treatments and recent clinical trials. Patients want their doctors to have access to these cutting-edge therapies. Protecting low-risk health IT is about empowering people with access to information. We need to protect that kind of innovation because innovation is an equalizer for consumers.

These technological benefits don't stop at our borders. Think about this statistic: One estimate shows that mobile health deployment in Africa could save as many as 1 million lives by 2017. From assisting nurses with scheduling to reminding pharmacists to refill their stock or even tracking emerging malarial epidemics, mobile health is already transforming the landscape of the developing world in very dramatic ways.

These stories only scratch the surface of where this technology is going. It is important how we treat innovation here in the United States. Other countries around the world are looking at how our government will regulate and oversee these low-risk technologies.

Our bill makes it so low-risk, highly innovative clinical and health software technologies—and the potential they have to empower people—are not undercut by these burdensome regulations. FDA's promise to use its enforcement discretion over low-risk health IT only serves to create confusion and uncertainty in the marketplace. Regulatory discretion by its very nature is something that can easily change over time, and discretion can be misused or abused.

Clear rules should be set because the current FDA regulatory model for medical devices is not well suited for low-risk health information technologies. In a House Energy and Commerce Committee hearing last year, the FDA submitted a letter to the committee that said:

> For 2011 and 2012, the average time for FDA review of medical device submissions that were identified as containing a mobile medical app was 67 days and the average total time from submission to FDA decision was 110 days.

When regulatory days turn into months, problems are going to persist, and that is not something we should leave to discretion. The regulatory time line for risky devices should not be the same for low-risk software that gets released every 60 days, has major updates every month, and sees regular changes every week. Having an approval process that takes longer than the shelf life of the average device operating system stifles opportunity and it stifles innovation.

Innovators, regulators, and consumers need clarity and certainty into how these regulations are going to be enforced. Since mobile wellness apps and most clinical decision support technologies pose little risk to patients, they should not be subject to the same costly painstaking processes as medical devices. The answer is the commonsense, risk-based regulatory approach the PROTECT Act provides. It protects innovation, it protects jobs here in the United States, and it protects jobs in this U.S.-based job sector. Most importantly, it protects patient safety by giving the FDA continued authority and oversight over health IT that is risky and by creating an appropriate regulatory framework for that which is lower risk.

With the introduction of the PROTECT Act, I would also like to acknowledge the great work of Senator LAMAR ALEXANDER of Tennessee, Senator ORRIN HATCH of Utah, Senator MICHAEL BENNET of Colorado, and others who have undertaken this effort in the past. These Senators have helped to lay the groundwork for the development of a risk-based framework for health IT. The ideas included in the PROTECT Act would not be possible without the progress they secured in previous Congresses and in the FDA's Safety and Innovation Act.

I am committed to working with anyone on these issues to exchange views and to exchange ideas so we can get the right policy balance our country needs and deserves.

Again, I thank my friends Senator KING from Maine and Senator RUBIO from Florida for joining me in this important effort. Together, we can achieve our shared vision of protecting patient safety, protecting innovation, and protecting U.S. economic job growth and opportunity.

Mr. President, I yield the floor.

The PRESIDING OFFICER. The Senator from Maine.

Mr. KING. Mr. President, it is a pleasure to join the Senator from Nebraska. I love the idea of the surf-and-turf caucus reaching across the country to try to find commonsense solutions. I often think about legislation and what we are attempting to do, and there is an attempt to codify common sense, to try to bring to the regulatory process, as it deals with medical devices, a little more thoughtfulness and cautiousness as it affects health information technology.

The first part of the bill actually sets up a process whereby we can examine in a thoughtful kind of way some of these issues to reduce the regulatory burden and at the same time foster innovation and, very importantly, protect patient safety. It sets up a process involving the National Institute of Standards and Technology and other parts of the administration so that the regulatory process in this area can be rationalized across agencies and better coordinated.

The heart of the bill, however, as the Senator just outlined, is our attempt to differentiate between medical software, which has a direct impact upon patient health, and software that is more peripheral and can range from the app I have on my iPhone, which is a pedometer that tells me how much I have walked each day and how much I should walk each day, to the kind of software that is being developed across the country to assist medical practices in their billing and in the operational part of the medical business.

I think one of the most important points, as the Senator pointed out, is that software evolves almost overnight, and if you go through this burdensome regulatory process—whether it is 60 days, 120 days, or 1 year—to get your software approved and then you find there is a bug you have to fix, that could restart the whole regulatory process. So I think we should acknowledge that this is a bit of preemptive legislation because the FDA thus far has not intruded very deeply into this process, and we believe it is important in order to define the areas where regulation and the protection of patient safety is important, but software that manages the billing process of a medical practice should not fall into that category and should not be subject to that level of regulation. That is really what we are talking about.

