EXHIBIT 3
DATE 3/8/13
SB 55

HB 615: Cancer Clinical Trials
Study Report

Monica J. Lindeen, Commissioner of Securities and Insurance, Montana State Auditor
March 19, 2012

Executive Summary

With the passage of HB 615, the 2011 Legislature directed the Office of the Commissioner of Securities and Insurance (CSI) to study issues related to the equitable treatment by insurers for cancer patients seeking to participate in cancer clinical trials. As commissioner, I sought input from an advisory council of medical providers, insurers, employers, patients and patient-advocates.

The council was asked to examine the barriers to participation in cancer clinical trials, define routine care, and advise CSI on needed policy changes. A group of 18 members met six times between August 2011 and March 2012 and produced the following report detailing their findings and recommendations in sections D and E, and Appendix A. The remainder of the report provides background information summarized by our staff from research and from presentations and discussions at advisory council meetings. The entire report was presented to the council for review and comment.

The council reached a consensus on a definition of routine care which is contained in Appendix A. The group recommends the Children, Families, Health and Human Services Interim Committee request and support legislation incorporating this definition into Montana law and that all health insurance plans over which the state has jurisdiction be prohibited from denying coverage for routine care during clinical trials.

For self-funded employer health plans, over which CSI has limited jurisdiction, the council recommends educational programs and materials to inform them of the consensus definition and the reasons they should cover routine care during clinical trials. The council forwarded several other recommendations regarding education to patients, insurers, and providers about their findings and the definition of routine care. In addition, there are recommendations to standardize processes for communication about clinical trial protocols between providers and payers. Members of the council have asked me to authorize the continuation of the advisory council through 2012 to provide the time to develop these systems and materials.

I am happy to lend my support for their continued work and to all the council's 14 recommendations contained in this report.

Monica J. Lindeen
Commissioner of Securities and Insurance
Montana State Auditor

A. INTRODUCTION

With the passage of HB 615, Montana's 62nd Legislature directed the Office of the Commissioner of Securities and Insurance (CSI) to study issues related to the equitable treatment by insurers for cancer patients seeking to participate in cancer clinical trials.

HB 615 directs CSI to:

- Convene an advisory committee (hereafter Cancer Clinical Trials Advisory Council) of representatives of insurance, reinsurance, and self insurance offerors in Montana, as well as patients, health care advisors, providers, and administrators;
- Assess whether violations of Montana statutes are occurring related to this denial of care or ineligibility of coverage and take appropriate action if any are found;
- Review a selection of other states' policies related to required treatment of cancer routine care coverage for insureds undergoing clinical trials; and
- Summarize and present findings and recommendations to the Children, Families, Health and Human Services Committee on or before March 31, 2012.

HB 615 directs the advisory committee to:

- Evaluate the causes of the routine care coverage denials or exclusion for patients recommended for participation in cancer clinical trials;
- Indentify necessary federal policy changes to address denials or exclusion for the purchasers of ERISA-regulated health care plans;
- Define routine care for cancer patients undergoing clinical trials; and
- Make findings and recommendations to address the above items.

B. BACKGROUND ON INSURANCE COVERAGE FOR CANCER PATIENTS ENGAGED IN CLINICAL TRIALS

1. Description of the problem

Some cancer patients in Montana and around the country who have a group health plan or health insurance coverage find that treatment of their routine care is not covered when they join or consider joining cancer clinical trials. The sponsor of a clinical trial, usually the federal government or a pharmaceutical company, generally pays for the new treatment or device being tested. If the patient has primary coverage with Medicare, the Medicare plan covers routine care, like radiation and chemotherapy, during the clinical trial.

Group health plans or health insurance issuers, however, often consider the entire treatment during the period of the trial to be "experimental or investigational" and determine it to have a potential negative impact on the cost of routine care. While coverage for cancer treatment is common in health plans, exclusions for "experimental or investigational" treatments are also common. A company's decision to deny a claim on that basis relies on their interpretation of "experimental or investigational," for which there is no uniform interpretation across issuers or plans.

A patient may appeal an adverse decision. CSI can assist any patient who files a complaint alleging a plan's failure to pay a covered benefit whether or not a clinical trial is involved. Urgent pre-service appeals are available but not always understood by providers or participants. Assistance with the appeals process may allow for an expedited resolution based on the urgency of the requested treatment as reviewed by external medical reviewers.

