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A Report to the Joint Standing Committee on Insurance and Financial Services of the 126th Maine Legislature

Review and Evaluation of LD 1600,

An Act to Require Health Insurers to Provide Coverage
for Human Leukocyte Antigen Testing To Establish
Bone Marrow Donor Transplantation Suitability

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I. Executive Summary

The Joint Standing Committee on Insurance and Financial Services (Committee) of the 126th Maine Legislature directed the Bureau of Insurance (Bureau) to review LD 1600, An Act to Require Health Insurers to Provide Coverage for Human Leukocyte Antigen Testing to Establish Bone marrow Donor Transplantation Suitability. The review was conducted as required by Title 24-A, Section 2752. This document and review is a collaborative effort of NovaRest, Inc., an actuarial consulting firm, and the Bureau.

LD 1600 requires that all health insurance policies provide coverage for laboratory fees arising from human leukocyte antigen (HLA) testing performed to establish bone marrow transplantation suitability, up to \$150.

The bill provides "(2) Prohibition. A testing facility may not bill, charge, collect a deposit from, seek payment or reimbursement from or seek recourse against an individual covered under the policy or contract or a person acting on behalf of the individual for any portion of the laboratory fees." We are uncertain regarding the intent of this provision. First, because insurance carriers are only required to cover laboratory fees up to \$150 the bill appears to prohibit testing facilities from charging more than \$150. We note the Bureau of Insurance does not typically regulate testing facilities and the \$150 limitation would be especially difficult to enforce against out-ofstate testing facilities. Second, if the intent is to require insurance coverage of the testing with no cost-sharing, we would suggest language requiring the insurance contract to cover without applying the deductible, coinsurance or copays.

For patients diagnosed with leukemia, lymphoma and other life-threatening diseases, a bone marrow or cord blood transplant may be their best or only hope for a cure. However, approximately 70% of patients who need a transplant do not have a matching donor in their family. Outcomes of unrelated donor transplants are approaching the rates of related donor transplants. In 2010, overall survival rates at one year were 71 percent (unrelated donor) and 78 percent (related donor). Because the Bone Marrow Donor Worldwide Registry (BMDW) now comprises over six million HLA-typed volunteer donors, the chance of identifying an HLA serologically identical donor has increased dramatically.³

http://www.nature.com/bmt/journal/v26/n4/full/1702529a.html

¹ Be the Match. How We Help Patients, Accessed 1/18/14, http://bethematch.org/About-Us/How-we-help-patients/

² U.S. Department of Health and Human Services, Understanding bone marrow and cord blood transplants, Accessed 1/28/14, $http://bloodcell.transplant.hrsa.gov/transplant/understanding_tx/transplant_faqs/index.html \#Survival_unrelated_rela$ ³ Bone Marrow Transplantation, Unrelated Donor Identification, Accessed 1/18/14,

Bone marrow screening tests are not included in the State's essential benefits package or the essential health benefits (EHBs) set by the Affordable Care Act, but transplant coverage is. Currently, most insurance carriers do provide coverage for potential donor screening testing done for a particular recipient. The proposed mandate would extend coverage to testing without a potential transplant recipient.

The National Organ Transplant Act (NOTA) in 1984, led to the creation of the National Bone Marrow Donor Registry (NBMDR) in 1987. Funding for the Registry comes from both military (Navy) and civilian (National Institutes of Health) branches of the federal government.

Potential donors without insurance coverage for the screening test may get tested for free at a NMDP bone marrow drive or through a free mail-in kit. The free tests are supported by donations or funding from NMDP. As of July 2009, the national Bone Marrow Transplant Registry in the US began to offer free registration testing to those potential unrelated donors that sign up for the transplant registry.

The "Be The Match" website states the target recruiting ages for new registry members is 18 to 44. "This is based on medical research that shows younger donors are best for patients and provide the greatest chance for transplant success," the website explains. "Because of this, doctors request donors in the 18 to 44 age group over 90% of the time." Individuals ages 45 to 60 who want to join the bone marrow registry must do so online and will be asked to make a \$100 payment to cover expenses. Currently much of the testing is funded through nonprofit organizations or fund raising, but that funding is not guaranteed in the future.

NovaRest, an actuarial consulting firm hired by the Bureau, estimated the premium increase to be \$0.01 per member per month (PMPM) if there is cost sharing and \$0.02 PMPM if no cost sharing is allowed based on \$125 average cost for the testing. The Affordable Care Act (ACA) requires States to defray the cost of mandated benefits not included in the Essential Health Benefits (EHB). The estimated increased coverage due to this mandate would be approximately \$48,000 per year.

II. Background

The Joint Standing Committee on Insurance and Financial Services (Committee) of the 126th Maine Legislature directed the Bureau of Insurance (Bureau) to review LD 1600, An Act to Require Health Insurers to Provide Coverage for Human Leukocyte Antigen Testing to Establish Bone Marrow Donor Transplantation Suitability. The review was conducted as required by Title 24-A, Section 2752. This document and review is a collaborative effort of NovaRest, Inc., an actuarial consulting firm, and the Bureau. In addition to the statutory criteria, the Committee asked that the review provide an analysis of:

- The extent to which coverage of bone marrow screening tests are included in the State's
 essential benefits package and covered by existing health plans, including whether
 carriers put a limit on the number of potential donors who are provided coverage for
 screening tests;
- Whether existing health care plans provide coverage for laboratory fees associated with donor drives or other widespread testing of unrelated donors;
- Whether copayments, deductibles or other cost-sharing requirements are imposed on
 existing coverage and, if this bill were enacted, an analysis of the financial impact of an
 allowance for cost-sharing compared to coverage without cost-sharing;
- Whether there are any comparative research studies documenting the potential savings in health care costs through facilitating bone marrow transplantation versus other treatments;
- If the bill expands coverage beyond the essential benefits package, the estimated costs to the State to defray the costs of including the coverage in qualified health plans; and
- Information on the estimated and actual costs of providing this coverage in the other
 New England states that have enacted similar laws, including information on whether
 initial costs of coverage may have moderated since enactment.

LD 1600 requires that all individual, group health and health maintenance organization (HMO) insurance policies provide coverage for laboratory fees up to \$150 arising from human leukocyte antigen testing performed to establish bone marrow transplantation suitability in accordance with the following requirements:

A. The individual covered under the policy or contract must meet the criteria for testing established by the National Marrow Donor Program, or its successor organization;

- B. The testing must be performed in a facility that is accredited by a national accrediting body with requirements that are substantially equivalent to or more stringent than those of the College of American Pathologists and is certified under the federal Clinical Laboratories Improvement Act of 1967, 42 United States Code, Section 263a; and
- C. At the time of the testing, the individual covered under the policy or contract must complete and sign an informed consent form that authorizes the results of the test to be used for participation in the National Marrow Donor Program, or its successor organization, and acknowledges a willingness to be a bone marrow donor if a suitable match is found.

The bill provides "(2) Prohibition. A testing facility may not bill, charge, collect a deposit from, seek payment or reimbursement from or seek recourse against an individual covered under the policy or contract or a person acting on behalf of the individual for any portion of the laboratory fees." We are uncertain regarding the intent of this provision. First, because insurance carriers are only required to cover laboratory fees up to \$150 the bill appears to prohibit testing facilities from charging more than \$150. We note the Bureau of Insurance does not typically regulate testing facilities and the \$150 limitation would be especially difficult to enforce against out-of-state testing facilities. Second, if the intent is to require insurance coverage of the testing with no cost-sharing, we would suggest language requiring the insurance contract to cover without applying the deductible, coinsurance or copays.

