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HEALTH CARE ISSUES INVOLVING THE CENTER FOR CONSUMER INFORMATION AND INSURANCE OVERSIGHT

HEARING

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED TWELFTH CONGRESS

FIRST SESSION

FEBRUARY 16, 2011

Serial No. 112–7

Printed for the use of the Committee on Energy and Commerce

energycommerce.house.gov

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U.S. GOVERNMENT PRINTING OFFICE

65–977 PDF WASHINGTON : 2011

For sale by the Superintendent of Documents, U.S. Government Printing Office
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[1] Mr. Angoff did not submit a prepared statement.

HEALTH CARE ISSUES INVOLVING THE CENTER FOR CONSUMER INFORMATION AND INSURANCE OVERSIGHT

WEDNESDAY, FEBRUARY 16, 2011

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
Washington, D.C.

The subcommittee met, pursuant to call, at 9:30 a.m., in room 2322 of the Rayburn House Office Building, Hon. Cliff Stearns (chairman of the subcommittee) presiding.

Members present: Representatives Stearns, Sullivan, Murphy, Burgess, Blackburn, Myrick, Gingrey, Scalise, Gardner, Griffith, Barton, DeGette, Schakowsky, Weiner, Green, Dingell, and Waxman (ex officio).

Staff present: Caroline Basile, Staff Assistant; Mike Bloomquist, Deputy General Counsel; Allison Busbee, Legislative Clerk; Karen Christian, Counsel, Oversight; Stacy Cline, Counsel, Oversight; Howard Cohen, Chief Health Counsel; Julie Goon, Health Policy Advisor; Todd Harrison, Chief Counsel, Oversight/Investigations; Sean Hayes, Counsel, Oversight/Investigation; Ruth Saunders, Detailee, ICE; Alan Slobodin, Deputy Chief Counsel, Oversight; Sam Spector, Counsel, Oversight; John Stone, Associate Counsel; Tim Torres, Deputy IT Director; Lyn Walker, Coordinator, Administration/Health Resources.

OPENING STATEMENT OF HON. CLIFF STEARNS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF FLORIDA

Mr. STEARNS. We convene this hearing of the subcommittee on Oversight and Investigation today to gather information on the entity responsible for overseeing the Administration's changes to the private insurance market, the Center for Consumer Information and Insurance Oversight.

It has been nearly a year since the health care law was enacted, and this is the first hearing this subcommittee has had since passage of the law devoted exclusively to its effects. This Center is responsible for the massive changes being made by the Administration to the private insurance market. It is responsible for new insurance market rules, the temporary high-risk pools, new medical loss ratio rules, and will assist States in implementing the massive new regulatory burdens imposed by the Administration.

Our witnesses today are a former Director of the Center and the current one, Mr. Jay Angoff, who ran the office from its inception

after the passage of the bill until earlier this year. We know very little about the creation of this office, and I hope this hearing this morning will finally shine some light on how this office was, in fact, created, how it is simply organized, and why it is recently moved from HHS to CMS on literally, literally the day the Republicans took the majority in the 112th Congress. Just a coincidence I am sure.

We also know little about how this office is funded. Is it paid for out of the Health Care Law that was signed last year? Is HHS taking money from another program? So we know very little, and what we do know has not made a favorable impression on us, perhaps because we don't understand.

Last year the New York Times reported, "In Bethesda, Maryland, more than 200 health regulators working on complicated insurance rules have taken over three floors of a suburban office building, paying almost double the market rate for the space in their rush to get started." So I hope the Administration and its regulators are better at writing regulations than perhaps writing leases.

Our other witness is Mr. Steve Larsen. Mr. Larsen was recently promoted to Director of the Center and had previously served in the Center's Office of Oversight, the office that was responsible for granting waivers from the Obama Administration's Health Care. I think it is an understatement to say that these waivers have been controversial.

The Administration's Health Care Plan was sold as all benefit and no downside, so when the public began hearing that while they would have to comply with all the new regulations and costs while other individuals would get waivers from the Administration and thus not have to comply and bear the same burdens, obviously they weren't happy. After all, they were promised that if they like their coverage, they could keep it. We heard this mantra over and over again. If you like your coverage, you can keep it.

They were promised lower premiums. They were promised lower costs, so simply what did they get? Lost coverage, higher premiums, and higher costs in our opinion, and when the damaging effects of the Administration's Health Care Plan got so bad that people were starting to notice, then it was time for waivers. The promises made by supporters of the law just simply have not come true.

The Chief Actuary for the Centers for Medicare and Medicaid Services recently testified that the law will likely not hold down costs. He went on to say that not everyone will be able to keep their coverage, even if they like it. Meanwhile, the adverse effects of the law on the private sector have been undeniable. Companies are considering dropping coverage, insurers are opting to exit from the market, and consumers are left with fewer options, in fact. And of those options available the premiums continue to rise thanks to the costly mandates and regulations in Obamacare.

It certainly doesn't get any better when you look at how the government is handling this Health Care Bill. Last month this subcommittee's hearing on the need for regulatory reform highlighted how numerous regulations in the Health Care Bill have been issued without even public comment. If an idea is controversial and lacks popular support, like end-of-life counseling, for example, then

it simply sneaks into the regulations in the hope that nobody will notice. No comment period. Just happens to appear.

So today, my colleagues, we will hear testimony about why so many companies and insurers need to be excluded, given waivers from this great Health Care Bill that the Administration has touted. Ironically, considering that if you listened to the Administration for the last 2 years, you would wonder why anyone would ever need to be protected from this law, yet today we have learned that over two and a half million people have been exempted from the Administration's Health Care Plan through these waivers. Two and a half million people need to literally, literally be protected from the devastating effects of the Health Care Bill the Administration has passed. Yes, protected.

Under the very standards determining whether a waiver will be granted, a company or insurer needs to show that unless a waiver was granted, beneficiaries were either going to face significant premium increases or a significant reduction in access to benefits. So we will hear today that these waivers are necessary because the plans they affect offer little coverage. We will likely hear at length today that the reason it is OK to give out these waivers is because in 2014, the exchanges will finally provide low-cost, quality health care, yet nearly every promise made about Obamacare has been broken.

During the debate on health care our party offered many solutions to expand access to health care services without raising costs or bankrupting the country. They were not passed. They were ignored. So I am hopeful today that we begin to examine the effects of the Administration's Health Care Bill. Americans from both parties will begin to see the value in our ideas, ideas that rely on commonsense and free-market solutions and perhaps not on decisions that are made by the federal bureaucracy.

I am very interested in the testimony we will hear today, because this Center is responsible for many of the changes in the Administration's Health Care Bill that it makes to the private insurance market, and I hope our witnesses will shine some light on the reasons for these changes. I know this is a busy season for them, so I appreciate them coming up here especially with the budget process and the budget being released this week. So I thank them sincerely for their time.

Today marks the beginning of what the public voted for in 2010, real and sustained oversight of the federal takeover of the health care industry, and with that I recognize distinguished colleague, Ms. DeGette.

[The prepared statement of Mr. Stearns follows:]

PREPARED STATEMENT OF HON. CLIFF STEARNS

We convene this hearing of the Subcommittee on Oversight and Investigations today to gather information on the entity responsible for overseeing the Administration's changes to the private insurance market—The Center for Consumer Information and Insurance Oversight. It has been nearly a year since the health care law was enacted, and this is the first hearing this subcommittee has had since passage of the law devoted exclusively to its effects.

This Center is responsible for the massive changes being made by Obamacare to the private insurance market. It is responsible for new insurance market rules, the temporary high risk pools, new medical loss ratio rules, and will assist states in im-

plementing the massive new regulatory burdens imposed by Obamacare. Our witnesses today are the former Director of the Center and the current one—Mr. Jay Angoff ran the office from its inception after the passage of Obamacare until earlier this year. We know very little about the creation of this office, and I hope this hearing will finally shine some light on how this office was created, how it is organized, and why it was moved from HHS to CMS on literally the day Republicans took the majority in the 112th Congress.

We also know little about how this office is funded—is it paid for out of the health care law signed last year? Is HHS taking money from another program? We know very little, and what we do know has not made a good impression. Last year the New York Times reported: "In Bethesda, Maryland, more than 200 health regulators working on complicated insurance rules have taken over three floors of a suburban office building, paying almost double the market rate for the space in their rush to get started." I hope Obamacare's regulators are better at writing regulations than writing leases.

Our other witness is Mr. Steve Larsen, Mr. Larsen was recently promoted to Director of the Center, and had previously served in the Center's Office of Oversight—the office that was responsible for granting waivers from Obamacare.

I think it is an understatement to say that these waivers have been controversial. Obamacare was sold as all benefit—no downside. So when the public began hearing that while they would have to comply with all of the new regulations and costs, while other individuals would get waivers from the Administration and thus not have to comply and bear the same burdens, they weren't happy.

After all, they were promised that if they like their coverage, they could keep it. They were promised lower premiums. They were promised lower costs. What did they get? Lost coverage. Higher premiums. Higher costs. And when the damaging effects of Obamacare got so bad that people were starting to notice? Then it was time for waivers.

The promises made by supporters of the law have not come true. The Chief Actuary for the Center for Medicare and Medicaid Services recently testified that the law will likely not hold down costs. He went on to say that not everyone will be able to keep their coverage, even if they like it. Meanwhile, the adverse effects of the law on the private sector have been undeniable: companies are considering dropping coverage, insurers are opting to exit from the market, and consumers are left with fewer options—and of those options available, the premiums continue to rise, thanks to the costly mandates and regulations in Obamacare.

It certainly doesn't get any better when you look at how the government is handling Obamacare. Last month this subcommittee's hearing on the need for regulatory reform highlighted how numerous regulations in Obamacare have been issued without public comment. If an idea is controversial and lacks popular support, like end of life counseling, then it is simply snuck into a regulation in the hope that nobody will notice.

Today we will hear testimony about why so many companies and insurers need to be excluded from the effects of Obamacare—ironic, considering that if you listened to the Administration for the last 2 years you'd wonder why anyone would ever need to be protected from this law—yet today we learn that 2.5 million people have been exempted from Obamacare through these waivers. 2.5 million people need to literally be protected from the devastating effects of Obamacare.

Yes, protected. Under the very standards determining whether a waiver will be granted, a company or insurer needed to show that unless a waiver was granted, beneficiaries were either going to face a "significant" premium increase or a "significant" reduction in access to benefits.