There are many reasons patients may not file appeals. Primary among them is that they are sick and wish to use their remaining energy to focus on their health and their family's needs,not on their health plan or health insurance coverage. Anecdotal evidence suggests that the barriers encountered in accessing trials may occur much earlier than the formal appeals process. Initial conversations between parties that may not have access to full information may screen out some patients. There may not be complete understanding that the request is for "routine care" not for the "experimental care" that is the subject of the trial. Past denials by one payer in a particular situation may lead to patients or providers to make incorrect assumptions about future actions by the same or other payers.

Many states and the federal government define "routine care" for cancer patients and require coverage of routine care for cancer patients. Those definitions generally say that routine care is the care a patient would get in the absence of a trial. In practice, however, that care can vary widely based on how a patient responds, the types of complications that arise, and the speed at which the disease progresses.

When a trial is added to the mixture of uncontrollable variables associated with routine cancer treatment, it is difficult, if not impossible, to determine whether the trial procedure is negatively impacting the cost of the overall treatment. Complications that arise may be a result of the trial, but they may not. Complications arise in many patients whether or not they are participating in a trial.

Recent studies show that trials do not add to the cost and in some cases may reduce costs. These studies are referenced on the CSI webpage at http://www.csi.mt.gov/commcorner/Cancer/CancerResources.asp. When the trial yields a positive medical result, the cancer patient may live longer and continue to need expensive routine treatment. On the other hand, positive results may mean the patient no longer needs expensive, ongoing treatment. This makes calculating long-term cost benefits of successful, new treatments difficult.

The denial of treatment is difficult for patients and their families who believe the trial provides an opportunity to increase the quality or length of life. Most often those patients do not have the energy to appeal their health plan or health insurance decision to deny courage of the routine care. Those with strong advocates or uncommon perseverance may have better success, leading to disparities in treatment.

Limits on access to clinical trials also concern oncologists, researchers and policy makers who understand the importance of clinical trials for the advancement of treatment and potential for finding cures for illnesses that take a heavy toll on individuals, families, communities and public resources.

2. Montana research on coverage of routine care during clinical trials

The Office of the Commissioner of Securities and Insurance can collect data from insurance companies under its investigative authority. Absent a legal mandate for insurance companies to specifically cover routine care during clinical trials and a requirement that CSI collect the data, the office has not used its limited resources to request information from insurance companies in regard to this issue. Tracking actual denials and appeals would be feasible, but may be of limited value. The Council members acknowledged that barriers to accessing clinical trials are likely encountered before an official claim or appeal is filed.

The Montana Cancer Consortium is a nonprofit organization whose mission is to bring state-of-the-art cancer treatment to Montana through clinical trials sponsored by the National Cancer Institute (NCI). The group works with oncologists across the state to manage grants from NCI for clinical trials. The Consortium does not track denials of coverage for routine care of patients interested in participating in clinical trials.

Two members of the Council, representatives from the Billings Clinic and New West Health Services, provided information to the Council.

As one of the leading clinics conducting trials sponsored by the National Cancer Institute (NCI), Billings Clinic has been tracking clinical trial information for about four years. Offering clinical trials is part of their mission statement. As of 2012, cancer centers are required to have 4% of their patients on clinical trials for American College of Surgeons' Commission on Cancer accreditation. The Billings Clinic has been putting approximately 10% of their patients on trials in all four phases for the last 6 years, relying in some measure on federal and state programs such as Medicare as well as the clinic's internal assistance plan for patients without insurance. In 2010 and 2011, the clinic offered clinical trial participation to 435 patients of the 2000 screened for clinical trials. Of those offered a clinical trial, 294 were enrolled. Of the 141 who were not enrolled, 30 were formally denied insurance coverage.

New West Health Services (NWHS) reported progress with their fully-insured plans related to clinical trials in the last several years, including a prior review procedure with Billings Clinic. Following successful review of the trial protocol, subsequent patients are approved in advance. They have a list of 20 trials, mostly in phase three, that have been approved. NWHS received 85 requests for participation in clinical trials from 2003-2011 and approved 61 (72%) of them. Thirteen were with self-funded plans and these were generally for phase three trials. Of the 24 that were denied, 13 were with self-funded plans. The majority of the trial care that was denied was for trials in phases one and two. Many health plan or health insurance documents describe these early phase trials as "experimental" which generally excludes them from coverage.

3. Anecdotal stories from patients and providers in Montana

Several Montanans testified at the 2011 legislative session about their experience with coverage difficulties when considering clinical trials. That testimony is archived on the legislative web page for the House and Senate hearings. The Council received public comment from patients and families during the course of the study. Two patients on the Council offered their experiences. Both were in the same self-funded government plan.