As the Senator mentioned, this law goes back to 1976. In thinking about 1976, Gerald Ford was President and software was a mink coat. We weren't really thinking about what we are doing today, and of course the legislation did not anticipate the kind of intense innovation and new thinking that is going on that is able to protect people's health just by giving them information about themselves. No doubt the time will come when a smartphone will be able to do blood pressure or temperature or certainly provide one's heart rate, and that is information we should have ourselves, not necessarily regulated by the Federal Government.

I am delighted to join the Senator from Nebraska and the Senator from Florida in introducing this piece of legislation. I think it is important. It is part of a larger project to try to bring our Federal regulatory process into the 21st century where time is of the essence, innovation is at the speed of light, and that we can't burden our people who are creating these innovations with a lengthy and, yes, expensive process that has a tendency to discriminate against smaller entrepreneurs and businesspeople.

I compliment the Senator from Nebraska for bringing this piece of legislation forward. I am absolutely delighted to join her in its sponsorship, and I look forward to moving it through the legislative process. There is a companion piece of legislation in the House, and I think this, as I said at the beginning, is an effort to get as close as we can to legislating common sense in this area, and I believe it will make a difference for businesses, for people, for patients, and for the health care system in America.

AMENDMENTS SUBMITTED AND PROPOSED

SA 2732. Ms. AYOTTE (for herself, Mr. GRAHAM, Mr. WICKER, Mr. MCCONNELL, Mr. CORNYN, Mr. INHOFE, Mr. THUNE, Mr. CHAMBLISS, Mr. JOHANNS, Mr. BURR, Mr. BOOZMAN,

Mr. COATS, Mr. PAUL, Mr. SESSIONS, Mr. ENZI, Mr. ROBERTS, Mr. ISAKSON, and Mr. TOOMEY) submitted an amendment intended to be proposed by her to the bill S. 1963, to repeal section 403 of the Bipartisan Budget Act of 2013; which was ordered to lie on the table.

TEXT OF AMENDMENTS

SA 2732. Ms. AYOTTE (for herself, Mr. GRAHAM, Mr. WICKER, Mr. MCCONNELL, Mr. CORNYN, Mr. INHOFE, Mr. THUNE, Mr. CHAMBLISS, Mr. JOHANNS, Mr. BURR, Mr. BOOZMAN, Mr. COATS, Mr. PAUL, Mr. SESSIONS, Mr. ENZI, Mr. ROBERTS, Mr. ISAKSON, and Mr. TOOMEY) submitted an amendment intended to be proposed by her to the bill S. 1963, to repeal section 403 of the Bipartisan Budget Act of 2013; which was ordered to lie on the table; as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. REPEAL OF REDUCTIONS MADE BY BIPARTISAN BUDGET ACT OF 2013.

(a) REPEALS.—

(1) ADJUSTMENT OF RETIREMENT PAY.—Section 403 of the Bipartisan Budget Act of 2013 is repealed as of the date of the enactment of such Act.

(2) CONFORMING AMENDMENT.—Title X of the Department of Defense Appropriations Act, 2014 (division C of Public Law 113–76) is hereby repealed.

(b) SOCIAL SECURITY NUMBER REQUIRED TO CLAIM THE REFUNDABLE PORTION OF THE CHILD TAX CREDIT.—

(1) IN GENERAL.—Subsection (e) of section 24 of the Internal Revenue Code of 1986 is amended to read as follows:

''(e) IDENTIFICATION REQUIREMENT WITH RESPECT TO QUALIFYING CHILDREN.—

''(1) IN GENERAL.—Subject to paragraph (2), no credit shall be allowed under this section to a taxpayer with respect to any qualifying child unless the taxpayer includes the name and taxpayer identification number of such qualifying child on the return of tax for the taxable year.

''(2) REFUNDABLE PORTION.—Subsection (d)(1) shall not apply to any taxpayer with respect to any qualifying child unless the taxpayer includes the name and social security number of such qualifying child on the return of tax for the taxable year.''.

(2) OMISSION TREATED AS MATHEMATICAL OR CLERICAL ERROR.—Subparagraph (I) of section 6213(g)(2) of the Internal Revenue Code of 1986 is amended to read as follows:

''(I) an omission of a correct TIN under section 24(e)(1) (relating to child tax credit) or a correct Social Security number required under section 24(e)(2) (relating to refundable portion of child tax credit), to be included on a return,''.

(3) EFFECTIVE DATE.—The amendments made by this subsection shall apply to taxable years beginning after the date of the enactment of this Act.

NOTICES OF HEARINGS

COMMITTEE ON RULES AND ADMINISTRATION

Mr. SCHUMER. Mr. President, I wish to announce that the Committee on Rules and Administration will meet on February 12, 2014 at 10 a.m., to hear testimony on the ''Bipartisan Support for Improving U.S. Elections: An Overview from the Presidential Commission on Election Administration.''