We will hear today that these waivers are necessary because the plans they affect offer little coverage. We will likely hear at length today that the reason it is ok to give out these waivers is because in 2014, the exchanges will finally provide low cost, quality health care. Yet, nearly every promise made about Obamacare has been broken.

During the debate on health care, our party offered many solutions to expand access to health care services without raising costs or bankrupting the country. We were ignored then. I am hopeful that as we begin to examine the terrible effects of Obamacare, Americans from all parties will begin to see the value in our ideas—ideas that rely on commonsense and free market solutions, not on decisions made by the federal bureaucracy.

I am very interested in the testimony we will hear today because this Center is responsible for many of the changes Obamacare makes to the private insurance market, and I hope our witnesses will shine some light on the reason for those changes.

I know that this is a busy season for them, especially with the budget being released this week, and I thank them for their time.

Today marks the beginning of what the public voted for in 2010: real and sustained oversight of the federal takeover of the healthcare industry.

I recognize, with pleasure, the Ranking Member, Ms. DeGette.

Ms. DEGETTE. Mr. Chairman, out of deference to the two hearings this morning, I am going to defer to the ranking member to make his opening statement first.

Mr. STEARNS. Mr. Waxman is recognized.

OPENING STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. WAXMAN. Thank you very much. I am a strong believer in effective oversight. It is essential to assure that the laws passed by Congress are implemented in the most effective and efficient way possible, and that is why I support oversight of the Affordable Care Act.

The Health Reform Law passed by Congress, signed into law by President Obama last year, provides tremendous benefits. Insurers are banned from discriminating against children with pre-existing conditions. Seniors are already benefiting from lower drug prices. Small businesses are getting tax cuts to pay for health insurance. The law has benefits for all Americans, and we ought to be doing what we can to make sure the Administration is implementing the law appropriately.

But I am concerned, Mr. Chairman, that this committee is using oversight as another means of blocking the implementation of the law. Over the last few weeks the committee issued a broad document request to the Department of Health and Human Services that require massive document searches for no apparent purpose. Already HHS has provided over 50,000 pages of documents in response to these requests. And already we are seeing Republican leaders make unsubstantiated allegations that wrongly accuse the Department of misconduct and mismanagement. Before they have even had the hearing and gotten the facts Republicans are telling us that the law has failed, and I believe that it is not true.

The subject of today's hearing is the formation of the HHS Center for Consumer Information and Insurance. This group within CMS has provided insurers from a provision of the Health Care Bill banning annual limits on health care coverage. The insurers are saying unless they get some of these waivers, the price of the insurance will go up before we get to the period of 2014, or the availability of the insurance will not be as much as it has been in the past. So we wrote into the law that we wanted the Department to give these waivers, at least until 2014, when the law will be fully in effect.

Our subcommittee chairman has asserted that the granting of these waivers show that health care reform is flawed. "If the law is so good, why are so many waivers to the law being granted." Senator Orrin Hatch decried the lack of transparency. Oversight Chairman Darrell Issa has asserted that unions have received special treatment because, "Bureaucrats are picking winners and los-

ers in a politicized environment where the winners are favored constituencies of the Administration."

But let us look at the facts. The waiver process has been transparent and efficient. HHS put out an interim final rule, three sets of guidance, and worked individually with each applicant to resolve any problem with waiver requests. Over 90 percent of all entities that applied for waivers were approved. The average wait time for approval of a completed waiver request was only 13 days. The process has been fair.

Contrary to Chairman Issa, there has been no favoritism to unions. The information HHS has provided to the committee shows that plans that serve union employees were almost five times as likely to have their waivers denied as non-union plans. Nine of the last ten largest applicants to be denied waivers were plans that provided care for union members.

The law and waiver process are designed to accommodate plans with low annual limits known as limited benefit plans or mini-med plans. These plans either have a set limit of dollars that they will spend on benefits or a limited amount of benefits that may be received or a cap on specific benefits. These are plans that by 2014 will no longer be able to do what they are doing because in 2014, all plans are going to have to cover the minimum health insurance package. They will not be able to discriminate on the basis of preexisting conditions, and consumers and small businesses will have improved access to affordable care through no health insurance exchanges.

The waivers are intended to provide a smooth transition between now and 2014. They affect a small population, less than 2 percent of all Americans with employer-based coverage, but for this group they provided valuable interim relief.

The Democratic staff has prepared an analysis of the waiver process that documents its success, and I ask this analysis be made part of today's hearing record.

I was the ranking member of the Oversight Committee when Dan Burton was Chairman, and during that time President Clinton was in office. No allegation was too wild for him not to pursue. The committee would demand thousands of documents, take up hundreds of hours of taxpayer's time in investigations that cost taxpayers millions of dollars, all with no regard for the basic facts of the case.

An allegation would come out before they got the information, and then when the information came out disproving the allegation, they were already ready for another allegation. They moved 1 day to the next with attacks, attacks, attacks.

Well, Mr. Chairman, I hope we are not going to see that go on in this committee and in this Congress. Let us be fair, let us get the facts, and let us see what the reality is before we make any of these accusations that I have been hearing.

I yield back the balance of my time.

[The prepared statement of Mr. Waxman follows:]

PREPARED STATEMENT OF HON. HENRY A. WAXMAN

Mr. Chairman, I am a strong believer in effective oversight. It is essential to ensuring that the laws passed by Congress are implemented in the most effective and efficient way possible. That is why I support oversight of the Affordable Care Act.

The health reform law passed by Congress and signed into law by President Obama last year provides tremendous benefits. Insurers are banned from discriminating against children with pre-existing conditions. Seniors are already benefitting from lower drug prices. Small businesses are already getting tax cuts to pay for health insurance. The law has benefits for all Americans—and we ought to be doing what we can to make sure the Administration is implementing the law appropriately.

But I am concerned that this Committee is using oversight as another means of blocking implementation of the law. Over the last few weeks, the Committee issued broad document requests to the Department of Health and Human Services (HHS) that require massive document searches for no apparent purpose. Already HHS has produced over 50,000 pages of documents in response to these requests.

And already we are seeing Republican leaders make unsubstantiated allegations that wrongly accuse the Department of misconduct and mismanagement.

The subject of today's hearing is the formation of HHS's Center for Consumer Information and Insurance Oversight and the waivers that CCIIO has provided insurers from a provision of the health care bill banning annual limits on health care coverage.

The Subcommittee Chairman has asserted that the granting of these waivers shows that the health care reform effort is flawed: "If the law is so good, why are so many waivers to the law being granted?" Senator Orrin Hatch has decried "the lack of transparency which has surrounded the waiver process." Oversight Chairman Darryl Issa has asserted that unions have received special treatment because "bureaucrats are picking winners and losers in a politicized environment where the winners are favored constituencies of the administration."

But let's look at the facts.

The waiver process has been transparent and efficient. HHS put out an interim final rule, three sets of guidance, and worked individually with each applicant to resolve any problem with waiver requests. Over 90% of all entities that applied for waivers were approved. The average wait time for approval of a completed waiver request was only 13 days.

The process has also been fair. Contrary to Chairman Issa, there has been no favoritism to unions. The information HHS has produced to the Committee shows that plans that serve union employees were almost five times as likely to have their waivers denied as non-union plans. Nine of the ten largest applicants to be denied waivers were plans that provided care for union members.

The law and the waiver process are designed to accommodate plans with low annual limits known as "limited benefit plans" or "mini-med" plans. These plans either have a set limit on dollar amounts of benefits that may be received or cap specific benefits.

In 2014 these plans will be unnecessary: all Americans will have improved health care coverage because insurers will no longer be able to discriminate on the basis of pre-existing conditions, and consumers and small businesses will have improved access to affordable care through new health insurance exchanges.

The waivers are intended to provide a smooth transition between now and 2014. They affect a small population—less than 2% of all Americans with employer-based coverage—but for this group they provided valuable interim relief.

Rather than indicating a flaw in the law, the waiver process shows HHS is implementing health reform in a way that helps consumers keep their plans without imposing undue burdens on insurers or risking loss of coverage.

The Democratic staff has prepared an analysis of the waiver process that documents its success. I ask that this analysis be made part of today's hearing record.

I was ranking member of the Oversight Committee when then Chairman Dan Burton ran amok investigating our last Democratic President. No allegation was too wild to pursue. The Committee would demand thousands of documents, and take up hundreds of hours of taxpayer time in investigations that cost taxpayers millions of dollars—all with no regard for the basic facts of the case.

I hope this is not happening here. When we hold oversight hearings, we should do so because we want to make sure that federal agencies are doing their jobs. We should not hold hearings to stop the vital work of government. And we should not hold hearings because the new Republican majority wants to disrupt the health care reform law.

As we conduct oversight on the law, I hope we will put partisanship aside and do the kind of thorough and fair investigations that have been the hallmark of this Committee.

And if we do that, the American people will see there is good news about the health care reform law and the ways it is helping all Americans.

Mr. STEARNS. Yields back the balance of his time and I recognize the gentlelady from Tennessee for 2 minutes.

Mrs. BLACKBURN. Thank you, Mr. Chairman. I welcome our witnesses today. We have been waiting a long time to ask these questions that we have for you, and reading your prepared remarks I think we would all be led to believe that this has been an unqualified success in its rollout. You talk a lot about benefits, but you don't talk a lot about expected costs, and we will want to talk with you about that.

I want to go to the waivers because there have been some 900 health plans that have been given waivers, and we will discuss those waivers as we move forward. I think we are going to want to know what happens in 2013, and 2014, when those companies are not able to get waivers. These waivers gave relief to some plans but will happen to—we want to know what is going to happen when the other mandates of Obamacare are phased in, and it seems to me that these are 900 new stories that the Administration probably is wanting to avoid because private sector plans that are working for people, they don't want to come under Obamacare. And so they are coming to you to get a waiver.

In Tennessee we have been down this costly road before, and Mr. Chairman, I have some charts on what happened in Tennessee that I would like to submit for the record.

As I have repeatedly stated in this committee, TennCare gave unlimited access to care, it incentivized use rather than controlled costs, it reached the point of consuming 35.3 percent of the State budget. That was in 2005. Nearly bankrupted the State, so I am going to want to know if you are using history as a guide, what is your plan for dealing with cost acceleration which comes on you very quickly if you look at the TennCare model which is the closest thing in this country to what you have.

Even our former governor, a Democrat, Phil Bredesen, did a lot to rein in exploding costs, implementing a program, but, there again, we saw what happened in our State.

I thank you, Mr. Chairman. I yield back.

Mr. STEARNS. And I thank the gentlelady. Recognize Dr. Burgess for 1 minute.