One of them experienced a trial that included a treatment considered to be outside of routine care for his very aggressive cancer. He believed his self-funded plan thought the extra treatment had the potential of interfering with the routine treatment and thus denied coverage of all treatments. Because he was given less than a year to live, he went ahead with the trial under coverage from a government-provided second insurance. He was eventually told that his first health plan would cover routine care on the condition that complications wouldn't be covered.

Another patient on the council described his experience with his health plan. He felt he was up against a stone wall, even though his doctor determined him to be a perfect candidate for a clinical trial that would extend his life. He said the CSI office likely doesn't get more complaints

because patients don't know what to do after they are denied coverage. He elaborated on all the actions he took, including calling the members of the board of the health plan until the trial was approved.

4. Current practice by insurers in Montana

Insurance companies consider coverage of routine care for patients hoping to enter clinical trials on a case-by-case basis. A company may cover routine care after consideration of the trial protocol or they may deny coverage, generally based on a plan's exclusion of "experimental or investigational" treatment. Patients have the opportunity to appeal the decision to deny coverage whether the coverage is fully insured or self-funded.

Many insurance companies also administer self-funded plans for large employers. The contractual agreement in those plans will govern when coverage is denied and when there is an appeal of their decision to deny coverage. The initial decision to deny is generally based on the insurance company's policies and its definitions regarding "medical necessity" and "investigational and experimental." As previously noted, adverse benefit determinations can be appealed.

5. The issue across the states and how states have responded

It is clear that other states consider the coverage of routine care for cancer patients undergoing clinical trials to be of concern. Since 1995, 34 states and Washington, D.C., have passed laws or implemented agreements requiring coverage for routine care for cancer patients. Following the example of the states, Congress included a provision requiring such coverage under the Patient Protection and Affordable Care Act (ACA) in 2010. Medicare has required coverage since at least September 2000 and Medicare's National Coverage Decisions (NCD) was considered by the Council.

Various state laws and compacts were considered by CSI staff and the Council in the course of the study. Links to sites that report on state laws, and several examples of laws and agreements are available on the CSI web page at http://www.csi.mt.gov/commcorner/Cancer/CancerResources.asp

6. History of the 2007 effort in Montana

In 2007, the Montana Legislature considered a bill (SB 428) requiring coverage of routine costs for cancer patients in clinical trials. The bill passed the Senate, but was tabled in the House with the understanding that cancer care providers, payers, and patient advocates would work toward resolving this important health care issue. A collaborative consensus solution was to be formulated by those most involved in the issue.

The resulting Montana Working Group to Improve Access to Clinical Trials was a consortium of the major stakeholders in the care of Montana's cancer patients. The charge of the group was to improve access to clinical trials by:

a. Defining routine care;
b. Clarifying clinical trial terminology;
c. Developing and implementing operational processes for smooth enrollment and continuation of participation;
d. Educating impacted parties about the solution; and
e. Helping implement the consensus solution.

At one point during the process, the working group described its purpose and activities in this way:

> "The Montana Working Group to Improve Access to Clinical Trials believes this agreement would improve research study recruitment and Montana's cancer patients' access to clinical trials as a treatment option without risk of personal financial burden. Cancer clinical trials provide outcomes data necessary to assess medical practice and build on evidence based, value driven health care. Scientific oversight helps to focus rational decision making within these studies. Montana healthcare payers could benefit from the advancement in science, [the] avoidance of useless treatment, and [the] continuous quality improvement cancer care clinical research provides.
>
> The goal of this agreement is to increase participation in select cancer-related clinical trials by making payment for services provided within the context of clinical trials ...predictable. After serious consideration of these concerns and discussion of the rationale for supporting clinical research efforts in Montana, the group agreed that health plans should be willing to provide coverage for the routine care costs of patient participation in approved clinical trials."

Three subcommittees of the working group listed below were established on June 14, 2007. Each subcommittee set out to draft portions of a voluntary agreement that would provide the framework for coverage of patient care costs for those enrolled in clinical trials within the scope of the individual's benefit plan.

a. Definitions subcommittee: Draft the definition of routine care and clarification of clinical terminology.
b. Operations subcommittee: Draft guidelines and operational processes
c. Implementation subcommittee: Draft steps for targeted statewide education and implementation.

Draft language for an agreement on definitions was written in October 2007, but consensus was not reached. The effort was abandoned shortly thereafter. Several members of the current Council served on the 2007 working group and lent their historical perspective to the process.

7. How this study is different than the 2007 effort

The informal process in 2007 intended to reach a consensus agreement in lieu of legislation. It involved negotiation between stakeholders with the hope of producing an agreement among those stakeholders that would then be implemented voluntarily.