For further information regarding this hearing, please contact Lynden Armstrong at the Rules and Administration Committee (202) 224–6352.

COMMITTEE ON RULES AND ADMINISTRATION

Mr. SCHUMER. Mr. President, I wish to announce that the Committee on Rules and Administration will meet at 10:30 a.m., on February 12, 2014, to conduct a business meeting to consider the nominations of Thomas Hicks and Myrna Perez to be members of the Election Assistance Commission.

For further information regarding this meeting, please contact Lynden Armstrong at the Rules and Administration Committee at (202) 224–6352.

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

Mr. HARKIN. Mr. President, I wish to announce that the Committee on Health, Education, Labor, and Pensions will to meet on February 13, 2014, at 10 a.m., in room SD–430 of the Dirksen Senate Office Building, to conduct a hearing entitled From Poverty to Opportunity: How a Fair Minimum Wage Will Help Working Families Succeed.''

For further information regarding this meeting, please contact Sarah Cupp of the committee staff on (202) 224–5363.

PRIVILEGES OF THE FLOOR

Mr. HARKIN. Mr. President, I ask unanimous consent that Elizabeth Lievens and David Pope, interns in my office, be granted floor privileges for the remainder of today.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. KING. Mr. President, I ask unanimous consent that Chris Sweitzer, a military fellow in the office of Senator PRYOR, be granted the privilege of the floor for the duration of the calendar year.

The PRESIDING OFFICER. Without objection, it is so ordered.

LETTER OF RESIGNATION

The PRESIDING OFFICER. The Chair lays before the Senate the letter of resignation of Senator MAX BAUCUS of Montana dated Thursday, February 6, 2014.

Mr. BEGICH. Mr. President, I ask unanimous consent that the letters relating to the resignation of the Senator from Montana, MAX BAUCUS, be printed in the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

U.S. SENATE,
Washington, DC, February 6, 2014.

Governor STEVE BULLOCK,
Montana State Capitol,
Helena, MT.

DEAR GOVERNOR BULLOCK: In order to assume the responsibility of serving as the United States Ambassador to China, I write to resign my seat in the United States Senate effective upon my appointment as Ambassador. Representing the people of Montana for 40 years has been the honor of a lifetime. I am grateful for the trust Montanans have bestowed on me and the opportunity to contribute to our great state and nation.

Respectfully,

MAX BAUCUS.

FEBRUARY 7, 2014.

Hon. JOSEPH R. BIDEN, Jr.,
President of the Senate,
Washington, DC.

DEAR VICE PRESIDENT BIDEN: In accordance with my letter of February 6, 2014 to Governor Bullock, this is to clarify that my resignation as United States Senator became effective at the close of business on February 6, 2014.

Sincerely,

MAX BAUCUS.

PROVIDING FOR EXTENSION OF ENFORCEMENT INSTRUCTION

Mr. BEGICH. Mr. President, I ask unanimous consent that the Finance Committee be discharged from further consideration of S. 1954 and the Senate proceed to its immediate consideration.

The PRESIDING OFFICER. Without objection, it is so ordered.

The clerk will report the bill by title.

The legislative clerk read as follows:

A bill (S. 1954) to provide for the extension of the enforcement instruction on supervision requirements for outpatient therapeutic services in critical access and small rural hospitals through 2014.

There being no objection, the Senate proceeded to consider the bill.

Mr. BEGICH. I ask unanimous consent that the bill be read for a third time, passed, and the motion to reconsider be laid upon the table.

The PRESIDING OFFICER. Without objection, it is so ordered.

The bill (S. 1954) was ordered to be engrossed for a third reading, was read the third time, and passed, as follows:

S. 1954

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. EXTENSION OF ENFORCEMENT INSTRUCTION ON SUPERVISION REQUIREMENTS FOR OUTPATIENT THERAPEUTIC SERVICES IN CRITICAL ACCESS AND SMALL RURAL HOSPITALS THROUGH 2014.

The Secretary of Health and Human Services shall continue to apply through calendar year 2014 the enforcement instruction described in the notice of the Centers for Medicare & Medicaid Services entitled ''Enforcement Instruction on Supervision Requirements for Outpatient Therapeutic Services in Critical Access and Small Rural Hospitals for CY 2013'', dated November 1, 2012 (providing for an exception to the restatement and clarification under the final rulemaking changes to the Medicare hospital outpatient prospective payment system and calendar year 2009 payment rates (published in the Federal Register on November 18, 2008, 73 Fed. Reg. 68702 through 68704) with respect to requirements for direct supervision by physicians for therapeutic hospital outpatient services).

COMMEMORATING THE 150TH ANNIVERSARY OF THE MAYO CLINIC

Mr. BEGICH. I ask unanimous consent that the HELP Committee be discharged from further consideration of S. Res. 339 and the Senate proceed to its immediate consideration.

The PRESIDING OFFICER. Without objection, it is so ordered.