Dr. BURGESS. For 1 minute?

Mr. STEARNS. We are going to go 1 minute to Mr. Burgess, 1 minute to Mr. Gardner, and 1 minute to Mr. Barton.

Dr. BURGESS. All right. Very well. Then let me just welcome our witnesses. It is good to see you again, Mr. Angoff. We had a nice visit last November. This is an issue that has been of great interest to me for quite some time. In fact, you were known by a different acronym when I met with you and, now I followed with interest that there have been some changes within the agency, and whether those are good or bad remains to be determined.

Mr. Waxman spoke eloquently of the problems that he saw in a previous Congress, but let me just allude to the problems that I

saw in the last Congress when we decided to be indifferent to oversight and not even ask a simple question. We passed this law in my opinion in a way that was poorly done, and then your agency, within the agency was set up with very little notice to the Congress. No one knew you were here, no one knew how much money you were spending, where it was coming from, and then we find out that in order for the Patient Protection and Affordable Care Act to work you had to give two and a half million people waivers. Well, it doesn't sound to me like the definition of a good solid foundation.

So I am grateful that we are doing the oversight now, grateful to the subcommittee chairman for calling this hearing. I wish we could have done this several months ago. I think it would have helped all of us, but thank you, Mr. Chairman. I will yield back.

Mr. STEARNS. Thank the gentleman, and Mr. Gardner, you are recognized for 1 minute.

Mr. GARDNER. Thank you, Mr. Chairman, and the witnesses for attending today for convening our first hearing, oversight hearing, on the Patient Protection and Affordable Care Act.

A lot of promises have been made about health care reform. Costs would be lower, people would have better access to health care. If people liked their coverage, they could keep it. Those promises are not being kept.

The waivers issued by HHS exempting health plans from the prohibition on annual or lifetime benefits or lifetime limits on benefits is a good case study. Over 900 health plans would have been forced to reduce benefits, raise costs to their enrollees, or drop the plans altogether because complying with the requirements of the Health Care Bill was just too expensive.

Even worse, these waivers are simply postponing reality. What will happen as other requirements of the law are phased in and health care plans, health plans are not able to comply with those further financial burdens? This is why this committee's investigation of the bill is so timely in the Center for Consumer Information and Insurance Oversight. We cannot wait until the exchanges are up and running to discover that they are not working. Congress can't stick its head in the sand and deny the law of economics. Companies that need waivers today will not suddenly be able to provide even more required benefits in 2012, when the Health Care Bill fully kicks in.

Many of the assumptions that are underpinning the Health Care Bill have proven to be false. For instance, it was estimated that 375,000 people would enroll in the high-risk pools. Instead, only 12,000 people enrolled. Recent articles and the news have discussed the increasingly unbearable burden that Medicaid places on State budgets. Medicaid is 21 percent of total State spending and annual spending growth on the program doubled between 2008, and 2009.

I am excited to get to work on this. I believe we have a lot of work to do and look forward to hearing from you before we end up bankrupting this country.

[The prepared statement of Mr. Gardner follows:]

PREPARED STATEMENT OF HON. CORY GARDNER

Thank you, Mr. Chairman, for convening our first oversight hearing on the Patient Protection and Affordable Care Act.

A lot of promises have been made about health care reform. Costs would be lower. People would have better access to health care. If people liked their coverage, they could keep it. Those promises are not being kept.

The waivers issued by HHS exempting health plans from the prohibition on annual or lifetime limits on benefits is a good case study. Over 900 health plans would have been forced to reduce benefits, raise costs to their enrollees, or drop the plans altogether because complying with the requirements of Obamacare was just too expensive. Even worse, these waivers are simply postponing reality. What will happen as other requirements of the law are phased in, and health plans are not able to comply with those further financial burdens?

This is why this Committee's investigation of Obamacare, and the manner in which it is being implemented by the Center for Consumer Information and Insurance Oversight is long overdue. We cannot wait until the exchanges are up and running in 2014 to realize that this system is not working. You cannot stick your head in the sand and deny the laws of economics forever. Companies that need waivers from Obamacare's requirements today will not suddenly be able to provide even more required benefits in 2012, when Obamacare fully kicks in. Many of the assumptions underpinning Obamacare have been proven to be false.

For instance, it was estimated that 375,000 people would enroll in the high-risk pools. Instead, only 12,000 enrolled. Recent articles in the news have discussed the increasingly unbearable burden that Medicaid places on state budgets. Medicaid is 21 percent of total state spending, and annual spending growth on the program doubled between 2008 and 2009. And yet this health care reform law would essentially add 20 million more people to the Medicaid rolls in 2014. These are simply unsustainable burdens, and if they are not fixed, they will break the world's greatest health care system and bankrupt this country. We need to fix this problem.

I am ready to get to work on this issue. I thank the witnesses for being here, and I yield back the balance of my time.

Mr. STEARNS. I thank my colleague and the distinguished chairman emeritus, Mr. Barton.

Mr. BARTON. Thank you, Mr. Chairman. I will put my formal statement in the record.

Today's hearing is the first of many, but I think it is telling, Mr. Chairman, that we are here today with an oversight hearing over an organization that is not explicitly authorized in the Act, whose job is to give waivers to a law that supposedly is going to lower costs, but the very reason they are giving waivers is because the cost of complying with the law is so large that over 900 companies or 900 insurance plans have been given waivers because they could not comply if they had to honor what the law said.

So this is going to be a good hearing. I appreciate each of you two gentlemen being here, and I will try to participate some, Mr. Chairman, but as you know, we have the FCC Commission downstairs simultaneously. So some of us have to try to be two places at one time, which is——

Mr. STEARNS. I appreciate your——

Mr. BARTON. Thank you, Mr. Chairman.

Mr. STEARNS [continuing]. Staying here.

Mr. BARTON. Thank our witnesses.

Mr. STEARNS. Thank you. The gentlelady, Ms. DeGette, is recognized.

OPENING STATEMENT OF HON. DIANA DEGETTE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF COLORADO

Ms. DEGETTE. Thank you very much, Mr. Chairman.

Last year President Obama signed into law landmark health reform legislation to improve health care access for millions of American families and small business owners, prohibit abusive insurance practices, and to reduce our Nation's deficit. Today's hearing is focused on implementation of the law's prohibition on annual and lifetime limits on health care coverage, an important consumer protection that prevents people with chronic or catastrophic illnesses from losing their coverage after they reach an arbitrary cap on expenses established by their insurer.

This is a provision that is already protecting consumers and will protect millions more individuals with chronic and expensive diseases like diabetes, and it is widely supported.

Mr. Chairman, I would like to insert into the record letters from the American Cancer Society and the American Heart Association about the importance of this provision.

Mr. STEARNS. By unanimous consent, so ordered.

Ms. DEGETTE. Thank you.

[The information appears at the conclusion of the hearing.]

Ms. DEGETTE. We are transitioning to this new policy, and millions of Americans with insurance are benefiting immediately, but a small percentage of insured Americans are in plans that will need waivers from these provisions until the Health Care Bill takes effect in its entirety in 2014. The law allows for those waivers which are the subject of today's hearing.

And, Mr. Chairman, you noted that two-and-a-half million people are subject to these waivers, but I would point out that is two-and-a-half million out of 164 million, which is less than 2 percent of the market.

The Center for Consumer Information and Insurance Oversight is responsible for implementing the consumer protections against insurers' annual limits. CCL announced that that process in a public role last summer and issued further guidance based on input from affected entities. CCO is granting waivers to this provision in cases where insurance providers show that compliance, "would result in a significant decrease in access to benefits," or, "would significantly increase premiums."

Republicans on this committee and elsewhere have made a number of allegations about this agency and its process for implementing the ban on annual limits. Senator Kyl and others have made statements suggesting that CCO may be providing waivers to political allies such as unions, and in fact, Mr. Chairman, you, yourself, have suggested that the volume of waivers granted indicates flaws in the Health Reform Law.

But the information and documents that the committee has received tell a different story. They show that the Administration is implementing the law in a fair, transparent, flexible, and efficient way. The Administration data shows over 90 percent of applicants who sought waivers—I am working on a cold. I will try not to sit too close. Ninety percent of the applicants who sought waivers for their plans received HHS approval. The average completed applica-

tion was approved by HHS within 13 days with over one-third approved in under 1 week.

Now, this is exactly the kind of governmental efficiency that everybody across the aisle should be standing up and applauding. We reviewed e-mails that the companies requesting waivers exchanged with CMS. Here is—formerly HCFA, by the way. Here is what a few of the companies had to say.

"I want to sincerely thank HHS for working so hard to process and approve our waiver application." "Thanks to you and all the staff at CCIIO for your consideration and effort." "We just want to thank you for the prompt and courteous service you gave these applications."

Mr. Chairman, these don't sound like businesses that are overburdened and fearful of government regulation. They sound like satisfied clients.

As for the claim of bias towards unions, the data received by the committee shows that the plans that serve union employees were almost five times more likely than average to be denied waivers. If the Administration is somehow biased in favor of unions, that frankly is a pretty strange way of showing it.

In the subcommittee's first hearing we learned from the Administration how the President's executive order on regulations has instructed agencies to implement laws in a manner that protects consumers while imposing the least burden possible on business. The implementation of the Annual Limits Provision provides a case in point in how the Administration is acting on those principles.

The plans that are receiving waivers need improvement. They are often so-called mini-med plans that offer limited benefits. In 2014, thanks to the new Health Care Bill almost all Americans will get better coverage than this, but for now these limited plans are the best coverage available for many of these workers, and the waiver process accommodates business and insurers so that consumers can retain access to these plans in bridge years.

Based on clear regulation and guidance CCO evaluates waiver requests on clearly-explained criteria such as premium changes in percentage terms and dollar terms, the number and type of benefits affected by the annual limits, and the number of enrollees under the plan seeking the waivers. Approvals once granted are rapidly posted on the HHS Web site. The overall process for implementing this important health reform provision and the waiver provisions within it embodies the principles that all of us on this committee seek in the regulatory process.

I look forward to hearing from our two witnesses today. I hope we can talk about facts and why this is necessary and why it is working, and I yield back.

[The prepared statement of Ms. DeGette follows:]

PREPARED STATEMENT OF HON. DIANA DEGETTE

Last year, President Obama signed into law landmark health reform legislation to improve health care access for millions of American families and small business owners, prohibit abusive insurance practices, and reduce our nation's deficit. Today's hearing is focused on implementation of the law's prohibition on annual and lifetime limits on health care coverage, an important consumer protection that prevents people with chronic or catastrophic illnesses from losing their coverage after they reach an arbitrary cap on expenses established by their insurer.