The current effort is the result of the passage of HB 615 and is designed to be a study, not an informal negotiation. The study bill directs CSI to research the issue and provide necessary resources. The outcome is a report on the recommendations and findings of an official advisory council to the Commissioner.

The CSI study, however, successfully produced a consensus definition among Council members for routine care during clinical trials. Council members believe there is more work to be done to educate providers, insurers and employers about the consensus definition; train providers on the role of CSI in coverage denial appeals; generate support for legislation to formalize the definition; and get agreement from self-funded plans. The Commissioner has agreed to continue to facilitate meetings of the Council for those purposes.

8. How the climate has changed since 2007

The context in 2011-12 was more conducive to progress on the issue of coverage for cancer patients' routine care while accessing a clinical trial. The Patient Protection and Affordable Care Act passed Congress in March 2010. One of its provisions requires the coverage of routine care costs for cancer patients in clinical trials. The provision goes into effect January of 2014. The National Association of Insurance Commissioners (NAIC is developing a model law for clinical trials, and that model law development is on the agenda for the Regulatory Framework (B) Task Force . Commissioner Lindeen serves on that committee. Commissioner Lindeen also serves as the Secretary-Treasurer of the NAIC.

In addition, new, scientific studies are available about the costs and benefits of clinical trials and were examined by Council members. Providers and payers alike are exploring new models for delivering and paying for care, improving health outcomes, and using electronic medical records. Commissioner Lindeen facilitates one such effort— the Montana Patient-Centered Medical Home Advisory Council. Finally, consumers are more engaged in the public discourse around health care. All these factors have helped stimulate more collaborative efforts, resulting in the following findings and recommendations.

C. CSI FINDINGS

1. Convene an advisory committee of representatives of insurance, reinsurance, and self insurance offerors in Montana, as well as patients, health care advisors, providers, and administrators.

In June, 2011, CSI made a general call to representatives of the required parties who might be interested in serving on the Council. CSI staff examined the responses to see how they fit the representation required in the law, spoke with participants to ascertain their level of interest, contacted others to fulfill the requirements, and announced the final Council participants on August 12, 2011. Council members are identified in Appendix B.

The creation of advisory councils is addressed in 2-15-122 MCA. Their purpose is to serve in an advisory capacity as defined in 2-15-102, MCA. In short, the law sets out the duties of advisory councils as "furnishing advice, gathering information, making recommendations and .... [not] administering a program or setting policy."

The "advisory committee" addressed in HB 615 is known as the Cancer Clinical Trials Advisory Council. The Council serves at the pleasure of the Commissioner and the names of its members have been filed with the Governor's office and the Secretary of State. The Council will exist no longer than two years. At its first meeting, the group selected a presiding officer. CSI staff took official minutes, which were approved by the Council and posted the CSI website. The Council followed rules of quorum. Except for government employees, members were entitled to pay and expense reimbursement.

The Council helped CSI evaluate the causes of the routine care coverage exclusions and denials, indentify policy changes at the federal level necessary to address these issues in ERISA-regulated self-funded plans, define routine care for cancer patients undergoing clinical trials, make findings and recommendations to the commissioner for possible resolution of issues identified, and respond to a draft study report.

The Council met six times between September 2011 and March 2012, when the final report and recommendations will be presented to the Interim Children, Families, Health, and Human Services Committee. Three meetings were held in person in Bozeman and three meetings were held via conference call. The agendas and official minutes of each meeting are available on the CSI website at http://www.csi.mt.gov/commcorner/Cancer/CancerMeetings.asp.

An interested parties list was maintained and its members informed of all meetings, electronic or in-person, and encouraged to give public comment. A public web page was available at the CSI website, which includes additional information about the Council's activities, instructions for joining the interested parties list, and resources from other states.

2. **Assess whether violations of Montana statutes are occurring related to this denial of care or ineligibility of coverage and take appropriate action if any are found;**

CSI does not currently collect data from insurance companies that will allow it to ascertain whether violations are occurring specifically related to clinical trials. Absent individual consumer complaints, or findings in a market conduct examination, CSI does not have knowledge about denials related to clinical trials.

Finding such a denial during a general market conduct examination would be unlikely unless specific intention was directed toward the issue, as only a small sample of cases are examined. Because there is no state law specifically requiring coverage of routine care for patients participating in clinical trials, a market conduct exam is unlikely to make a public finding related to failure to cover routine care during clinical trials, even if it found evidence. This will change with the implementation of federal law in 2014 when the coverage is required. If Montana conforms its law to the federal law, CSI would have the authority to enforce required coverage of routine care during clinical trials, and access to trials would improve.