Bone marrow transplantation (BMT) and peripheral blood stem cell transplantation (PBSCT) are procedures that restore stem cells that have been destroyed by high doses of chemotherapy and/or radiation therapy, due to disease. There are three types of transplants:

- o In autologous transplants, patients receive their own stem cells.
- o In syngeneic transplants, patients receive stem cells from their identical twin.
- o In allogeneic transplants, patients receive stem cells from their brother, sister, or parent. A person who is not related to the patient (an unrelated donor) also may be used.⁴

The requirements of LD 1600 will potentially increase the number of matched patients to suitable donors. Every four minutes someone is diagnosed with a blood cancer, like leukemia. For many, their only hope for a cure is a bone marrow transplant. Matching a patient with a

⁴ National Cancer Institute, Bone Marrow Transplantation and Peripheral Blood Stem Cell Transplantation, Accessed 1/29/14, http://www.cancer.gov/cancertopics/factsheet/Therapy/bone-marrow-transplant

⁵ Be the Match, Transplant Basics, Accessed 1/28/14, http://bethematch.org/Transplant-Basics/

donor is much more complex⁶ than finding two people with the same blood type. The donor's stem cells must have similar genetic markers as the patient's. These markers are called human leukocyte antigens or HLA type.⁷

The common procedure in searching for a bone marrow donor for a particular patient is first to examine the patient's parents, brothers, and sisters in search of an HLA-identical donor. If no identical individuals are found, then the search is begun for an unrelated donor. 8

Doctors look for a donor with a close HLA match to the patient. This close HLA match is the most important factor in finding the best donor for a patient. 9

The National Organ Transplant Act (NOTA) in 1984, led to the creation of the National Bone Marrow Donor Registry in 1987. Start-up funding for the Registry came from both military (Navy) and civilian (National Institutes of Health) branches of the federal government.

The National Marrow Donor Program (NMDP) requires evaluation of donor-recipient histocompatibility matching prior to unrelated hematopoietic cell transplantation (HCT). The minimum acceptable match was originally defined by serologic splits (antigen level of resolution) at these 3 loci (6 possible antigens) and required at least 5 matches, that is, a 5 of 6 match. This requirement has changed little over the years. Currently, to request a donor for transplantation, the minimal acceptable level of matching remains a 5 of 6 match for a HLA donor.

In 1990, the NMDP became a separate private nonprofit organization in Minneapolis, and was contracted by Health and Human Services (HHS) to operate the registry, replacing the Red Cross. Responsibility for maintaining the public US BMT donor registry resides with the Division of Transplantation of the Healthcare Systems Bureau of the Health Resources & Services Administration (HRSA) of HHS. HRSA does not operate the registry itself, but contracts out the federally-funded service. For the renewal to occur each time, Congress must pass enabling legislation that is then signed into law by the President. To date, at each renewal, the registry contract has been awarded to the NMDP. The Office of Naval Research continues to fund scientific research and minority donor testing, conducted by the NMDP.

http://bloodjournal.hematologylibrary.org/content/87/2/800.full.pdf

⁶ Be the Match, Matching patients with donors, Accessed 1/28/14, http://bethematch.org/Transplant-Basics/Matching-patients-with-donors/

⁷ Blood & Marrow Transplant Information Network, Finding a Donor, Accessed 1/28/14, http://www.bmtinfonet.org/before/findingdonor

⁸ American Society of Hematology, Blood, Accessed 1/28/14,

⁹ Be the Match, Matching patients with donors, Accessed 1/28/14, http://bethematch.org/Transplant-Basics/Matching-patients-with-donors/

Legislation in 1991 led to the first allocation of federal funds for donor typing. Continued citizen efforts to include the recruitment of donors from under-represented racial/ethnic groups as a program priority, led to new NMDP recruitment programs starting in the mid-90s, when existing ethnic-specific recruitment groups were incorporated into the NMDP Network for the first time. ¹⁰

Some money for the Bone Marrow Screening Fund has come from the voluntary contribution check off on tax forms in Maine. This was recently eliminated. Other local funding comes from the recipient, through family and friends raising money for donor drives. Michael's Fund and the Maine Leukemia Foundation help fund donors as well.

More than 17,900 bone marrow transplants were performed in the United States in 2011^a.

Number of Transplants Performed ^a	Type of Transplant
10,403 ^b	Autologous (the cells for transplant were provided by the patient)
3,114	Related allogeneic (the cells for transplant were provided by the patient's sibling or another family member)
4,421	Unrelated allogeneic (the cells for transplant were provided by a volunteer donor)

a. These data are of transplants performed from January 1, 2008 through December 31, 2011. These data were reported to the Center for International Blood and Marrow Transplant Research® (CIBMTR).

The extent to which coverage of bone marrow screening tests are included in the State's essential benefits package and covered by existing health plans, including whether carriers put a limit on the number of potential donors who are provided coverage for screening tests;

Currently, bone marrow screening tests are not included in the State's essential benefits package or the essential health benefits (EHBs) set by the Affordable Care Act, but transplant

b. Many U.S. transplant centers voluntarily report autologous transplant data to the CIBMTR. Because these data are not required to be reported, this number represents only a portion of the actual autologous transplants performed. 11

¹⁰ http://bmtbasics.org/basics-2/finding-a-donor/donor-registries-background/

¹¹ Health Resources and Services Administration, General Frequently Asked Questions, Accessed 1/29/14, http://bloodcell.transplant.hrsa.gov/ABOUT/General FAQs/index.html

coverage is. Historically, when an insured is covered for a transplant, donor testing is covered at least for the patient's immediate family.

Anthem and Maine Community Health Options (MCHO) cover donor testing of unrelated donors under an insured member's policy if their insured needs a transplant that has been determined to be medically necessary and there is no suitable familial match. They do not provide testing of unrelated donors under the potential donor's policy. There is no limit to the number of individuals covered for testing.

MEGA stated that their health benefit plans do not provide benefits to address the coverage for the cost of testing for bone marrow donation suitability.

Aetna responded that they only cover immediate family members.

Whether existing health care plans provide coverage for laboratory fees associated with donor drives or other widespread testing of unrelated donors;

If a covered individual requires a transplant, typically the individual's insurer will cover the testing of family members and other volunteer donors for the insured individual.

Aetna, Cigna, Maine Community Health Options and MEGA do not provide coverage for donor drives or other widespread testing of unrelated donors.

Harvard Pilgrim's policy is that bone marrow donation is included in organ donor protocols. The plan will cover evaluation of donor organ for tissue (histologic) HLA testing, compatibility and has no limits on how many tests. They will also cover donor drives if they are billed.

Cigna covers individuals being tested as donors for one of its members. The recipient's level of coverage would be specific to their plan and transplant benefits.

Anthem responded that their medical policy does not specifically address donor drives but testing at such a drive would likely be covered, if authorized as medically necessary, and if the tests were submitted by a participating provider.

Whether copayments, deductibles or other cost-sharing requirements are imposed on existing coverage and, if this bill were enacted, an analysis of the financial impact of an allowance for cost-sharing compared to coverage without cost-sharing

Depending on deductible levels and copays the cost sharing can range from 0% to 100%. The financial impact would increase if there was no cost sharing, but since the total cost is estimated to be minimal, the added cost would be minimal. We estimate a financial impact of \$0.01 permember-per-month (PMPM) with cost sharing and \$0.02 PMPM if no cost sharing is allowed.

Aetna responded that based on Maine's historical experience and the historical experience of other Northeast states with HLA mandates, they believe that implementing this proposed level of coverage, with and without cost-sharing, would generate an immaterial increase in premiums, administrative expenses and indirect costs.