This is a provision that is already protecting consumers, and will protect millions more—individuals with chronic and expensive diseases like diabetes.

We are transitioning to this new policy, and millions of Americans with insurance are benefitting immediately. But a small percentage of insured Americans are in plans that will need waivers from these provisions until the health care bill takes effect in its entirety in 2014. The law allows for these waivers, which are the subject of today's hearing.

The Center for Consumer Information and Insurance Oversight, or CCIIO, is responsible for implementing the consumer protections against insurer's annual limits. CCIIO announced that process in a public rule last summer and issued further guidance based on input from affected entities.

CCIIO is granting waivers to this provision in cases where insurance providers show that compliance "would result in a significant decrease in access to benefits" or "would significantly increase premiums."

Republicans on this committee and elsewhere have made a number of allegations about CCIIO and its process for implementing the ban on annual limits. Senator Kyl and others have made statements suggesting CCIIO may be providing waivers to "political allies" such as unions. The subcommittee chairman has suggested that the volume of waivers granted indicates flaws in the health reform law.

But the information and documents the Committee has received tell a different story. They show that the Administration is implementing the law in a fair, transparent, flexible, and efficient way.

The Administration data show that over 90% of applicants who sought waivers for their plans received HHS approval. The average completed application was approved by HHS within 13 days—with over one third approved in under one week. This is exactly the kind of government efficiency that my friends across the aisle ought to be standing up and applauding.

We reviewed emails that the companies requesting waivers exchanged with CMS. Here's what a few of the companies had to say: "I want to sincerely thank HHS.for working so hard to process and approve our waiver application." "Thanks you and all the staff at OCIIO for your consideration and effort." "We just want to thank you for the prompt and courteous service you gave these applications." Mr. Chairman, these don't sound like businesses that are overburdened and fearful of government regulation - they sound like satisfied clients.

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In the Subcommittee's first hearing, we learned from the Administration how the President's Executive Order on regulations has instructed agencies to implement laws in a manner that protects consumers while imposing the least burden possible on business. The implementation of the annual limits provision provides a case in point of how the Administration is acting on these principles.

The plans that are receiving waivers need improvement. They are often so-called mini-med plans that offer limited benefits. In 2014, thanks to the health care bill, almost all Americans will get better coverage. But for now, these limited plans are the best coverage available for many workers—and the waiver process accommodates business and insurers so that consumers can retain access to these plans in the bridge years.

Based on clear regulation and guidance, CCIIO evaluates waiver requests on clearly explained criteria, such as premium changes in percentage terms and dollar terms, the number and type of benefits affected by the annual limits, and the number of enrollees under the plan seeking the waivers. Approvals, once granted, are rapidly posted on the HHS Web site.

The overall process for implementing this important health reform provision, and the waiver provisions within it, embodies the principles that Republicans and Democrats alike seek in the regulatory process. It is fair. It is efficient. It is transparent. And it is allowing over two million Americans to keep their existing health insurance coverage.

I look forward to hearing from our witnesses. I hope we can discuss the facts about CCIIO and its waiver process today rather than propagating myths about healthcare reform's implementation.

Mr. STEARNS. I thank the ranking member, and let me open up by saying I ask unanimous consent that the contents of the document binder be introduced into the record subject to any necessary redactions by the staff.

Without objection, the documents will be entered into the record.

[The information appears at the conclusion of the hearing.]

Mr. STEARNS. And let me address the two of you before we start your opening statement. You are aware that the committee is holding an investigative hearing and when doing so has had the practice of taking testimony under oath. Do you have any objection to testifying under oath?

OK. The Chair also advises both of you that under the rules of the House and the rules of the Committee you are entitled to be advised by counsel. Do you desire to be advised by counsel during your testimony today?

OK.

[Witnesses sworn.]

Mr. STEARNS. You are now under oath and subject to the penalties set forth in Title XVIII, Section 1001, of the United States Code. If you would be so kind now as to give us, each of you, your 5-minute summary of your opening statement.

Thank you. Mr. Larsen.

TESTIMONY OF STEVE LARSEN, DEPUTY ADMINISTRATOR AND DIRECTOR, CENTER FOR CONSUMER INFORMATION AND INSURANCE OVERSIGHT, CENTERS FOR MEDICARE AND MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES; AND JAY ANGOFF, SENIOR ADVISOR, OFFICE OF THE SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES

TESTIMONY OF STEVE LARSEN

Mr. LARSEN. Mr. Chairman——

Mr. STEARNS. I think you need to bring the mike a little closer.

Mr. LARSEN. Can you hear me now?

Mr. STEARNS. We can hear you good. Thank you.

Mr. LARSEN. OK.

Mr. STEARNS. Thank you, Mr. Larsen.

Mr. LARSEN. My full testimony has been submitted for the record. I serve as Director of the Center for Consumer Information and Insurance Oversight within CMS. Since taking on this role I have been involved in implementing many of the provisions of the Affordable Care Act, ACA, including overseeing private health insurance reforms, establishing the health insurance exchanges, and ensuring that consumers have access to information about their rights and coverage options.

Prior to becoming the Director of CCIIO I served as the Director of the Office of Oversight within CCIIO, which works with the States to implement the new insurance market rules, including the new restrictions on annual dollar limits on health insurance benefits.

As Director of CCIIO I am committed to improving the health insurance system so that it works for consumers now and in 2014, when consumers will have more quality health care options. I am working to make sure that Americans who have insurance today can keep that coverage as we transition to the improved system in 2014.

As part of improving the current health insurance system, the Affordable Care Act ensures that consumers are provided meaningful and reliable coverage for their premium dollars by phasing in restrictions on annual limits and insurance policies between now and 2014. This is one of the subjects that you have asked me to discuss today.

Right now over 160 million Americans get their health insurance through an employer; however, not all coverage offered by employers is the same. A very small percentage of employees are offered policies with low annual limits, caps on the amounts of benefits that are provided under the policy in a year. Often, these policies are offered by employers who hire lower-wage, part-time, or seasonal workers.

While having such limited coverage may be better than no coverage at all, this coverage, unfortunately, can fail those that need it most. These policies can have high deductibles and annual dollar caps as low as $2,500. Some are better, with $5,000 or even $25,000 in coverage, but in the case of a serious illness or accident, the coverage can be inadequate.

In 2014, consumers will be able to purchase fuller health insurance coverage in State-based exchanges, competitive marketplaces, where consumers and small businesses can shop for private coverage and will have the market power similar to large employers. Small businesses with fewer than 25 employees will be eligible for tax credits to help pay for their employees' coverage, and small businesses with up to 100 employees in a State will be able to join the shop exchanges.

But in the time between now and 2014, we need to maintain the coverage that employees have until better options are available for them. For policies with low annual limits, immediate compliance with the new Affordable Care Act protections that restrict annual limits could cause disruption of this coverage.

The Affordable Care Act directs the Secretary to implement the restrictions on annual limits in a manner that ensures continued access to coverage. This is accomplished by phasing in the annual restrictions for most policies and for this year we established a waiver process for the small percentage of policies that are substantially below the restricted annual limits set in the regulation.

These waivers only apply to this single provision of the ACA. Insurance companies and employers that receive waivers must comply with all other parts of the Affordable Care Act. Our goal has been to implement the law but to do so in a manner consistent with the statute and in a way that preserves employees' coverage options until 2014.

All employers and insurers that offer limited benefit plans may apply for a waiver if they demonstrate that there will be a significant increase in premiums or a significant decrease in access to coverage without the waiver. Applying for a waiver is simple, a basic process that CCIIO clearly published on our Web site. We administer the process fairly without regard to the type of the applicant or size of business. We published our standards for reviewing applications in the regulations implementing the law and again in the bulletins implementing the regulations.

The vast majority of waivers were granted to health plans that are employer based, more than 95 percent. Of the waivers approved, 47 percent were to self-insured employer plans, 26 to HRAs, and 21 percent to Taft-Hartley plans, which are multi-employer plans governed by collective bargaining agreements, and 3 percent to issuers, insurance companies who provide these policies.

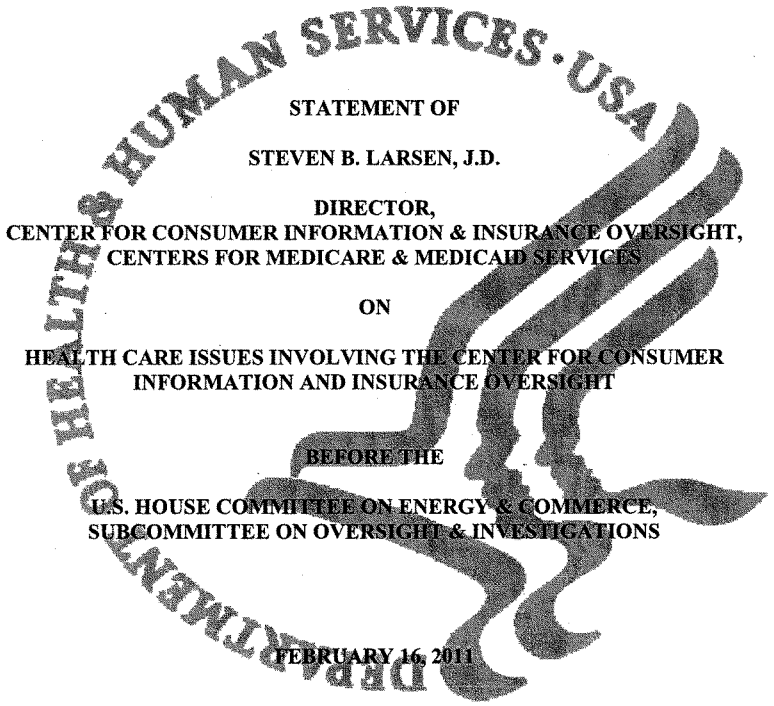
The limited benefit plans for which waivers are allowed cover an extremely small portion of people who have employer-sponsored health plans. Since setting up the waiver program CCIIO has granted waivers to plans covering approximately 2.4 million people out of the 150 million or so who have employer-sponsored health coverage. This is less than 2 percent of all covered people in the private insurance market.

The vast majority of employers who applied for a waiver reacted to the application process positively. We have been open to feedback from applicants, and based on their input we improved the application process so that it is timely and responsive to their needs. We view our work as a partnership between the Federal Government, States, employers, and consumers who are constantly striving to meet—and we are constantly striving to meet—our stakeholders' needs.