Most major medical plans cover cancer treatment and it would be illegal for the plan to fail to provide coverage according to their contract. CSI would assist any patient who files a complaint alleging a plan's failure to pay a covered benefit whether or not a clinical trial is involved. An expedited appeals process would allow for timely resolution based on the medical necessity of the treatment as reviewed by independent medical reviewers. This can occur even if a plan has denied a claim based on an exclusion for "experimental or investigational" treatment.

To date, there has been only one complaint to CSI involving a clinical trial. The patient was covered under an ERISA-regulated, self-funded plan, over which CSI has no regulatory authority. However, CSI was able to help negotiate a solution informally. Under federal law, states now have additional authority to assist with patient appeals under ERISA-regulated self-funded plans. Further, federal law now requires external independent medical review for non-grandfathered self-funded plans, if the internal appeal is not settled. The state already requires this for fully-insured plans.

Given the testimony at the legislature and the experience of members of the Council, it is likely that difficulty accessing trials is more widespread than the anecdotal information suggests. It is likely that limitations on access to clinical trials more often occur informally at an earlier stage, with no paper record of the actions. Patients in this situation may not know they can file complaints with CSI; they may not believe filing a complaint would be effective; they may be too sick to file, or they may simply be unable to successfully negotiate with insurance companies. Providers and patient advocates may also experience many of these barriers. If cancer patient advocates or case managers had more understanding of plan benefits and the consumer ombudsman function of CSI, access for patients might improve. Health plans are now required

to provide consumers specific notices of their internal and external appeal rights and CSI's phone number must be included in those notices.

CSI considered asking insurance carriers to provide information and data that shows they are meeting their contractual obligations to pay for cancer treatment when patients are in clinical trials. The Council, however, expressed a desire to move toward resolution rather than looking back, and suggested that additional data collection is unlikely to yield useful results.

CSI can measure the success of the Council's effort through enacted policy changes, educational offerings, the number and resolution of formal appeals, and an examination of data on how many Montana patients participate in trials. This data is required by the American College of Surgeons for trials sponsored by the National Cancer Institute.

3. **Review a selection of other states' policies related to required treatment of cancer routine care coverage for insureds undergoing clinical trials;**

CSI staff conducted research from readily-available sources to provide a report to the Council on other states' policies. The information has been posted on the CSI web page at http://www.csi.mt.gov/commcorner/Cancer/CancerResources.asp

4. **Summarize and present findings and recommendations to the Children, Families, Health and Human Services Committee on or before March 31, 2012.**

CSI was available at the request of the Children, Families, Health and Human Services Committee to present a final report at the committee's regularly scheduled meeting on March 19 and 20, 2012. In addition, CSI will be available to provide additional reports related to on-going activity, either written or in person, at the request of the interim committee. Members of the Council developed initial drafts of this report, were provided preliminary review of this final report, and were advised of the presentation of it to the interim committee.

RECOMMENDATIONS FROM THE COMMISSIONER TO THE INTERIM COMMITTEE

1. The Commissioner supports the recommendations of the Council found in Section E, and recommends them to the interim committee.
2. The committee should consider that the expertise of the Council was focused on cancer and the proposed definition was limited to that disease. Other life-threatening diseases and conditions are also the subject of clinical trials and the Council's proposed definition should be expanded to include those prior to insertion into Montana law.

D. COUNCIL FINDINGS

1. Evaluate the causes of the routine care coverage denials or exclusion for patients recommended for participation in cancer clinical trials;

Patients, providers and insurers on the Council informed each other of their experience and perspective on the issue. Additional experts and the public were invited to provide information on the problem and potential solutions. Public comment was advertised and taken at each council meeting. Comments were recorded in the official minutes of the Council at the CSI web page at http://www.csi.mt.gov/commcorner/Cancer/CancerMeetings.asp.

At its first meeting, the members of the Council spoke to their perspective on the causes of coverage denials and where they thought problems existed. CSI staff summarized comments in a draft list of causes of denial. Members discussed the document on-line and at the second meeting, and agreed to set it aside until some agreement had been reached on the definition of routine care. At that time Council members hoped the barriers to access could be addressed alongside potential solutions.

At its fourth meeting, the Council considered a revised draft. They decided to distinguish between barriers that could be addressed by education, those that could be addressed by process changes, and those that needed policy changes. The Council appointed a subcommittee to work on a summary of barriers. At its fifth meeting, Council members acknowledged that many initial barriers identified had been resolved through discussion and mutual education. The Council did not finalize the draft document, but elected to summarize their agreements in this report.