Cigna responded that the financial impact really does depend on the plan design and level of cost share, but in general the expectation is that the impact would be minimal across all types of costs referenced.

Anthem responded that they estimate a claims cost of \$0.034 PMPM, which would drive a minimal impact on premiums. They do not anticipate an impact on administrative expenses.

Whether there are any comparative research studies documenting the potential savings in health care costs through facilitating bone marrow transplantation versus other treatments

There are medical studies quantifying effectiveness for various aspects of types of treatments. An article provided by the National Marrow Donor Program (NMDP) concluded that "the time taken from diagnosis to transplant is recognized to adversely affect patient outcome, and provision of unrelated donors has been identified as a key source of delay." The article identified areas in need of improvement to shorten the time a donor would be available such as recruiting from ethnic minority groups, donor registries may need to increase the number of new donors typed to high resolution for better matches and moving towards better donor quality instead of just high numbers of donors.

Also an article in the publication *Stem Cells* ¹³ analyzed five studies on the cost-effectiveness and third-party charges of bone marrow transplants. The conclusion was that related matches are the most cost-effective procedure for many diseases, however, they felt that future treatment advances would increase the cost-effectiveness of unrelated transplants.

¹² Bone Marrow Transplantation (2013) 48, 210-219

¹³ Westerman, I. L. and Bennett, C. L. (1996), A Review of the Costs, Cost-Effectiveness and Third-Party Charges of Bone Marrow Transplantation. *Stem Cells*, 14: 312–319. doi: 10.1002/stem.140312

If the bill expands coverage beyond the essential benefits package, the estimated costs to the State to defray the costs of including the coverage in qualified health plans

We estimate the cost to the state beyond the essential benefits package would be less than \$48,000 a year.

Information on the estimated and actual costs of providing this coverage in the other New England states that have enacted similar laws, including information on whether initial costs of coverage may have moderated since enactment.

In Anthem's initial response they indicated "of the four states identified, there are Anthem Plans in New Hampshire and Connecticut. Looking at Maine, New Hampshire, and Connecticut Anthem's analysis indicates a cost of \$0.034 per member per month."

Connecticut's cost impact did not vary significantly over the past three years. The total projected cost remained at \$0.05 PMPM for that period. While Connecticut does not cap the reimbursement it does not allow the cost share to exceed 20% of the cost of the test. Anthem provided the following table of number and cost of claims for Connecticut and New Hampshire.

Connecticut:

Year	2011	2012	2013	Average
Claim Count	637	930	693	753
Paid Claims	\$27,748	\$36,687	\$27,434	\$30,623

New Hampshire:

 Year
 2011
 2012
 2013
 Average

 Claim Count
 287
 362
 265
 305

 Paid Claims
 \$21,644
 \$18,153
 \$13,528
 \$17,775

Anthem noted significantly higher expenses for screening tests in New Hampshire of about \$0.26 PMPM in 2010. At that time New Hampshire did not have a cap in place and there were abuses by the facility and registry documented by the New Hampshire Attorney General in February 2012. Insurance companies were billed between \$700 and \$4,300 for tests that cost a fraction of those amounts.¹⁴

Cigna responded by saying "since it is already standardly covered by Cigna, our pricing team says the mandate would not have a notable impact on costs. Other than the issue in New Hampshire

¹⁴ Press Release, New Hampshire, Department of Justice, Office of the Attorney General, February 2, 2012

where the donor organization was investigated by the attorney general, similar mandates in other states have not been a big issue to Cigna."

Final review by CIGNA of the 2013 claim data in New Hampshire continues to show utilization is low for insured business. As they had only 21 claims for HLA screening in 2013, it would be difficult to determine if it costs have moderated since enactment or to predict if there will be increases. It seems to reason that very aggressive recruiting in bone marrow donor drives would likely increase utilization but that would not be predictable. The range of the 21 charges submitted to Cigna for the 2013 claims was \$49-\$337. These billed charges totaled \$4,431.66 and Cigna paid \$1,741.66 for HLA screening in 2013. Typically Cigna paid less than the billed charges due to contracted rates and in all cases but one, Cigna paid less than \$150. The range of paid claims was \$16.56 to \$149.40, with one charge paid at \$161.66. Member cost share (coinsurance, copay, deductible) was \$0 with the exception of one member who paid \$27.59 toward a deductible.

Harvard Pilgrim noted they "cannot provide costs and volumes before and after the mandate. Anecdotally we have not seen utilization spike dramatically, but we were providing coverage for the test prior to the mandate in New Hampshire so it isn't clear how the mandate impacted behavior."

Compass Health Analytics, an actuarial consulting firm, prepared a review of state-mandated health insurance benefits for the Commonwealth of Massachusetts in January 2013. In their report they estimated the premium impact of the HLA mandate to be \$0.0055 or 0%.

III. Social Impact

- A. Social Impact of Mandating the Benefit
- 1. The extent to which the treatment or service is utilized by a significant portion of the population.

Nationally, each year, nearly 20,000 people age 0-74 years might benefit from a potential life—saving bone marrow transplant.¹⁵

The NMDP Network has more than four million volunteer donors and has Donor Centers and Transplant Centers in 14 countries. About 40% of the transplants facilitated by the NMDP involve either a U.S. patient receiving bone marrow and/or stem cells from an international donor, or an international patient receiving bone marrow/stem cells from a U.S. donor. The NMDP coordinates more than 130 stem cell transplants each month. ¹⁶

This year, more than 130,000 Americans will be diagnosed with a serious blood disease. Leukemia (a blood cancer) will strike 44,000 Americans this year, including 3,500 children. It will kill about half of the adults and about 700 of the children. ¹⁷

Testimony indicated that in Maine between 1,000 to 2,000 people are tested for donor compatibility each year, at a cost of \$100 to \$150 per test. In 2012 1,600 donors joined the registry in Maine. According to the Bone Marrow Donor Program, since its inception 226 Mainers have become donors and 263 have received transplants. Most of those have taken place in the past ten years.

2. The extent to which the service or treatment is available to the population.

HLA testing is available at donor centers, online and through donor drives.

There are currently no NMDP Donor Centers in Maine, however, the following Donor Centers cover all or part of Maine.

¹⁵ Health Resources and Services Administration, How many people need a bone marrow transplant?, Accessed 1/29/14, http://bloodcell.transplant.hrsa.gov/about/general_faqs/index.html

¹⁶ Surgey.com, Bone Marrow Transplantation, Accessed 1/29/14, http://www.surgery.com/procedure/bone-marrow-transplantation/demographics

¹⁷ Institute for Justice, Bone Marrow Statistics, Accessed 1/29/14, http://ij.org/bone-marrow-statistics

Dana-Farber Cancer Institute

450 Brookline Avenue Boston, MA 02215 (617) 632-2561 (866) 875-3324 http://www.dfci.org/nmdp

The HLA Registry

A Division of Community Blood Services 102 Chestnut Ridge Road Montvale, NJ 07401 (201) 389-0480 (800) 336-3363 http://www.communitybloodservices.org

National Marrow Donor Program Northeast District

700 Spring Garden Street Philadelphia, PA 19123-3594 (877) 868-8010 (877) 868-8010 http://www.BeTheMatch.org

3. The extent to which insurance coverage for this treatment is already available.

Aetna considers compatibility testing of prospective donors who are members of the immediate family (first-degree relatives, i.e. parents, siblings and children) and harvesting and short-term storage of peripheral stem cells or bone marrow from the identified donor medically necessary when an allogeneic bone marrow or peripheral stem cell transplant is authorized by Aetna. Aetna does cover testing of immediate family members.