As we work toward 2014, we are implementing the ACA carefully and responsibly so that coverage is maintained and the market is not disrupted.

Thank you for the privilege of appearing before you, and I would be happy to answer any questions.

[The prepared statement of Mr. Larsen follows:]



STATEMENT OF

STEVEN B. LARSEN, J.D.

DIRECTOR,
CENTER FOR CONSUMER INFORMATION & INSURANCE OVERSIGHT,
CENTERS FOR MEDICARE & MEDICAID SERVICES

ON

HEALTH CARE ISSUES INVOLVING THE CENTER FOR CONSUMER INFORMATION AND INSURANCE OVERSIGHT

BEFORE THE

U.S. HOUSE COMMITTEE ON ENERGY & COMMERCE,
SUBCOMMITTEE ON OVERSIGHT & INVESTIGATIONS

FEBRUARY 16, 2011

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

House Committee on Energy & Commerce
Subcommittee on Oversight & Investigations

Hearing on "Health Care Issues Involving the Center for Consumer Information and Insurance Oversight"

February 16, 2011

Chairman Stearns, Ranking Member DeGette, and Members of the Subcommittee, thank you for the opportunity to discuss the Department of Health and Human Services' work implementing the Affordable Care Act. I serve as the Director of the Center for Consumer Information & Insurance Oversight (CCIIO) within the Centers for Medicare & Medicaid Services. Since taking on this role, I have been involved in CCIIO's implementation of many of the provisions of the Affordable Care Act, including oversight of private health insurance reforms, assisting States to implement Health Insurance Exchanges (Exchanges), and ensuring that consumers have access to information about their rights and coverage options. Prior to becoming the Director of CCIIO, I served as the Director of the Office of Oversight within CCIIO, which is charged with working with the States to ensure compliance with the new insurance market rules, such as the prohibitions on rescissions and pre-existing condition exclusions for children, as well as ensuring consumer value for premium payments through the medical loss ratio standards and the enforcement of the new restrictions on annual dollar limits on benefits.

As a former State Insurance Commissioner, I understand the key role that States play in the regulation of insurance and insurance markets. I have seen first-hand the importance of holding insurance companies accountable, and understand the need to make quality, affordable coverage more accessible to all health care consumers. Then again, I have also served as an executive in a for-profit, publicly-traded managed care company, and understand the need for reasonable regulations as well as competitive and robust markets. The Affordable Care Act appropriately balances these objectives.

By 2014, the Affordable Care Act helps create new competitive private health insurance markets, called Exchanges. These Exchanges will provide individuals and small businesses with

a "one-stop" shop to find and compare affordable, quality health insurance options. Through these State-based Exchanges, Americans will no longer be on their own in trying to find comprehensive, quality, affordable health coverage. Exchanges will bring new transparency to the market so that consumers will be able to compare plans based on price and quality. By increasing competition between insurance companies and allowing individuals and small businesses to band together to purchase insurance, Exchanges will lower health care costs.

Today, millions of Americans are already benefiting from the Affordable Care Act. Many parents across the country are able to protect their children by allowing their children to stay on their insurance until their children are 26 years old. We estimate that more than 1.2 million young adults will be able to maintain insurance coverage through their parents' health plans because of this new policy. This is an important protection for these young adults and a huge relief for their parents.

Potentially more than 41 million Americans will benefit from the preventive services provision of the Affordable Care Act, which requires that important early detection services like mammograms and colonoscopies be available to Americans in new plans without expensive co-pays or deductibles. Consumers in new plans who face denied claims have the right to appeal such decisions made by their health plans to deny or limit coverage. They can get an internal review by their insurer, and a review by an outside, independent decision-maker. Insurers are no longer permitted to rescind insurance policies simply because a consumer made an inadvertent error on a form.

Consumers can also use an important new tool to gain access to an unprecedented amount of information about insurance options and public programs available to them by zip code. In eight months, www.HealthCare.gov has had more than 4 million visitors and the number of insurance options listed there continues to grow rapidly. Visitors can get information in plain English – and Spanish – about the coverage options available to them, their protections, and their rights as health care consumers.

States play a crucial role in the implementation of the Affordable Care Act. Since enactment, we have worked actively with the Governors, insurance commissioners, Medicaid directors, and other stakeholders to implement programs that are helping consumers and businesses with coverage. It has been our priority to work collaboratively with our State partners as the provisions of the Affordable Care Act go into effect.

Rising insurance costs have made it difficult for American employers to provide quality, affordable coverage for their workers and retirees while also remaining competitive in the global economy. Many Americans who retire before they are eligible for Medicare and without employer-sponsored insurance see their life savings disappear because of the high cost of insurance in the individual market. Millions more see their insurance disappear, leaving them vulnerable to high costs and poor quality care. The Early Retiree Reinsurance Program (ERRP) provides much-needed financial relief for employers so early retirees and their families can continue to have quality, affordable insurance. More than 5,000 employers – including many State and local governments – have been accepted into the program from all 50 states and the District of Columbia. The ERRP serves as one bridge to the new Exchanges that will become available in 2014.

The Pre-existing Condition Insurance Plan (PCIP) program is another bridge to 2014, when all Americans, regardless of health status, will have access to affordable coverage. The PCIP provides a lifeline to uninsured Americans who private insurers have refused to insure because of a pre-existing condition to receive the health insurance without denials, limitation on benefits, or higher premiums because of their condition. Thousands of Americans who were locked out of accessible private insurance coverage before the passage of the law now have this valuable and needed coverage. I'm pleased that enrollment has jumped 50 percent in the last few months, but we clearly have a ways to go. The Department is actively working with States, consumer groups, chronic disease organizations, health care providers, social workers, other Federal agencies, and the insurance industry to promote the plan, including holding meetings with State officials, consumer groups, and others.

For Americans who can access insurance in the individual and small group markets, the Affordable Care Act protects them from unreasonable rate increases. CCIIO is helping States improve their rate review processes. In 2010, we provided the first round of what will eventually be $250 million in funding to strengthen States' ability to review and reject unreasonable rate hikes. HHS is committed to working with States, who are the primary regulator of insurance rates and solvency.

Finally, the Affordable Care Act builds on current efforts by States to hold insurance companies accountable for the way they use consumer premiums. Starting this year, insurers must spend at least 80 or 85 percent of premium dollars, depending on the market, on health care and quality improvement efforts instead of CEO bonuses, profits, or marketing. And those that do not meet this standard will be required to provide rebates to their customers. This provision ensures consumers receive value for their premium dollars and encourages insurers to invest in the health of their policyholders. There are signs that this provision has already helped moderate premium increases.

The Bridge to 2014

As Director of CCIIO, I am committed to continued improvement of the health insurance system so that it works for consumers both now and with the additional reforms that start in 2014. It is essential that we make sure that Americans who have insurance today – even if that insurance is highly limited – can keep that coverage until reforms take effect to increase their ability to choose among comprehensive, affordable insurance options in 2014.

As part of our package of consumer protections called the Patient's Bill of Rights, we began implementing the Affordable Care Act's phase out of limited benefit insurance products – a subject area that you have asked me to discuss. When consumers are covered under health plans with limited benefits, consumers do not always have access to coverage when they need it. In some cases, policies have "lifetime" dollar limits on benefits, and in some cases, insurers have "annual" limits or dollar-amount caps on what they will pay for benefits during a single year for the benefits that they cover. In 2009, over 100 million Americans were in health insurance plans

with a lifetime limit, and roughly 18 million Americans were enrolled in a plan with an annual limit.

The Affordable Care Act prohibits lifetime limits in all health insurance plans starting in new plan years on or after September 23, 2010. It also provides that, as of January 1, 2014, no group health plan or individual market plan that is not a "grandfathered" plan may have annual limits on coverage. However, Congress recognized that there should be a transition period between now and 2014, when the Exchanges will be up and running, during which annual limits would be phased out. Section 2711 of the Public Health Service Act provides that group health plans and issuers may continue to impose a "restricted" annual limit with respect to essential health benefits until the consumer protections take effect in 2014. More importantly, the statute directs the Secretary to define "restricted annual limit" during the interim period in a way that will "ensure that access to needed services is made available with a minimal impact on premiums." This statutory directive recognizes that for some health plans, an immediate transition to high or no annual limits could significantly raise premiums or reduce coverage with adverse consequences. As such, the Secretary must address this concern in implementing the provision during the transition years between passage of the Affordable Care Act and the availability of new quality, affordable options in 2014.

In June of last year, we issued regulations providing that the "restricted annual limit" is $750,000 for group and non-grandfathered individual plans with plan and policy years starting between September 23, 2010 and September 22, 2011; in other words, plans must provide at least $750,000 in coverage for essential benefits such as hospital, physician and pharmacy benefits. The limit will be $1.25 million for plan and policy years starting between September 23, 2011 and September 22, 2012, and $2 million for plan and policy years starting between September 23, 2012 and December 31, 2013. The rising limits will increasingly ensure that consumers have coverage when they really need it.

Most group health plans either already exceeded the new restricted annual limits or could comply with the new restricted annual limits with a negligible or minimal impact on premiums

or coverage. However, a very small percentage of the market provides coverage well below the new annual limits – in some cases as low as $2,500 or $5,000 in annual dollar limits on benefits. It is this small percentage of policies in particular that, without an accommodation, would sustain more than a "minimal" impact on premiums or coverage if they were to provide coverage at or above the annual limits provided for in the regulation.

To be sure, limited benefit plans are not adequate coverage and can leave consumers with unexpected medical bills in the event of hospitalization or chronic disease. We are committed to allowing Americans to keep the coverage they have and preventing disruptions in coverage. As a result, pursuant to the statutory language, CCIIO established a process where those plans with annual limits below $750,000 could apply for a one-year waiver from the law. The waiver process, which is grounded in our regulation and fleshed out in subsequent guidance, allows employers and insurers to continue offering limited coverage if they can show that complying with the regulation would cause their enrollees to experience a significant increase in premiums or decrease in access to benefits.

The waiver process uses a simple, basic process that is administered fairly without regard to the type of applicant or size of business, with the goal of minimizing market disruption and maintaining coverage. Guidance on how to apply for a waiver was posted on our website on September 3, 2010. Applicants must submit: 1) the terms of the plan; 2) the number of enrollees; 3) a description of the annual limits; 4) a narrative describing how compliance would lead to a significant increase in premiums or a significant decrease in access to benefits; and 5) an attestation of the facts of the application by the CEO or plan administrator.