Education

Council members understood that other parties did not have the benefit of the education that occurred on the Council and would need to be convinced through an educational outreach effort. The following findings would need to be addressed in such an effort:

Council findings—

a. Oncologists are trained and expected to enroll patients in clinical trials not only to advance treatment for the long term, but to provide the best possible care for their current patients.
b. Clinical trials do not generally add to the cost of patient care.
c. Single employer self-funded plans are not regulated by CSI and (except for self-funded state government plans and MEWAS) cannot be compelled by state legislation. However, self-funded plans respond to market forces and educational efforts, and should be offered education and asked to begin or continue covering routine care for cancer patients in clinical trials according to the definition in appendix A. The coverage will be required for self-funded plans in federal law on January 1, 2014.

d. Self-funded plans that purchase stop loss coverage must include their intent to cover routine care during clinical trials in their Summary Policy Documents in order to ensure the stop loss coverage and pricing are in place.
e. With adoption of the recommended definition (see below) great strides will be made in the following areas:
    i. Routine care is better defined and treated as distinct from experimental or investigational treatments, and that coverage for routine care for patients enrolled in clinical trials in any phase is the same as that provided patients not in a trial;
    ii. Patient and provider confusion about policy language and insurer practice during clinical trials will be addressed;
    iii. Insurer concerns about providers recommending coverage for "off label" trials will be addressed;
    iv. Patients and providers will be assured that coverage determinations by insurers regarding requests about clinical trials will be more consistent;
    v. More patients can focus on their health, wellness, and family concerns instead of their fears about cost and coverage.

Policy Changes

The Council agreed that a clear policy statement needs to be adopted implementing the definition of routine care and clinical trials identified below.

Council Findings—

a. Clinical trials administer experimental new treatments which are generally paid for by the trial sponsor. Some insurers in some cases consider that the new treatment has the potential to impact routine care administered during clinical trials and may deny coverage for the routine care in addition to the new treatment.
b. Language written in plan documents for exclusion of "experimental or investigational" treatments can lead to initial denial of coverage before being submitted for medical review. A patient, unable to pay for routine care out-of-pocket, may be forced to forgo a promising treatment available through clinical trials.
c. There are no industry-wide, standard definitions of "experimental or investigational" which can lead to inconsistent interpretation and coverage by insurers.
d. The process for patients to appeal coverage decisions is not well-known. Patients with greater persistence, energy and support may be better able to work with their plans to get their requests reviewed. New notice requirements in the federal law will help.
e. Inconsistencies in these situations can be diminished if insurers and providers adopted a common definition and insurers covered the routine care.

Process Changes

The Council also discussed various processes that might be improved to reduce barriers. They discussed a recommendation that all trial requests be routinely submitted for medical review

with the patient receiving written notice of the outcome and right to appeal. However, they agreed that if plans are prohibited from denying routine care coverage, the review would not be necessary.

Council Findings—

a. There would be a smoother, more predictable approval process if insurers had consistent access to summaries of trial protocols for review prior to coverage determination.
b. The process developed between New West Health Services and Billings Clinic for prior approval of particular clinical trials, has resulted in streamlined coverage agreement for patients enrolled in those trials. This process could be replicated by other payers and clinics.
c. Additional collection of data about approvals and denials of routine care during clinical trials is unlikely to yield accurate results and should not be required. The benefit of having more data may not justify the cost of gathering it. It is better to just fix the problem by requiring or agreeing to cover routine care.

2. Indentify necessary federal policy changes to address these issues for the purchasers of ERISA-regulated health care plans;

Experts on the Council and CSI staff discussed ERISA-regulated, self-funded health plans and federal reform as it relates to regulation of coverage for routine care for cancer patients enrolled in clinical trials. The Affordable Care Act requires policy changes for all non-grandfathered plans by January 1, 2014. Comments were recorded, summarized, and reviewed by the Council.

Council Findings—

a. ERISA is a very broad law from the 1970s that relates to many different employee benefits, including pensions, but also relates to health plans that are employer sponsored.
b. State insurance regulation does apply to fully-insured employer-sponsored health plans, but does not apply to self-funded employer-sponsored health plans, except for MEWA's (multiple employer welfare associations).
c. ACA and HIPAA provisions apply to self-funded ERISA-regulated health plans, with some exceptions.
d. Self-funded government plans are not regulated by ERISA or the CSI. There are specific sections state law dedicated to regulation of self-funded government plans, and many provisions of HIPAA and the ACA do apply to self-funded government health plans.
e. The NAIC is working on models to incorporate the ACA into state laws, including clinical trials. The new federal law provides an opportunity for the Council to impact federal

regulation or guidance, but state models will not apply to single-employer, self-funded health plans.

f. The NAIC could place a more specific definition of routine care in the NAIC model. The Council could provide comments to the NAIC committee who is creating model law.
g. The Council or the commissioner could also provide comments on clinical trials to the Center for Consumer Information and Insurance Oversight (CCIIO).