Harvard Pilgrim's policy is that bone marrow donation is included in organ donor protocols. The plan will cover evaluation of donor organ for tissue (histologic) HLA testing, compatibility and has no limits on how many tests. They also will cover the cost for donor drives, if billed.

Cigna covers screening if the recipient is in transplant case management and is part of the Lifesource contracts.

Anthem covers testing of unrelated donors if there is not a suitable familial match and the insured needs a transplant that has been determined to be medically necessary.

4. If coverage is not generally available, the extent to which the lack of coverage results in a person being unable to obtain the necessary health care treatment.

Lack of a substantial number of potential donors available on the National Registry could lead to delays in treatment for the recipient of the transplant. Without insurance coverage the \$100 cost for the screening test could deter potential donors.

The Dana-Farber website states: "If your insurance will not cover the tissue-typing fee, we are able to cover the cost of your test. However, if you would like to make a tax-deductible donation to help our recruitment efforts, we would greatly appreciate it."

Without health insurance covering the cost of testing, either the donor's funds or donations are used to pay for the swab testing. According to written testimony by Steven and Lisa Cota when Steve's lifelong friend Gregory, "Gregg" Sanborn needed a transplant they had to turn to donations to defray the costs. "As a result of this effort to find a donor and promote the need for donors, over a thousand people were added to donor roles."

In his testimony Patrick Roy stated "everyone should want the chance to save a life, and they should have that opportunity. At the time of my swab test, if I had had to cover the \$100 swab test, unfortunately I would not have done so."

According to testimony by Todd Ellison "having bone marrow testing covered by insurers (thus alleviating the burden of cost to those tested) will allow a greater number of people to be tested and added to the roles of potential bone marrow donors. Increasing the number of possible donors will ultimately result in increasing the number of "matches" for bone marrow transplantation.

5. If coverage is not generally available, the extent to which the lack of coverage involves unreasonable financial hardship.

The lack of insurance coverage for the initial test may be a deterrent for individuals that might otherwise be willing to be tested. Patients who are diagnosed with cancer and need a bone marrow transplant may be faced with covering the cost associated with the initial testing themselves, multiplied times many individuals and tests. In most cases the insurance of an insured patient will cover the testing of at least family members and potentially unrelated potential donors. If the insurance does not cover needed testing, the potential cost for a patient paying could be high.

Many cheek swab tests range in price from \$100 to \$150. A prospective donor can also order a cheek swap kit from various non-profit organizations. There are organizations such as *Swab a Cheek* and *Cheekswab* that are dedicated to increase the number of donors. However, if these organizations do not receive adequate funding they may not be able to continue.

As John P. Gallivan testified, "It is a shame that families like mine are forced to spend an exorbitant amount of money just to find a match. We didn't want people to be hesitant to get tested in Wethersfield, so with the help of our friends we covered the cost of the drive ourselves."

6. The level of public demand and the level of demand from providers for this treatment or service.

During the public hearing for LD 1600, advocates for this bill testified about the battle to find suitable donors and the need to defray the cost for those willing to enter the registry. There are advocacy groups dedicated to increasing public awareness about registering to become a bone marrow donor.

Demand for this benefit comes "primarily from prospective recipients and their families and from the National Marrow Donor Program. The NMDP indicated they receive approximately 1,200 new requests for registry searches per month nationally. One study in 2001 indicated that approximately 15 percent of patient searches do not find a match." ¹⁸

7. The level of public demand and the level of demand from the providers for individual or group coverage of this treatment.

In testimony from Patricia Lang, the director of the Rhode Island Blood Center she stated that with the insurance mandates in the New England states their file of registered potential donors has grown from 35,000 to 95,000

8. The likelihood of meeting a consumer need as evidenced by the experience in other states.

Evidence in other states is limited. Rhode Island, Massachusetts, Missouri and New Hampshire

¹⁸ Review and Evaluation of Public Act 09-188, An Act Concerning Wellness Programs and Expansion of Health Insurance Coverage, University of Connecticut, December 2009.

have already passed similar legislation. Even with the support of the insurance mandate, though, less than 50% of those taking the screening test have insurance coverage.

9. The relevant findings of the state health planning agency or the appropriate health system agency relating to the social impact of the mandated benefit.

State agencies did not provide findings pertaining to the proposed legislation.

10. The alternatives to meeting the identified need.

Close relatives, especially brothers and sisters, are more likely than unrelated people to be HLA-matched. However, only 25 to 35 percent of patients have an HLA-matched sibling. ¹⁹

The alternative for the health insurance company paying for coverage is that most patients will reach out to friends, family, non-profit organizations and even employers to help defray the cost of testing when willing participants cannot afford the \$100-\$150. Per the testimony of Steven Cote "family, friends and communities banded together to host stem cell donor drives: monies were donated to pay for those who wanted desperately to help in some way but could not afford the \$100 fee for the non-invasive swab test."

11. Whether the benefit is a medical or a broader social need and whether it is inconsistent with the role of insurance and the concept of managed care.

HLA testing required by LD 1600 does not meet a medical need for the person being tested as a potential donor. The coverage is not inconsistent with the role of insurance to provide medically necessary services for a condition. However this mandate may step outside of the role of insurance in that it requires providers to pay for testing to establish bone marrow donor transplantation suitability unrelated to the need of an insured member. It is unusual for health insurance companies to reimburse for a test that will not necessarily benefit their insured. For example, Aetna already covers the cost of family member testing. The testing is provided for a person who needs a transplant, and not for potential future use.

It is possible that the passing of this legislation will meet a broader social need in that it would encourage more individuals to get tested and be available as donors. This outcome would have the potential to assist more patients in need of life-saving bone marrow transplants. At any

¹⁹ National Cancer Institute, Bone Marrow Transplantation and Peripheral Blood Stem Cell Transplantation, Accessed 1/29/14, http://www.cancer.gov/cancertopics/factsheet/Therapy/bone-marrow-transplant

given time, about 7,500 American are actively searching the national registry for an unrelated donor. Only 2 percent of the population is on the national registry. At least 1,000 people die each year because they cannot find a matching donor.²⁰

The benefit is reduced since a significant number of those on the national bone marrow registry cannot be located or will not donate when asked to do so. The percentages of donors who are available and willing are: 65 percent for Caucasians; 47 percent for Hispanics; 44 percent for Asians; 34 percent for African-Americans.

12. The impact of any social stigma attached to the benefit upon the market.

There is no known social stigma associated with being tested as a potential donor.

13. The impact of this benefit upon the other benefits currently offered.

This legislation could impact the number of transplants performed, if it results in more donor matches.

14. The impact of the benefit as it relates to employers shifting to self-insurance and the extent to which the benefit is currently being offered by employers with self-insured plans.

As premiums increase due to mandated benefits, some employers choose to self-insure in order to have more control over the benefits they provide to employees and to control the cost of premiums. We cannot estimate the impact on premiums, but believe there would be no shifting to self-insured plans.

15. The impact of making the benefit applicable to the state employee health insurance program.

Aetna's analysis indicates that the impact would be immaterial.

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²⁰ Institute for Justice, *Op cit*.

IV. Financial Impact

- B. Financial Impact of Mandating Benefits
- 1. The extent to which the proposed insurance coverage would increase or decrease the cost of the service or treatment over the next five years.

If the service is covered by insurance it is logical to expect the increase in demand and availability of insurance coverage to increase the cost of the service. It is also possible that the mandate could lead to new testing technologies that may be more expensive and increase the overall cost of the service. Since this act covers \$150 per service, we expect that the cost will increase to that amount, especially if insured cost sharing is not allowed.

2. The extent to which the proposed coverage might increase the appropriate or inappropriate use of the treatment or service over the next five years.