We have posted additional guidance detailing the criteria CCIIO uses to determine if the premium increase or access decrease would be significant. Further guidance also lays out specific disclosure requirements that approved applicants must meet. Approved applicants must notify enrollees and potential enrollees of the plan's annual limits and the fact that the plan does not meet the standards of most plans covered by the Affordable Care Act. This notice is to

ensure that consumers are aware that their coverage may not be available in the event of a catastrophic event or chronic disease.

The annual limit waiver process has been carried out in a way that reflects a commitment to transparency and responsible implementation. CCIIO regularly posts a list of approved annual limit waivers. The list includes the name of the company, the date their application was received, the plan effective date, the number of enrollees covered, the date the application was completed, and the date the waiver was approved.

After we initiated the process in September, applications were received at a relatively steady rate. However, we experienced an increase in applications in December, due to the fact that employers and insurers must submit their applications 30 days before the start of their plan year. Many plan years begin on January 1; for that reason we received a large number of applications at the beginning of December. CCIIO worked very hard to ensure that we could process those applications and make timely decisions with respect to these applicants.

As of February 1, 2011, CCIIO has approved 90 percent of waiver applications from employers, insurers, and other applicants. The vast majority of waivers, more than 95 percent, were granted to health plans that are job-related. These include self-insured employer health plans, health reimbursement arrangements, collectively-bargained multiemployer plans, and health plans sold by issuers to fully-insured employers.

It is important to note that these limited benefit plans cover an extremely small portion of people covered by employer-sponsored health plans in the United States. Since setting up this program, CCIIO has granted waivers to plans covering approximately 2.4 million people, out of the 160 million people who have employer-sponsored health coverage.[1] This is slightly more than 1 percent of all covered lives in the private insurance market.

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[1] Kaiser Family Foundation - Kaiser's "Employer Health Benefits 2010 Annual Survey," September 2010 (http://ehbs.kff.org/).

Moving Forward

Until now, very little data were available about these limited benefit plans. We are now analyzing the data we have received and have begun determining what approach we should take for plan years beginning September 23, 2011 and beyond to 2014. In the future, we will proceed in a manner that minimizes market disruption and ensures Americans have health coverage. The overriding purpose of this waiver program is to ensure that Americans do not lose their health coverage before better health insurance options become available in 2014.

As we lay the groundwork for 2014, it is our intention to continue implementing vital consumer protections while offering enough flexibility to ensure that the market is not disrupted. We look forward to 2014 when Americans will have access to more affordable, comprehensive health insurance plans without annual limits that cap their benefits. When the insurance market reforms in the Affordable Care Act are fully implemented, limited benefit plans will be a thing of the past.

In the meantime, I look forward to continuing to work on our bridge toward 2014, strengthening CCIIO's partnership with Congress, the States, consumers, and other stakeholders across the country. Thank you for the opportunity to discuss the work that CCIIO has been doing to implement the Affordable Care Act.

Mr. STEARNS. Thank you, Mr. Larsen. Mr. Angoff.

TESTIMONY OF JAY ANGOFF

Mr. ANGOFF. Mr. Chairman, Madam Ranking Member——

Mr. STEARNS. I think you have to pull it a little closer, and you got the mike on. Right?

Mr. ANGOFF. Yes, sir.

Mr. STEARNS. OK.

Mr. ANGOFF. Yes, sir.

Mr. STEARNS. OK. There you go.

Mr. ANGOFF. Mr. Chairman, Madam Ranking Member, members of the committee, I appreciate the opportunity to testify here today to discuss the Department of Health and Human Services work to implement the Affordable Care Act.

I currently serve as Senior Advisor to HHS Secretary Kathleen Sebelius. I also served as the Director of the Office of Consumer Information and Insurance Oversight, known as OCIIO, during its 9 months as an independent division of HHS until its recent merger into the Centers for Medicare & Medicaid Services, or CMS.

OCIIO's accomplishments during that period include the following: during its first 3 months, the establishment of two major programs, the Pre-Existing Condition Insurance Plan and the Early Retiree Reinsurance Program, and the development and implementation of our new Web site, healthcare.gov. During its first 6 months, the promulgation of regulations implementing the insurance market reforms of the Affordable Care Act. Among other things, those rules now enable young adults to stay on their parents' policies until age 26; they prohibit insurers from discriminating against those under 19 with pre-existing conditions or from canceling coverage; and, they eliminate lifetime limits on coverage.

During its first 7 months, we implemented three major grant programs to States: rate review grants, which are enabling States to establish or strengthen their capacity to review and, where appropriate, to disapprove proposed health insurance rate increases; exchange planning grants, which are enabling States to begin the work necessary for establishing their exchanges; and, consumer assistance grants, which are enabling States to develop or strengthen existing programs enabling consumers to obtain insurance and to more effectively deal with their insurance companies.

By the end of 2010, the promulgation of the medical loss ratio rule and the rate review rule. Under our medical loss ratio rule, insurers in the individual and small group markets must spend at least 80 cents of the premium dollar on health care costs and quality improvement activities and no more than 20 cents of the premium dollar on administrative expenses. Insurers that don't meet this standard must either reduce their premiums or issue rebates to their policyholders.

Under the rate review rule, insurers must publicly justify proposed increases exceeding 10 percent, which are then reviewed for reasonableness by the State, or if the State does not review rates, by HHS.

These reforms, Mr. Chairman, are already having a positive effect in the marketplace. For example, the Trade Press is now reporting that, as a result of the medical loss ratio rule, insurance

companies are streamlining their expense structures, moderating their increases, and improving their benefit packages. And more than 1.2 million adults can now remain on their parents' health insurance plans because of our dependent coverage until 26 rule, part of what we call the Patients' Bill of Rights.

Most importantly, individuals are being helped. People like Kayla Holmstrom, who was in a motorcycle accident when she was 9 and has a chronic bone infection but who is studying to become a nurse at South Dakota State University and can now stay on her parents' policy until she is 26. And people like James Howard from Katy, Texas, who has brain cancer and was canceled by his insurance company but was able to get coverage through the PCIP Program that may well have saved his life.

While the American health system has always set examples of shining successes and good care if you can get it, the system has failed other citizens for too long. People with pre-existing conditions have been locked out of coverage by insurance companies. After long careers we have told Americans to keep working until they reach the age of 65 because without a job as a practical matter they can't get health insurance because insurance companies surcharge them both based on their age and based on health status. We have allowed insurance companies to select out risks and to segment the market, to cherrypick the healthy and to exclude the less healthy.

The Affordable Care Act, Mr. Chairman, is changing this. It is building a more equitable health care system which empowers consumers, establishes new consumer protections under the law, and gives consumers new information so they can make the best choices for themselves and their families. It is putting consumers back in control of their health care coverage by giving them an unprecedented amount of clear information on the health care market, protections that bolster the rights of consumers in dealing with insurance companies, and an innovative new marketplace.

Most importantly, beginning in 2014, the Affordable Care Act will allow individuals, families, and small business owners to pool their purchasing power through new State-based exchanges in which insurers will compete based on price and quality, and people will be able to make apples-to-apples comparisons.

In conclusion, Mr. Chairman, I have every confidence that the new Center for Consumer Information and Insurance Oversight within CMS will continue the vital work of the Office of Consumer Information and Insurance Oversight, and I look forward to the results it will produce. Thank you for the opportunity to appear before you today, and I would be happy to answer any questions you or the members of the committee may have.

Mr. STEARNS. I thank you, and I thank both of you for your opening statements. I will open with my series of questions.

The ranking member indicated the efficiency of the Obamacare and how the people who got the waivers sent thank you letters back. I would submit that is like saying to a person who won the lottery, are you happy with the efficiency of the lottery that you won? They would explicitly say, yes, and be glad to send a lot of thank you letters back.

But having said that, Mr. Larsen, I just looked through your resume, and I noticed that Governor O'Malley appointed you as a member of the Maryland Health Service Cost Review Commission that actually sets the rates in the State. Is that true?

Mr. LARSEN. That is correct.

Mr. STEARNS. Are you still on that board?

Mr. LARSEN. No, I am not.

Mr. STEARNS. When did you leave that board?

Mr. LARSEN. When I started with the Federal Government.

Mr. STEARNS. OK. So I was a little concerned. I wasn't sure——

Mr. LARSEN. No, I am not.

Mr. STEARNS. OK. Let me move to this, Mr. Larsen, to this area of waivers. When we ask questions, we each have 5 minutes, so if you could just answer yes and no, and if we reach an impasse here, I will certainly give you a little time, but I am hopeful that you can answer most of the questions yes or no.

I have been informed that you folks are considering or have given a waiver to the entire State of Florida. Is this true?

Mr. LARSEN. We established a process that permits States——

Mr. STEARNS. No, not——

Mr. LARSEN [continuing]. To apply.

Mr. STEARNS. Has the State of Florida received a waiver? Yes or no?

Mr. LARSEN. Yes.

Mr. STEARNS. OK.

Mr. LARSEN. Well, may I clarify?

Mr. STEARNS. Oh, sure.

Mr. LARSEN. The process that we set up for the States essentially allows the States to apply on behalf of——

Mr. STEARNS. I understand.

Mr. LARSEN [continuing]. The issuer.

Mr. STEARNS. Just in curiosity, did New York State get a waiver, the entire State?

Mr. LARSEN. Not to my knowledge.

Mr. STEARNS. So only Florida. Can you list to me all the States that got a complete waiver?

Mr. LARSEN. Yes. I can confirm, I think it is Ohio, Tennessee, Florida, and there may be one more.

Mr. STEARNS. And New York City being considered? New York?

Mr. LARSEN. I don't believe New York applied, but I can double check.

Mr. STEARNS. Can I ask you this question? Has New York applied?

Mr. LARSEN. The State of New York?

Mr. STEARNS. State of New York. Our understanding they have applied.

Mr. LARSEN. Oh, they have applied.

Mr. STEARNS. OK. New York——

Mr. LARSEN. But we haven't made a decision.

Mr. STEARNS. Oh. I understand, but New York has applied. OK. So the question is, obviously, why would Florida need a waiver, why would New York need a waiver, and all these other States you are giving complete current blocks for these States? You know, I think for many of us under the 10th Amendment we believe the

States should be able to come up with their own health care and perhaps handle their health insurance market better than the government.

Simply tell me why would the State of Florida, perhaps New York, and why are these people, why do you think Florida needs a waiver, the entire State?