3. Define routine care for cancer patients undergoing clinical trials;

At its second meeting, the Council initiated efforts to narrow its focus and reach agreement on a definition for routine care for cancer patients that will best serve the needs of Montana consumers, providers and insurers. CSI staff presented definitions contained in numerous other state laws and agreements, in Medicare, and in the Affordable Care Act. One Council member drafted another option based on Oregon's model. The Council discussed the portion of the 2007 draft statement containing the definition of routine care for cancer patients and generally agreed that the document was needlessly lengthy and outdated.

After considerable discussion, the Council voted to use the current ACA definition as a starting point for Montana's definition and discuss clarifications or additions that would further refine the meaning for Montana.

Council Findings—

a. Most definitions of routine care for cancer patients in clinical trials were similar, stating that it was the same care that any cancer patient would receive in the absence of a trial.
b. The federal law provides a floor for state action. A state may not adopt a policy that is less protective than federal law.
c. The definition of routine care cannot be understood and adopted without defining clinical trials.
d. Costs of the experimental treatment in clinical trials must be borne by the trial sponsor.
e. Cost of administering the new treatment alongside the routine care should be borne by the payer.
f. Complications occur during cancer treatment, whether or not a patient is on a clinical trial. Council members agreed it would be nearly impossible to know if a particular complication was caused by the trial treatment. Studies have shown that complications associated with trial treatment are not causing significant cost increases.

E. COUNCIL RECOMMENDATIONS TO THE COMMISSIONER

On Education

1. That CSI provide specific education to cancer clinics in the state about the definition of routine care, the requirements in state and federal law, and the process for patient internal and external appeals.
2. That the Commissioner authorize the Council to continue to meet to develop an educational campaign directed toward patients, advocates, providers, and insurers to achieve the understanding developed between parties on the Council.
3. That the Commissioner convene an appropriate group of major self-funded employer plans and authorize the Council to provide education.
4. That the Commissioner support the Council's efforts to encourage voluntary commitment by self-funded plans to cover routine care during clinical trials according to the definition, and award those plans with positive public recognition.

On State Policy

5. That plan documents and benefit policies be amended to cover routine care for patients enrolled in clinical trials, based on the definition of routine care adopted by the Council.
6. That the Commissioner ask the Interim Children, Families, Health and Human Services Committee request legislation adopting the Council's recommended definition of routine care and clinical trials and requiring all plans within the state's jurisdiction to cover routine care.
7. That CSI propose legislation to update Montana's laws on patient appeals to mirror Federal Law.

On Process

8. That CSI ask insurers on the Council to agree on what information they need from providers about the trials and produce a standard request document.
9. That the Commissioner authorize the Council to continue to meet as needed to facilitate discussion between insurers, self-funded plans and providers on the standard request document.
10. CSI should make the document available to all insurers and recommend its usage where applicable.

On Federal Policy

11. That CSI encourage the NAIC and CCIIO to ensure that all group and individual health plans be subject to the same regulations regarding coverage for routine care for patients enrolled in clinical trials.
12. That CSI support an agreement and a legislative resolution encouraging employers who self fund to voluntarily cover routine costs for cancer patients who are participating in clinical trials, prior to 2014 when the federal law goes into effect.

On a Definition of Routine Care

13. That Montana's definition be incorporated into Montana law along with a prohibition on denying coverage of routine care during clinical trials.
14. That Montana's additions to the definition be presented to the NAIC and CCIIO for consideration in federal guidance on the issue of clinical trials.

Appendix A

COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CLINICAL TRIALS.

"(a) COVERAGE.—

"(1) IN GENERAL.—If a group health plan or a health insurance issuer offering group or individual health insurance coverage provides coverage to a qualified individual, then such plan or issuer—

"(A) may not deny the individual participation in the clinical trial referred to in subsection (b)(2);

"(B) subject to subsection (c), may not deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and services furnished in connection with participation in the trial; and

"(C) may not discriminate against the individual on the basis of the individual's participation in such trial.

"(2) ROUTINE PATIENT COSTS.—

"(A) INCLUSION.—For purposes of paragraph (1)(B), subject to subparagraph (B), routine
patient costs include all items and services consistent with the coverage provided in the plan (or coverage) that is typically covered for a qualified individual who is not enrolled in a clinical trial.