Since there will be less or no upfront cost it may be more likely that an individual is willing to get tested, but unwilling to make the potentially lifesaving donation should the need arise. As reported by the Institute of Justice "a significant number of those on the national bone marrow registry cannot be located or will not donate when asked to do so." The collection of marrow is not a simple matter and involves recovery and loss of work time.

Even if all potential donors do not go through with the actual donation, it is reasonable to believe that the increase in matches will have a positive impact on the number of actual transplants that take place. How many of these transplants will be for citizens of Maine rather than patients matched in other states, or other countries, is unknown.

3. The extent to which the mandated treatment or service might serve as an alternative for more expensive or less expensive treatment or service.

Currently, there are no other widely used methods to the current HLA screening test to match potential donors with patients that need hematopoietic stem cell transplants.

4. The methods which will be instituted to manage the utilization and costs of the proposed mandate.

²¹ Institute for Justice, *Op cit*.

Typically an insurance company can limit covered services to those that are medically necessary for their members, but LD 1600 would not necessarily be for the benefit of the insured. The mandate for the HLA testing may result in carriers negotiating with preferred labs for the reimbursement for HLA tests. Anthem suggested that the legislation include a provision that allows a carrier to require the use of certain codes specified by the carrier for reimbursement. This would help to ensure the claims are properly adjudicated and avoid issues that have occurred in the past in other states.

5. The extent to which insurance coverage may affect the number and types of providers over the next five years.

The mouth swab test can be self-administered at home and with the usage in Maine limited to 1,000 to 2,000 tests a year we do not foresee any new providers to process the tests in the next five years.

6. The extent to which the insurance coverage of the health care service or providers may be reasonably expected to increase or decrease the insurance premium or administrative expenses of policyholders.

Aetna did indicate "reimbursement for donor fairs would be administratively difficult if the claims are not submitted through a provider or entity that can submit claims electronically.

Unum testified "as drafted, however, Unum is concerned that LD 1600 would include its supplemental critical illness insurance that has been exempt from the definition of health insurance with respect to mandated benefits and coverage laws, see Title 24-A MRSA 704(2), since that law was enacted in 2001." If this were true, the cost of this type of insurance would also increase.

Aetna Response: "Based on Maine's historical experience and the historical experience of other Northeast states with HLA coverage mandates, we believe that implementing this proposed level of coverage, with and without cost-sharing, would generate an immaterial increase in premiums, administrative expenses and indirect costs."

Cigna Response: "The financial impact really does depend on the plan design and level of cost share, but in general the expectation is that the impact would be minimal across all types of costs referenced."

NovaRest, an actuarial consulting firm, estimated the premium increase to be \$0.01 PMPM if there is cost sharing and \$0.02 PMPM if no cost sharing is allowed.

7. The impact of indirect costs, which are costs other than premiums and administrative costs, on the question of the cost and benefits of coverage.

There will not be any additional cost effect beyond benefit and administrative costs.

8. The impact on the total cost of health care, including potential benefits and savings to insurers and employers because the proposed mandated treatment or service prevents disease or illness or leads to the early detection and treatment of disease or illness that is less costly than treatment or service for later stages of a disease or illness.

An article provided by the National Marrow Donor Program (NMDP) concluded that "the time taken from diagnosis to transplant is recognized to adversely affect patient outcome, and provision of unrelated donors has been identified as a key source of delay." ²²

According to testimony by Steve Cote "the number of registered donors will also multiply, leading to further matches and lives saved moving forward." There is potentially a savings if a patient is matched with a donor sooner and medical costs that would take place between the need for a transplant and the actual transplant are eliminated.

In testimony by Ellen Guilford she stated, "I truly believe had he had a donor back in March or April, Gregg's body and immune system would not have been so ravaged and it would have been easier for him to fight the infection that often accompanies receiving a donation. It is having a registry full of potential donors waiting to help 'us' when we are in need that will ultimately save lives."

9. The effects of mandating the benefit on the cost of health care, particularly the premium and administrative expenses and indirect costs, to employers and employees, including the financial impact on small employers, medium-sized employers and large employers.

The cost of healthcare will increase to the extent that more tests are administered and the cost per test is increased. Currently much of the testing is funded through nonprofit organizations, but that funding is not guaranteed in the future. To the extent that insurance coverage replaces

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²² Bone Marrow Transplantation (2013) 48, 210-219

the nonprofit efforts, it will not impact the total cost of health care. We estimate the impact on premium to be between \$0.01 and \$0.02 PMPM.

10. The effect of the proposed mandates on cost-shifting between private and public payers of health care coverage and on the overall cost of the health care delivery system in this State.

To the extent that these services are currently covered by MaineCare and will be paid for by private insurance after the mandate is implemented, the cost may be shifted from the public payers to private payers. Individuals with private insurance tend to use that coverage before using public programs, when they have access to both.

This program may shift costs from current nonprofit efforts to private insurance.

V. Medical Efficacy

- C. The Medical Efficacy of Mandating the Benefit
- 1. The contribution of the benefit to the quality of patient care and the health status of the population, including any research demonstrating the medical efficacy of the treatment or service compared to the alternative of not providing the treatment or service.

There are no alternatives for the current mouth swab testing. The swab testing is effective in identifying potential donors, which increases the number of transplants that are possible. The sooner a donor can be located the more effective the transplant may be.

2. If the legislation seeks to mandate coverage of an additional class of practitioners:

This is not applicable.

VI. Balancing the Effects

- D. The Effects of Balancing the Social, Economic, and Medical Efficacy Considerations
- 1. The extent to which the need for coverage outweighs the cost of mandating the benefit for all policyholders.

Bone marrow transplantations (BMT) are procedures that restore stem cells that have been destroyed by illness, high doses of chemotherapy and/or radiation therapy. For patients diagnosed with leukemia, lymphoma and other life-threatening diseases, a bone marrow transplant may be their best or only hope for a cure. Yet 70% of patients who need a transplant do not have a matching donor in their family²³ and rely on finding a donor outside of their family.

Currently there are other agencies that run donor drives and cover the cost of testing, but their continued funding is not guaranteed.

2. The extent to which the problem of coverage can be resolved by mandating the availability of coverage as an option for policyholders.

It is likely that only those who would benefit from the services would purchase the coverage. This would result in an alternative coverage that would cost more than the additional cost of services because of the administrative charges that would be added to benefit costs. This cost would be reduced if the option was only available when the coverage was initially purchased, but it would then be less effective because many individuals would not anticipate needing the coverage and, therefore, would not purchase it.

3. The cumulative impact of mandating this benefit in combination with existing mandates on costs and availability of coverage.

The estimated cost of current Maine mandates is detailed in Appendix C. For most of these mandates, our estimate is based on the net impact on premiums as estimated at the time the mandate was enacted. Four of the mandates – mental health, substance abuse, chiropractic, and screening mammograms – require carriers to report annually the amount of claims paid for these benefits and the estimates are based on that data. The true cost for the Maine mandates

²³ Be the Match, How We Help Patients, Accessed 1/18/14, http://bethematch.org/About-Us/How-we-help-patients/

are impacted by the fact that:

- 1. Some services would be provided and reimbursed in the absence of a mandate.
- 2. Certain services or providers will reduce claims in other areas.
- 3. Some mandates are required by Federal law.