Mr. LARSEN. Sure. Sure. So the waiver program is set up to ensure that that small percentage of employees under these small benefit policies can continue coverage. So in a small number of States there are State programs that authorize or require these limited-benefit policies. And so we made the determination to allow the States to apply on behalf of the issuers in their State.

Mr. STEARNS. Now, the big question is, OK, all these States, you are 1 year into this, and you are recognizing large States and small States, you are giving waivers, what happens in 2014? In fact, these waivers are only for 1 year, aren't they?

Mr. LARSEN. That is correct.

Mr. STEARNS. OK. So then all these States will have to come back in the year 2013?

Mr. LARSEN. We made the decision for a 1-year waiver in order to gather better information about these types of policies——

Mr. STEARNS. If they needed a waiver——

Mr. LARSEN [continuing]. And we will determine——

Mr. STEARNS [continuing]. In 2011, won't they need a waiver in 2012, and '13, so you will go back and give a waiver——

Mr. LARSEN. Well——

Mr. STEARNS [continuing]. Presumably again?

Mr. LARSEN [continuing]. I was trying to answer. We haven't made a determination about——

Mr. STEARNS. OK.

Mr. LARSEN [continuing]. What happens. These policies and these waivers represent a glide path, if you will, a transition to 2014, so we set them up to do the first year, to gather data, and then determine what the next steps would be between now and 2014.

Mr. STEARNS. Would it be fair to say then the year 2014, none of these people will get waivers, or will you consider giving waivers ever after the exchange is in place?

Mr. LARSEN. In 2014, consumers will have access to full coverage, not the types of limited-benefit policies that they have today, so in 2014, there won't be limited-benefit policies to be waived from. Consumers will have access to the full range of benefits.

Mr. STEARNS. I guess the basic question was McDonald's is a large corporation that got a waiver. Is that true?

Mr. LARSEN. The carrier that provides coverage to McDonald's, yes.

Mr. STEARNS. Got a waiver. And didn't Waffle House get a waiver? I don't know. I think the staff is saying yes.

Mr. LARSEN. OK.

Mr. STEARNS. So I assume—I would think you should know these.

Mr. LARSEN. Well, I haven't memorized the list of——

Mr. STEARNS. Well, some of the big ones like McDonald's and so forth I would think you would know.

Mr. LARSEN. Well, I do know about McDonald's.

Mr. STEARNS. Well, let me ask you. Did Denny's get one?

Mr. LARSEN. I would have to look at the list.

Mr. STEARNS. OK. How many private corporations, do you know, just off hand? A dozen or 100 or——

Mr. LARSEN. Well——

Mr. STEARNS [continuing]. Because you got 915 that got waivers, and you said you denied 61, so out of that 915 you gave me a percent. How—so I guess some of the large corporations got these waivers.

Mr. LARSEN. When we think about the waivers, we think about the type of employers and issuers that have applied. So self-insured employers, for example——

Mr. STEARNS. OK.

Mr. LARSEN [continuing]. Represent 49 percent of the applicants, we have——

Mr. STEARNS. I can't miss this question. Where in the Health Care Bill does the word waiver—can you give me the specific line where it says waivers will be granted to health care providers in the Health Care Bill? Where do you get your——

Mr. LARSEN. Sure. The annual limits provision of the Affordable Care Act specifically directs the Secretary to implement this provision in a way that ensures——

Mr. STEARNS. But the word waiver is not in there.

Mr. LARSEN. I don't know whether the word——

Mr. STEARNS. We couldn't find it anywhere. So you are saying your interpretation is implying that your definition of waiver is through that interpretation of the language?

Mr. LARSEN. To comply with the requirements of the ACA.

Mr. STEARNS. OK. My time is expired.

The ranking member, Ms. DeGette.

Ms. DEGETTE. Thank you very much. Mr. Larsen, when you say that a waiver was given to Florida, that doesn't mean every insured person in Florida was given a waiver. Correct?

Mr. LARSEN. That is correct.

Ms. DEGETTE. I mean, basically, what it is is waivers were given to some States that had State laws that would violate the new federal law, and they were given specifically for these individual market plans within those States. Correct?

Mr. LARSEN. Sure. States that have—yes.

Ms. DEGETTE. So how many States did that involve?

Mr. LARSEN. I think we have approved four States to date.

Ms. DEGETTE. Four States. And those States were approved based on their State laws that might have affected those individual plan markets. Correct?

Mr. LARSEN. Even the applicants in the States had to still satisfy the regulatory standard for getting a waiver.

Ms. DEGETTE. So there was no political—someone from the White House didn't call you folks up and say, approve these States because it is going to be important in the election next year.

Mr. LARSEN. No, and we applied the standards consistently across all applicants——

Ms. DEGETTE. Thank you.

Mr. LARSEN [continuing]. Whether it was State applicant or——

Ms. DEGETTE. Now, Mr. Larsen, some have alleged that the process through which waivers to annual limits are granted lacks transparency, so I want you to walk us through the process by which your agency makes waiver decisions. Can you briefly describe the factors that you take into account when evaluating waiver requests?

Mr. LARSEN. Yes, and the standards were set out in the regulation that we issued subsequent to the passage of the ACA. The standard——

Ms. DEGETTE. Can you briefly describe those standards?

Mr. LARSEN. Sure. So the regulatory standard requires that an applicant show that there either be a significant increase in premiums or significant decrease in access to care. So that is the regulatory standard. We then issued subsequent guidance, I believe in November, that articulated factors that we use in evaluating those two standards, which include whether the compliance with the restrictions on the annual limits would result in a decrease in access to benefits, looking at the policies' current annual limits. If the annual limits are particularly low, there will be more of an impact, looking at the change in percent of—the change in premiums in terms of percentage, and then the change in premiums in terms of absolute dollar values, and then the number and types of benefits that would be impacted by application of the law.

Ms. DEGETTE. And is my understanding accurate that CCIIO has reached out and continues to reach out to stakeholders to make sure that you are addressing any concerns that they may have regarding the waiver process?

Mr. LARSEN. We do.

Ms. DEGETTE. And in which way?

Mr. LARSEN. Well, we have constant interaction with the applicants as they file, and if they have issues, hopefully they are brought to my attention, and we seek to resolve them, and I think as was mentioned earlier we have what I believe is very positive feedback that we have received from applicants.

Ms. DEGETTE. Now, as you describe, you put out an interim final rule and guidance on the waiver process, and about 90 percent of the applicants for waivers have been approved, so that would seem to me that the process is working because people understand what the criteria are, and they understand how to go through the process.

But there has been one concern that has been raised, and not by this committee but by Chairman Issa's committee, the Oversight Committee, they said that you had not adequately defined some of the criteria you use in making decisions. For example, he said you hadn't published a clear bright line numerical definition of a large premium increase.

So I guess my question is is it accurate that you have not published a strict numerical definition of what constitutes a large or significant premium price increase?

Mr. LARSEN. That is right. We do not have——

Ms. DEGETTE. And can you tell me why not?

Mr. LARSEN. Sure. We took the view that applying an absolute number would not adequately allow us to fairly process the applications as they came in because the applications in terms of the num-

ber of employees affected, in terms of their baseline premiums, they all—they vary significantly. So, for example, you could have a policy that had a very high premium but a low percent impact but actually still has a significant impact on people that pay the premiums.

So picking an absolute number we didn't think would be the best approach.

Ms. DEGETTE. But just because you don't have an absolute number doesn't mean you don't have criteria. Correct?

Mr. LARSEN. No. We do have criteria.

Ms. DEGETTE. Thank you very much. I yield back.

Mr. STEARNS. The gentlelady yields back. Our next—Dr. Burgess.

Dr. BURGESS. Thank you, Mr. Chairman, and Mr. Angoff, it has already been pointed out we have 5-minute increments in which our lives are lived, so I am going to ask you a series of questions, and I am going to ask us to go fairly quickly, so if we can, yes or no answers.

When you came and visited me in my office, I believe it was November 30, I had some questions then you were kind enough to answer. We had the luxury of additional time, but today we need to go fairly quickly, so I am going to list a number of functions that it is my understanding were under your—when you were the head of OCIIO, the previous agency, that they were under your purview. So please let me know as I read through this list, please acknowledge that they were under your jurisdiction, or if they were not, let me know that as well.

So children with pre-existing conditions?

Mr. ANGOFF. Yes.

Dr. BURGESS. Healthcare.gov?

Mr. ANGOFF. Yes.

Dr. BURGESS. Rescissions.

Mr. ANGOFF. Yes.

Dr. BURGESS. No rescissions.

Mr. ANGOFF. Right. The rule prohibiting rescissions.

Dr. BURGESS. The co-op program?

Mr. ANGOFF. Yes.

Dr. BURGESS. Federal high risk pool?

Mr. ANGOFF. Yes, which is the same as the pre-existing condition insurance plan.

Dr. BURGESS. Waivers for insurance plans?

Mr. ANGOFF. Yes.

Dr. BURGESS. Grandfathered regulations?

Mr. ANGOFF. Yes.

Dr. BURGESS. Early retiree programs?

Mr. ANGOFF. Yes.

Dr. BURGESS. Annual limits?

Mr. ANGOFF . Yes.

Dr. BURGESS. Waivers for businesses?

Mr. ANGOFF. Yes.

Dr. BURGESS. State exchanges?

Mr. ANGOFF. Yes.

Dr. BURGESS. Coverage for children under parents' plans?

Mr. ANGOFF. Yes.

Dr. BURGESS. Age 26.

Mr. ANGOFF. Right.

Dr. BURGESS. And the medical loss ratio?

Mr. ANGOFF. Yes, sir.

Dr. BURGESS. So all these things are functions for which you were responsible for overseeing and implementing?

Mr. ANGOFF. Correct.

Dr. BURGESS. Can you help us—I have got a copy of the Patient Protection Affordable Care Act here. Can you direct us to the section of PPACA that authorizes OCIIO to speak in acronyms for just a moment?

Mr. ANGOFF. The Secretary has discretion to manage and operate her office, but to answer your question, Congressman, there is no particular specific authorization in the bill that says there shall be created an Office of Consumer Information and Insurance Oversight. That is part of the Secretary's discretion.

Dr. BURGESS. So there is no authorization statute in the law that was signed by the President on March 23 of last year?

Mr. ANGOFF. Well, the functions are authorized. The specific office, there is no section of the bill which——

Dr. BURGESS. So what about CCIIO, the follow-on organization? Is there a section in here that I have missed that authorizes the follow-on organization? CCIIO, whatever exists today?

Mr. ANGOFF. There is no section specifying the name OCIIO or CCIIO.