"(B) EXCLUSION.—For purposes of paragraph (1)(B), routine patient costs does not include—

"(i) the investigational item, device, or service, itself;
"(ii) items and services that are provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient;
"(iii) a service that is clearly inconsistent with widely accepted and established standards of care for a particular diagnosis; or
"(iv) items or services customarily provided by a clinical trial sponsor.

"(3) USE OF IN-NETWORK PROVIDERS.—If one or more participating providers is participating in a clinical trial, nothing in paragraph (1) shall be construed as preventing a plan or issuer from requiring that a qualified individual participate in the trial through such a participating provider if the provider will accept the individual as a participant in the trial.

"(4) USE OF OUT-OF-NETWORK.—Notwithstanding paragraph (3), paragraph (1) shall apply to a qualified individual participating in an approved clinical trial that is conducted outside the State in which the qualified individual resides.

"(b) QUALIFIED INDIVIDUAL DEFINED.—For purposes of subsection (a), the term 'qualified individual' means an individual who is a participant or beneficiary in a health plan or with coverage described in subsection (a)(1) and who meets the following conditions:

"(1) The individual is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of cancer.

"(2) Either—

"(A) the referring health care professional is a participating health care provider and has concluded that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1); or

'(B) the participant or beneficiary provides medical and scientific information establishing that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1).

"(c) LIMITATIONS ON COVERAGE.—This section shall not be construed to require a group health plan, or a health insurance issuer offering group or individual health insurance coverage, to provide benefits for routine patient care services provided outside of the plan's (or coverage's) health care provider network unless out-of network
benefits are otherwise provided under the plan (or coverage).

"(d) APPROVED CLINICAL TRIAL DEFINED.—

"(1) IN GENERAL.—In this section, the term 'approved clinical trial' means a phase I, phase II, phase III, or phase IV clinical trial that is conducted in relation to the prevention, detection, or treatment of cancer that is not designed exclusively to test toxicity or disease pathophysiology, that has therapeutic intent, and is described in any of the following subparagraphs:

"(A) FEDERALLY FUNDED TRIALS.—The study or investigation is approved or funded (which may include funding through in-kind contributions) by one or more of the following:

"(i) The National Institutes of Health.
"(ii) The Centers for Disease Control and Prevention.
"(iii) The Agency for Health Care Research and Quality.
"(iv) The Centers for Medicare & Medicaid Services.
"(v) cooperative group or center of any of the entities described in clauses (i)through (iv) or the Department of Defense or the Department of Veterans Affairs.
"(vi) A qualified non-governmental research entity identified in the guidelines issued by the National Institutes of Health for center support grants.
"(vii) Any of the following if the conditions described in paragraph (2) are met:
"(I) The Department of Veterans Affairs.
"(II) The Department of Defense.
"(III) The Department of Energy.

"(B) The study or investigation is conducted under an investigational new drug application reviewed by the Food and Drug Administration.

"(C) The study or investigation is a drug trial that is exempt from having such an investigational new drug application.

"(2) CONDITIONS FOR DEPARTMENTS.—The conditions described in this paragraph, for a study or investigation conducted by a Department, are that the study or investigation has been reviewed and approved through a system of peer review that the Secretary determines—

"(A) to be comparable to the system of peer review of studies and investigations used by the National Institutes of Health, and

"(B) assures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review.

Appendix B

Cancer Clinical Trials Advisory Council

Last	First	Organization/Position
Peura	Rachel	BCBSMT
Miltenburger	Richard	Mountain West Benefits
Burns	Paul	Cancer Patient
Cook	Cori	EBMS, Vice President/General Council
DeJongh	Sharon	Bozeman Deaconess Cancer Center
Dewsnup	Ron	Allegiance Benefit Plan Management, President & General Manager
Diaz	Marien	Symetra Life Insurance Company
Duszkiewicz	Jo	Billings Clinic
Foster	Michael	Catholic Hospitals
Geller	Robert	Billings Clinic
Schallenkamp	John	Billings Clinic
Harrer	Grant	Benefis Health System, Oncologist
Hartman	Cory	New West Health Services, Director of Medical Services
Hensold	Jack	Bozeman Deaconess Cancer Center
Hill	Russ	DOA, Health Care & Benefits Division
Marchello	Ben	Frontier Cancer Center, Senior Partner, Medical Oncologist
Page Nei	Kristin	American Cancer Society Cancer Action Network
Ruff	Diane R	Administrator, Associated Employers Group Benefit Plan & Trust
Steele	Brenden	Cancer Patient