VII. Appendices

Appendix A: Letter from the Committee on Insurance and Financial Services with Proposed Legislation

SENATE

GEOFFREY M. GRATWICK, District 32, Chair RICHARD G. WOODBURY, District 11 RODNEY L. WHITTEMORE, District 26

COLLEEN MCCARTHY REID, Legislative Analyst MOLLY GALLANT, Committee Clerk



HOUSE

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State of Maine
ONE HUNDRED AND TWENTY-SIXTH LEGISLATURE
COMMITTEE ON INSURANCE AND FINANCIAL SERVICES

January 28, 2014

Marti Hooper Senior Insurance Analyst Life and Health Division Bureau of Insurance 34 State House Station Augusta, Maine 04333

Dear Ms. Hooper:

Title 24-A Maine Revised Statutes Annotated, Section 2752 requires the Joint Standing Committee on Insurance and Financial Services to submit legislation proposing health insurance mandates to the Bureau of Insurance for review and evaluation if there is substantial support for the mandate among the committee after a public hearing on the proposed legislation. Pursuant to that statute, we request that the Bureau of Insurance prepare a review and evaluation of LD 1600, An Act to Require Health Insurers to Provide Coverage for Human Leukocyte Antigen Testing to Establish Bone Marrow Donor Transplantation Suitability.

A copy of the bill is enclosed. Please prepare the evaluation using the guidelines set out in Title 24-A § 2752. In addition, we ask that the Bureau provide an analysis of the following issues:

- The extent to which coverage of bone marrow screening tests are included in the State's essential benefits package and covered by existing health plans, including whether carriers put a limit on the number of potential donors who are provided coverage for screening tests;
- Whether existing health care plans provide coverage for laboratory fees associated with donor drives or other widespread testing of unrelated donors;
- Whether copayments, deductibles or other cost-sharing requirements are imposed on existing coverage and, if this bill were enacted, an analysis of the financial impact of an allowance for cost-sharing compared to coverage without costsharing;

100 STATE HOUSE STATION, AUGUSTA, MAINE 04333-0100

TELEPHONE 207-287-1314

LD 1600 Letter Page 2

- Whether there are any comparative research studies documenting the potential savings in health care costs through facilitating bone marrow transplantation versus other treatments;
- If the bill expands coverage beyond the essential benefits package, the estimated costs to the State to defray the costs of including the coverage in qualified health plans; and
- Information on the estimated and actual costs of providing this coverage in the other New England states that have enacted similar laws, including information on whether initial costs of coverage may have moderated since enactment.

Please submit the report to the committee before March 10, 2014. If you have any questions, please do not hesitate to contact us or our legislative analyst, Colleen McCarthy Reid.

Sincerely,

Geoffrey M. Gratwick

Senate Chair

Sharon Anglin Treat

House Chair

Printed on recycled paper

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Legislative Document

126th MAINE LEGISLATURE

SECOND REGULAR SESSION-2014

H.P. 1172	House of Representatives, December 30, 2013
An Act To Require Health Insurer	s To Provide Coverage for
Human Leukocyte Antigen Testing	g To Establish Bone Marrow
Donor Transplantation Suitability	-

Approved for introduction by a majority of the Legislative Council pursuant to Joint Rule 203.

Received by the Clerk of the House on December 23, 2013. Referred to the Committee on Insurance and Financial Services pursuant to Joint Rule 308.2 and ordered printed pursuant to Joint Rule 401.

MILLICENT M. MacFARLAND

Clerk

No. 1600

Presented by Representative RANKIN of Hiram.

organization;

Cosponsored by Senator LANGLEY of Hancock and

Representatives: BEAVERS of South Berwick, BECK of Waterville, COOPER of Yarmouth, DAUGHTRY of Brunswick, GATTINE of Westbrook, KINNEY of Limington, KORNFIELD of Bangor, LONGSTAFF of Waterville, NADEAU of Winslow, PLANTE of Berwick, THERIAULT of Madawaska, Senators: MILLETT of Cumberland, PATRICK of Oxford.

- 1 Be it enacted by the People of the State of Maine as follows: 2 **Sec. 1. 24 MRSA §2317-B, sub-§12-I** is enacted to read: 3 12-I. Title 24-A, sections 2769, 2847-U and 4260. Coverage for the cost of testing 4 for bone marrow donation suitability, Title 24-A, sections 2769, 2847-U and 4260; 5 Sec. 2. 24-A MRSA §2769 is enacted to read: 6 §2769. Coverage for the cost of testing for bone marrow donation suitability 7 1. Required coverage. All individual health insurance policies and contracts must 8 provide coverage for laboratory fees up to \$150 arising from human leukocyte antigen testing performed to establish bone marrow transplantation suitability in accordance with 9 10 the following requirements: A. The individual covered under the policy or contract must meet the criteria for 11
- B. The testing must be performed in a facility that is accredited by a national accrediting body with requirements that are substantially equivalent to or more stringent than those of the College of American Pathologists and is certified under the

testing established by the National Marrow Donor Program, or its successor

17	federal Clinical Laboratories Improvement Act of 1967, 42 United States Code,
18	Section 263a; and
19	C. At the time of the testing, the individual covered under the policy or contract must
20	complete and sign an informed consent form that authorizes the results of the test to
21	be used for participation in the National Marrow Donor Program, or its successor
22	organization, and acknowledges a willingness to be a bone marrow donor if a suitable
23	match is found.
24	2. Prohibition. A testing facility may not bill, charge, collect a deposit from, seek
25	payment or reimbursement from or seek recourse against an individual covered under the
26	policy or contract or a person acting on behalf of the individual for any portion of the
27	laboratory fees.
28	Sec. 3. 24-A MRSA §2847-U is enacted to read:
29	§2847-U. Coverage for the cost of testing for bone marrow donation suitability
30	1. Required coverage. All group health insurance policies, contracts and
31	certificates must provide coverage for laboratory fees up to \$150 arising from human
32	leukocyte antigen testing performed to establish bone marrow transplantation suitability
33	in accordance with the following requirements:
34	A. The individual covered under the policy, contract or certificate must meet the
35	criteria for testing established by the National Marrow Donor Program, or its
36	successor organization;

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1 2 3 4 5	B. The testing must be performed in a facility that is accredited by a national accrediting body with requirements that are substantially equivalent to or more stringent than those of the College of American Pathologists and is certified under the federal Clinical Laboratories Improvement Act of 1967, 42 United States Code, Section 263a; and
6 7 8 9 10	C. At the time of the testing, the individual covered under the policy, contract or certificate must complete and sign an informed consent form that authorizes the results of the test to be used for participation in the National Marrow Donor Program, or its successor organization, and acknowledges a willingness to be a bone marrow donor if a suitable match is found.
11 12 13 14	2. Prohibition. A testing facility may not bill, charge, collect a deposit from, seek payment or reimbursement from or seek recourse against an individual covered under the policy, contract or certificate or a person acting on behalf of the individual for any portion of the laboratory fees.
15	Sec. 4. 24-A MRSA §4260 is enacted to read:
16	§4260. Coverage for the cost of testing for bone marrow donation suitability
17 18 19 20	1. Required coverage. All individual and group health maintenance organization contracts must provide coverage for laboratory fees up to \$150 arising from human leukocyte antigen testing performed to establish bone marrow transplantation suitability in accordance with the following requirements:
21 22	A. The individual covered under the contract must meet the criteria for testing established by the National Marrow Donor Program, or its successor organization;
23 24 25 26 27	B. The testing must be performed in a facility that is accredited by a national accrediting body with requirements that are substantially equivalent to or more stringent than those of the College of American Pathologists and is certified under the federal Clinical Laboratories Improvement Act of 1967, 42 United States Code, Section 263a; and
28 29 30 31 32	C. At the time of the testing, the individual covered under the contract must complete and sign an informed consent form that authorizes the results of the test to be used for participation in the National Marrow Donor Program, or its successor organization, and acknowledges a willingness to be a bone marrow donor if a suitable match is found.
33 34 35 36	2. Prohibition. A testing facility may not bill, charge, collect a deposit from, seek payment or reimbursement from or seek recourse against an individual covered under the contract or a person acting on behalf of the individual for any portion of the laboratory fees

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Department of Professional and Financial Regulation, Bureau of Insurance.

