reasons, cancer treatment given in the context of clinical trials should be viewed as routine and customary care.

1. UW Comprehensive Cancer Center is one of 38 NIH designated Comprehensive Cancer Centers (CCCs) in the US. In addition to Madison, cancer clinical trials also are conducted in many other parts of the state, including communities such as Milwaukee, Appleton, Green Bay, Janesville, La Crosse, Manitowoc, Marshfield, Menomonee Falls, Oconomowoc, Racine, Rhinelander, Waukesha, and Wausau.

2. Currently 22 states have legislation or agreements for insurers to cover routine care costs in cancer clinical trials. Over half of the CCCs are in the states with legislation or agreements to cover routine care costs for clinical trials. Wisconsin lags behind the other CCC states with insurance coverage of routine care costs.

3. Several studies published since 2000 have found that patient routine care costs for cancer clinical trials are not appreciably higher than costs for patients not enrolled in trials. Financial impact data collected by states with legislative mandates also indicate that coverage of routine care costs does not seem to be prohibitive.

4. Lack of insurance coverage for routine care costs in cancer clinical trials is a significant barrier to many patients who might otherwise enroll in a trial and also denies many cancer patients throughout Wisconsin access to the range of new cancer treatment options available in clinical trials.

5. Over 20 years of laboratory research breakthroughs on how cancer cells function have provided the knowledge to develop new anti-cancer strategies. Many new, potentially useful treatments are currently only available through clinical trials.

6. In 2000, Medicare began reimbursing routine care costs of clinical trials. The change in policy not only gives 40 million seniors access to cancer clinical trials, but could speed new cancer treatments into regular use.

7. For the vast majority of cancers that have spread (metastasized) there is no curative treatment. Breast, colon, prostate, lung, and pancreas cancers with widespread metastases are examples of incurable tumors. At present, many patients with these cancers receive standard cancer treatment that is expensive and has many side effects with minimal benefits. Cancer clinical trials provide the means to both develop successful treatments and offer more treatment choices to patients.

**The Importance of Clinical Trials**

Tamoxifen is an important medicine used in breast cancer treatment for the past three decades. Early in its use tamoxifen was prescribed only for older women. Clinical trials have shown that tamoxifen can reduce breast cancer recurrence in women who have tumors testing positive for hormone receptors regardless of age. For cancers where the hormone receptors are negative tamoxifen is not useful.

In the early 1990's after a new diagnosis and surgery for breast cancer tamoxifen was prescribed for many years and often patients were told they would take it for the rest of their lives. Clinical trials comparing longer with shorter durations of tamoxifen showed that the majority of benefit was gained in the first 5 years. Now it is standard to prescribe post surgery tamoxifen for only 5 years.

Therapy given within the framework of a clinical trial should be considered mainstream cancer care and should be fully supported in the treatment setting. The clinical trials process has been a standard approach for cancer clinicians for many years. The numerous clinical trials done in breast cancer now provide a very useful data base that guides our use of tamoxifen as well as chemotherapy. Clinical trials results provide important information about toxicity compared to benefit and define questions and directions for new clinical trials and treatments.

## PROPOSED LEGISLATION

Provide health care coverage of the routine care costs of cancer clinical trials approved by one of the following: National Institutes of Health (NIH), US Food and Drug Administration (FDA), US Department of Defense (DOD), US Department of Veterans Affairs (VA), or an institution that is approved by the Office for Human Research Protections of the US Department of Health and Human Services.