37

38 39 Sec. 5. Exemption from review. Notwithstanding the Maine Revised Statutes,

Title 24-A, section 2752, this Act is enacted without review and evaluation by the

'age 3 - 12	26LR2402(01)-1		
1	Sec. 6. Application. The requirements of this Act apply to all policies, contracts		
2	and certificates subject to this Act that are executed, delivered, issued for delivery,		
3	continued or renewed in this State on or after January 1, 2015. For purposes of this Act,		
4	all contracts are deemed to be renewed no later than the next yearly anniversary of the		
5	contract date.		
6	SUMMARY		
_			
7	This bill requires health insurance coverage for laboratory fees up to \$150 arising		
8	from human leukocyte antigen testing performed to establish bone marrow		
9	transplantation suitability.		

Appendix B: Cumulative Impact of Mandates

Bureau of Insurance

Cumulative Impact of Mandates in Maine

Report for the Year 2012

This report provides data for medical insurance coverage of mandates as required by 24-A M.R.S.A. §2752 and compiled by the Bureau of Insurance. While some data was provided through annual mandate reports by insurers, other figures were estimated as a part of the proposed mandates study. The following provides a brief description of each state mandate and the estimated claim cost as a percentage of premium. Many of these mandates are now required by the federal Affordable Care Act (ACA). In addition, the ACA requires benefits covered by the benchmark plan which includes all state mandates to be covered by all individual and small group plans effective January 1, 2014. A summary chart is provided at the end of this report.

• *Mental Health* (Enacted 1983)

Mental health parity in Maine for listed conditions became effective July 1, 1996, and was expanded effective October 1, 2003. The percentage of mental health claims paid has been tracked since 1984 and has historically been between 3% and 4% of total group health claims and was reported as 3.3% in 2012. Mental health claims stayed below 3.5%, despite the fact that an expansion of the list of conditions for which parity is required was fully implemented in 2005. Mental health coverage is included in the essential health benefits for individual and small group plans beginning 2014. This report includes claims as paid under the law requirements for 2012. Individual mental health claims were only 1.9% in 2012 as a mandated offer. We have assumed that individual mental health claims will increase under ACA and will be similar to group claims in 2014.

• Substance Abuse (Enacted 1983)

The state mandate required the provision of benefits for alcoholism and drug dependency and applied only to groups of more than 20. Effective October 1, 2003, substance abuse was added to the list of mental health conditions for which parity is required. Effective on January 1, 2014 the federal Affordable Care Act requires substance abuse treatment benefits for individual and small group plans as part of the essential health benefits.

The percentage of claims paid has been tracked since 1984. For 2012, substance abuse claims paid were 0.7% of the total group health claims. Despite implementation of the parity requirement, there was a long-term decrease in the percentage, likely due to utilization review, which sharply reduced the incidence of inpatient care. We estimate substance abuse claims will remain at the current levels going forward.

• *Chiropractic* (Enacted 1986)

This mandate generally requires coverage for the services of chiropractors to the extent that the same services would be covered if performed by a physician. Using annual experience reports from the carriers, the percentage of claims paid has been tracked since 1986 and, in 2012, was 1.0% of total health claims. The level has typically

been lower for individual than for group. We estimate the current levels going forward. Although it is likely that some of these costs would have been covered even in the absence of a mandate, we have no basis for estimating how much. We have included the entire amount, thereby overstating the impact of the mandate to some extent.

• Screening Mammography (Enacted 1990)

This mandate requires that benefits be provided for screening mammography. The U.S. Preventive Services Task force has recommended that screening mammograms begin at a later age and be done less frequently. While it is possible this will lead to reduced utilization, the American Cancer Society, The American College of Obstetricians and Gynecologists, and many oncologists have not accepted these recommendations. We, therefore, estimate the current level of 0.71% in all categories going forward. Coverage is required by ACA for preventive services.

• **Dentists** (Enacted 1975)

This mandate requires coverage for dentists' services to the extent that the same services would be covered if performed by a physician. It does not apply to HMOs. A 1992 study done by Milliman and Robertson for the Mandated Benefits Advisory Commission estimated that these claims represent 0.5% of total health claims and that the actual impact on premiums is "slight." It is unlikely that this coverage would be excluded in the absence of a mandate. We include 0.1% as an estimate.

• **Breast Reconstruction** (Enacted 1998)

This mandate requires coverage for reconstruction of both breasts to produce a symmetrical appearance after a mastectomy. At the time this mandate was being considered in 1995, one carrier estimated the cost at \$0.20 per month per individual. We do not have a more recent estimate. We include 0.02% in our estimate of the maximum cumulative impact of mandates.

• Errors of Metabolism (Enacted 1995)

This mandate requires coverage for metabolic formula and up to \$3,000 per year for prescribed modified low-protein food products. At the time this mandate was being considered in 1995, Blue Cross estimated the cost at \$0.10 per month per individual. We do not have a more recent estimate. We include 0.01% in our estimate.

• *Diabetic Supplies* (Enacted 1996)

This mandate requires that benefits be provided for medically necessary diabetic supplies and equipment. Based on data collected in 2006, most carriers reported that there would be no cost increase or an insignificant cost increase because they already provide this coverage. Based on our report we estimate 0.2%.

• *Minimum Maternity Stay* (Enacted 1996)

This mandate requires that if a policy provides maternity benefits, the maternity (length of stay) and newborn care benefits must be provided in accordance with "Guidelines for Prenatal Care." Based on carrier responses indicating that they did not limit maternity stays below those recommended, we estimate no impact.

Pap Smear Tests (Enacted 1996)

This mandate requires that benefits be provided for screening Pap smear tests. HMOs would typically cover these costs and, for non-HMO plans, the relatively small cost of this test would not in itself satisfy the deductible, so there would be no cost unless other services were also received. We estimate a negligible impact of 0.01%. Coverage is required by ACA for preventive services.

Annual GYN Exam Without Referral (Enacted 1996)

This mandate only affects HMO plans and similar plans, and it requires the provision of benefits for annual gynecological exams without prior approval from a primary care physician. To the extent the Primary Care Physician (PCP) would, in absence of this law, have performed the exam personally rather than referring to an OB/GYN, the cost may be somewhat higher; therefore, we include 0.1%.

• Breast Cancer Length of Stay (Enacted 1997)

This mandate requires that benefits for breast cancer treatment be provided for a medically appropriate period of time as determined by the physician in consultation with the patient. Our report estimated a cost of 0.07% of premium.

• Off-label Use Prescription Drugs (Enacted 1998)

This mandate requires coverage of off-label prescription drugs in the treatment of cancer, HIV, and AIDS. Our 1998 report stated a "high-end cost estimate" of about \$1 per member per month (0.6% of premium) if it is assumed there is currently no coverage for off-label drugs. Because the HMOs claimed to already cover off-label drugs, in which case there would be no additional cost; and, providers testified that claims have been denied on this basis, we include half this amount, or 0.3%.

• *Prostate Cancer* (Enacted 1998)

This mandate requires prostate cancer screenings if recommended by a physician, at least once a year for men 50 years of age or older until a man reaches the age of 72. No increase in premiums should be expected for the HMOs that provide the screening benefits currently as part of their routine physical exam benefits. Our report estimated additional claims cost for non-HMO plans would approximate \$0.10 per member per month. With the inclusion of administrative expenses, we would expect a total cost of approximately \$0.11 per member per month, or approximately 0.07% of total premiums.

• Nurse Practitioners and Certified Nurse Midwives (Enacted 1999)

This law mandates coverage for nurse practitioners and certified nurse midwives and allows nurse practitioners to serve as primary care providers. This mandate is estimated to increase premium by 0.16%.

• Coverage of Contraceptives (Enacted 1999)

This mandate requires health plans that cover prescription drugs to cover contraceptives. Our report estimated an increase of premium of 0.8%.

• Registered Nurse First Assistants (Enacted 1999)

This mandate requires health plans that cover surgical first assistants to cover registered nurse first assistants if an assisting physician would be covered. No material increase in premium is expected.

• Access to Clinical Trials (Enacted 2000)

This mandate requires that coverage be provided for an eligible enrollee to participate in approved clinical trials. Our report estimated a cost of 0.19% of premium.

• Access to Prescription Drugs (Enacted 2000)

This mandate only affects plans with closed formularies. Our report concluded that enrollment in such plans is minimal in Maine and therefore the mandate will have no material impact on premiums.

• Hospice Care (Enacted 2001)

No cost estimate was made for this mandate because the Legislature waived the requirement for a study. Because carriers generally covered hospice care prior to the mandate, we assume no additional cost.

• Access to Eye Care (Enacted 2001)

This mandate affects plans that use participating eye care professionals. Our report estimated a cost of 0.04% of premium.

• **Dental Anesthesia** (Enacted 2001)

This mandate requires coverage for general anesthesia and associated facility charges for dental procedures in a hospital for certain enrollees for whom general anesthesia is medically necessary. Our report estimated a cost of 0.05% of premium.

• Prosthetics (Enacted 2003)

This mandate requires coverage for prosthetic devices to replace an arm or leg. Our report estimated a cost of 0.03% of premium for groups over 20, and a cost of 0.08% of premium for small employer groups and individuals.

• *LCPCs* (Enacted 2003)

This mandate requires coverage of licensed clinical professional counselors. Our report on mental health parity indicated no measurable cost impact for coverage of LCPCs.

Licensed Pastoral Counselors and Marriage & Family Therapists (Enacted 2005)

This mandate requires coverage of licensed pastoral counselors and marriage & family therapists. Our report indicated no measurable cost impact for this coverage.

• *Hearing Aids* (Enacted 2007)

This mandate requires coverage for \$1,400 for each ear every 36 months for children age 18 and under. The mandate was phased-in between 2008 and 2010, and our report estimated a cost of 0.1% of premium.

• Infant Formulas (Enacted 2008)

This mandate requires coverage for amino acid-based elemental infant formulas for children two years of age and under, regardless of delivery method. This mandate is effective January 2009, and our report estimated a cost of 0.1% of premium.

• Colorectal Cancer Screening (Enacted 2008)

This mandate requires coverage for colorectal cancer screening for persons fifty years of age or older, or less than 50 years of age and at high risk for colorectal cancer according to the most recently published colorectal cancer screening guidelines of a national cancer society. This mandate is effective January 2009. No carriers stated they denied coverage prior to this mandate; therefore, our report estimated no impact on premium.

• Independent Dental Hygienist (Enacted 2009)

This mandate requires individual dental insurance or health insurance that includes coverage for dental services to provide coverage for dental services performed by an independent practice dental hygienist. This mandate applies only to policies with dental coverage; therefore, there is no estimated impact on medical plan premiums.

• Autism Spectrum Disorders (Enacted 2010)

This mandate requires all contracts to provide coverage for the diagnosis and treatment of autism spectrum disorders for individuals five years of age or under. Coverage may be limited for applied behavior analysis to \$36,000 per year. This mandate is effective January 2011, and our 2009 report estimated a cost of 0.7% of premium once the mandate is fully implemented if it included those under age 21. Because the current mandate only applies to those up to age five, the estimate was reduced to 0.3% of premium.

• Children's Early Intervention Services (Enacted 2010)

This mandate requires all contracts to provide coverage for children's early intervention services from birth to 36 months for a child identified with a developmental disability or delay. Benefits may be limited to \$3,200 per year. This mandate is effective January 2011, and our report estimated a cost of 0.05% of premium.

COST OF EXISTING MANDATED HEALTH INSURANCE BENEFITS

Year Enacted	Benefit	Type of Contract Affected	Est. Maximum Cost as % of Premium
1975	Must include benefits for dentists' services to the extent that the same services would be covered if performed by a physician.	All Contracts	0.10%
1983	Benefits must be included for treatment of alcoholism and drug dependency.	All Contracts	0.70%
1975 1983	Benefits must be included for Mental Health Services ,	Groups	3.30%
1995 2003	including psychologists and social workers.	Individual	3.30%
1986 1994	Benefits must be included for the services of chiropractors to the extent that the same services would be covered by a physician. Benefits must be included for therapeutic, adjustive	Group	1.0%
1995 1997	and manipulative services. HMOs must allow limited self-referred for chiropractic benefits.	Individual	0.50%
1990	Benefits must be made available for screening mammography .	Group	0.71%
1997		Individual	0.71%
1995	Must provide coverage for reconstruction of both breasts to produce symmetrical appearance according to patient and physician wishes.	All Contracts	0.02%
1995	Must provide coverage for metabolic formula and up to \$3,000 per year for prescribed modified low-protein food products.	All Contracts	0.01%
1996	If policies provide maternity benefits, the maternity (length of stay) and newborn care benefits must be provided in accordance with "Guidelines for Prenatal Care."	All Contracts	0
1996	Benefits must be provided for medically necessary equipment and supplies used to treat diabetes and approved selfmanagement and education training.	All Contracts	0.20%
1996	Benefits must be provided for screening Pap tests.	All	0.01%
1996	Benefits must be provided for annual gynecological exam without prior approval of primary care physician.	Group managed care	
1997	Benefits provided for breast cancer treatment for a medically appropriate period of time determined by the physician in consultation with the patient.	All Contracts	0.07%
1998	Coverage required for off-label use of prescription drugs for treatment of cancer, HIV, or AIDS.	All Contracts	0.30%
1998	Coverage required for prostate cancer screening .	All Contracts	0.07%

	Coverage of nurse practitioners and nurse midwives and	All Managed Care	
1999	allows nurse practitioners to serves as primary care providers.	Contracts	
1999	Prescription drug must include contraceptives .	All Contracts	0.80%
1999	Coverage for registered nurse first assistants .	All Contracts	0
2000	Access to clinical trials.	All Contracts	0.19%
2000	Access to prescription drugs.	All Managed Care Contracts	0
2001	Coverage of hospice care services for terminally ill.	All Contracts	0
2001	Access to eye care.	Plans with participating eye care professionals	0
2001	Coverage of anesthesia and facility charges for certain dental procedures.	All Contracts	0.05%
2002	Comment for myselfation devices to male or any order	Groups >20	0.03%
200120032003	Coverage for prosthetic devices to replace an arm or leg	All other	0.08%
2003	Coverage of licensed clinical professional counselors	All Contracts	0
2005	Coverage of licensed pastoral counselors and marriage & family therapists	All Contracts	0
2007	Coverage of hearing aids for children	All Contracts	0.1%
2008	Coverage for amino acid-based elemental infant formulas	All Contracts	0.1%
2008	Coverage for colorectal cancer screening	All Contracts	0
2009	Coverage for independent dental hygienist	All Contracts	0
2010	Coverage for autism spectrum	All Contracts	0.3%
2010	Coverage for children's early intervention services	All Contracts	0.05%
	Total cost for groups larger than 20:		8.11%
	Total cost for groups of 20 or fewer:		8.16%
	Total cost for individual contracts:		7.66%