Dr. BURGESS. Neither branch of the federal agency was specifically authorized under the legislation.

Mr. ANGOFF. But the functions that those agencies carry out are authorized in the bill.

Dr. BURGESS. So when in the timeline were you hired by the Administration for the purposes of creating and running OCIIO?

Mr. ANGOFF. I was hired, I believe my first day on the job was February 16, and——

Dr. BURGESS. February 16 of 2010?

Mr. ANGOFF. February 16 of 2010. The——

Dr. BURGESS. Happy anniversary then.

Mr. ANGOFF. Oh, thank you very much.

Dr. BURGESS. And I have the Federal Register from April 19, 2010——

Mr. ANGOFF. Right.

Dr. BURGESS [continuing]. Which talks about the Secretary organizing your agency.

Mr. ANGOFF. Yes. Before you wished me happy anniversary I was about to say that the office was authorized on April 19.

Dr. BURGESS. So March 23, signed into law, April 19, Federal Register, within a month of passage the Administration realized that they needed and the legislation lacked and they were able to divert funds to hire you, create OCIIO, and do this whole creation basically out of thin air, out of whole cloth because it wasn't authorized in statute.

Mr. ANGOFF. Well, obviously I wouldn't agree with that characterization.

Dr. BURGESS. Well, OK. Well, what about—this is pretty simple then. Where did the money come from? Where was the funding for OCIIO?

Mr. ANGOFF. The money came from the $1 billion that was appropriated as part of the ACA and then in addition, there are certain statutes, certain provisions of the Affordable Care Act which carried with them funding to carry out those particular provisions.

Dr. BURGESS. So would a correct characterization be you were able to skim money off say some areas like the money for the high risk pools to fund your organization?

Mr. ANGOFF. No. That is not a characterization, and that is not an accurate characterization because—for this reason.

Dr. BURGESS. Perhaps you would be able to provide to the Committee a detailed budget of where the money came from, the million dollar initial authorization, but there were other agencies making draws on that as well. Presumably you had at the end of the day your agency merged into another one, how many employees were working for you?

Mr. ANGOFF. Two hundred and fifty-two.

Dr. BURGESS. All right. That is not inexpensive to hire 252 people in Washington or Maryland.

Mr. ANGOFF. No. If I could just go back, though, Congressman, just to one point because I think it is very important to realize that the Act has certain sections which carry with it specific appropriations for those sections.

Dr. BURGESS. Let me just ask you very briefly. Do you have and can you produce for the Committee a delegation of authority from the Secretary of HHS that we can use to better understand what your services were at OCIIO?

Mr. ANGOFF. Yes. There was such a delegation, and I am happy to produce it.

Dr. BURGESS. I yield back. Thank you, Mr. Chairman.

Mr. STEARNS. Thank the gentleman, and the gentleman from Michigan, Mr. Dingell, is recognized for 5 minutes.

Mr. DINGELL. Please respond yes or no to this—these questions if you can, and if the answer is no, would you also please submit a detailed explanation for the record?

One, the underlying goal of the Affordable Care Act was to provide affordable quality health care for all. Do you believe the limited benefits plans provide that quality and that they provide comprehensive care to consumers? Yes or no?

Mr. ANGOFF. No.

Mr. DINGELL. OK. Next, we know that millions of Americans do rely on limited-benefit plans. Do you believe consumers have been adequately informed about the benefit limits under these plans? Yes or no?

Mr. ANGOFF. No.

Mr. DINGELL. The waivers are for how long? Only for 1 year. Right?

Mr. ANGOFF. Yes, sir.

Mr. DINGELL. And they will be reviewed at the end of that year?

Mr. ANGOFF. Yes, sir.

Mr. DINGELL. So you will have the chance to reissue the waiver or to deny the waiver at that particular time.

Mr. ANGOFF. That is correct.

Mr. DINGELL. This is a transitional step, is it not?

Mr. ANGOFF. Yes, it is.

Mr. DINGELL. And the purpose is to see to it that you don't take away from the recipients of the benefits under these plans, the benefits that they are receiving while you set up the larger plan as required by the statute. Is that right?

Mr. ANGOFF. That is exactly right.

Mr. DINGELL. Now, under ACA the Secretary has authority to determine what is restricted annual limits, and the responsibility to also protect consumer access to essential health benefits. We know that we allow an appropriate transition time. Some States, employers, and insurers would be unable to comply with the no annual limits provision and without an adverse impact on coverage or premiums. Is that correct?

Mr. ANGOFF. Yes, sir.

Mr. DINGELL. Do you believe that waivers are necessary to provide an uninterrupted, affordable transition coverage to individuals?

Mr. ANGOFF. I do.

Mr. DINGELL. And you will be reviewing these matters as we move towards 2014, and the full statute goes into effect.

Mr. ANGOFF. That is correct.

Mr. DINGELL. Is that right? Do you believe that the necessary guidance and assistance from the CCIIO has been readily available and accessible to assist potential applicants in completing the waiver application process? Yes or no?

Mr. ANGOFF. Yes.

Mr. DINGELL. Do you believe that CCIIO has dedicated an adequate amount of staff time to be responsive to potential applicants regarding the waiver application process? Yes or no?

Mr. ANGOFF. I do.

Mr. DINGELL. And you have put considerable effort into seeing to it that those resources are available for that purpose.

Mr. ANGOFF. Yes, we have.

Mr. DINGELL. Do you believe that the waiver process has provided an ample and an adequate transition time for employers and employees to comply with the Affordable Care Act?

Mr. ANGOFF. Yes, sir.

Mr. DINGELL. And that, of course, is, again, one of the purposes of the waiver provisions.

Mr. ANGOFF. Yes, it is.

Mr. DINGELL. Waivers are being granted. Is that right?

Mr. ANGOFF. Yes, it is.

Mr. DINGELL. Now, do you believe that the enrollees will receive greater information about the limited benefits in their health plan under the waiver process?

Mr. ANGOFF. I do.

Mr. DINGELL. Now, let us try and summarize. The—we are moving towards the establishment of the national plan which takes place in about 2014. This is going to be a very complicated exercise and a complicated plan. You will be reviewing these waivers periodically to see to it that they further your purposes of and the purposes of the statute in getting us where we can have a good workable national plan which provides to an orderly transition to that. Is that correct?

Mr. ANGOFF. That is correct.

Mr. DINGELL. Now, if you did not grant these waivers, what would be the practical result? As I read it, you would be kicking all these people off their plans, they would receive no benefits, and so we would have a very large problem of a lot of people not receiving any coverage at all. Is that correct?

Mr. ANGOFF. Yes, it is.

Mr. DINGELL. The plans are—a lot of these plans are subject to criticism on the adequacy of the benefits provided, but nonetheless, that is better than having no plans to cover these people, which could happen if you did not give the waiver. Is that correct?

Mr. ANGOFF. That is true.

Mr. DINGELL. Mr. Chairman, I note that I have 18 seconds to yield back. Thank you.

Mr. STEARNS. I thank the gentleman, and next we will go to Mr. Murphy.

Mr. MURPHY. Thank you, Mr. Chairman. The Institute of Medicine has been asked by HHS to make recommendations on the criteria and methods for determining and updating the essential health benefits package called for by the Affordable Care Act, and you know, Congress did not call for definition of medical necessity in the bill. While the House bill included a definition, it was not included in the final bill as amended.

But as I understand it Health and Human Services has asked the Institute of Medicine to review definitions and applications of medical necessity, which we didn't call for in the Affordable Care Act, and is outside the scope of defining essential benefits.

Can you tell me what authority does HHS believe it has to include this in the definition of essential health benefits?

Mr. LARSEN. Well, I can try and answer that. I apologize. I know that the Institute of Medicine has been tasked with helping HHS define what essential benefits are, and that will also be supplemented with a study by the Department of Labor. I have to confess I am not familiar with the medical necessity component of the task that has been asked, so I can follow up.

Mr. MURPHY. Can you do that? I would really appreciate if you would follow up. That would be great. Thank you.

Mr. LARSEN. I will do that.

Mr. MURPHY. Now, I want to ask a little bit more about these waivers. One of the waivers from the State of Ohio, my neighbor in Pennsylvania, and it is interesting a statement from Mary Jo Hudson, who is the Director of the Ohio Department of Insurance, was this. She said, "Not allowing a blanket waiver for all companies for basic and standard open enrollment in group conversion options would lead to an unlevel playing field. Some companies will seek waivers while others won't."

I think that is a good point, but how are you sure you haven't created some sort of an unlevel playing field, make sure everyone affected by the bill, the annual limits, know that they can apply for waiver?

Mr. LARSEN. Yes, thank you, and I don't think we have created an unlevel playing field. There are a small number of States that, through State policy, have encouraged or required insurance companies to offer these as we call them, mini-med policies, in order

to make sure that there is a policy available for some people who otherwise couldn't afford coverage.

And in establishing the waiver process and particularly the State process, we did want to make sure that people who have that coverage can, today, continue that coverage. So we set up a process that allows for the States, when there is a State policy or law or program that requires carriers or establishes a program that offers these types of mini-med policies to apply for a waiver.

Mr. MURPHY. It still is a situation in question, is everybody well-informed? Are you comfortable with how people are informed that they can apply for waivers, and they understand the terms and conditions of—once they can obtain a waiver?

Mr. LARSEN. We are. Again, I think we have been very transparent in publicizing this. The States are aware of it. We have worked through a number of different outside entities and trade groups and the NEIC to make sure that the word got out that there was an option to apply for these types of waivers.

Mr. MURPHY. How about a medical loss ratio? A number of States have applied for things, Georgia, Iowa, Maine, South Carolina, Texas, et cetera, all requesting waivers for medical loss ratio. Have any of the States contacted you about waivers for the MLR?

Mr. LARSEN. I would answer that in two ways. Before the medical loss ratio regulation was issued in December, we received a number of letters from States because the statute contemplates a State-based waiver process, but we hadn't set up the process yet. So we did receive letters from States before the regulations were issued.

Since the regulations were issued in December that laid out the process for applying, I believe we have received three States——

Mr. MURPHY. Would you let us know all the States that have that under—and what standards would a State obtain an exemption?

Mr. LARSEN. Sure. Well, the standards are set out in the regulation.

Mr. MURPHY. Just make sure we know that.

Mr. LARSEN. Yes.

Mr. MURPHY. The other thing I want to know is with the waivers that are being granted on multiple levels, has anyone done an economic or financial analysis of what this means in terms of the overall financial stability or instability, whatever, of the entire health care package?

Would either of you know what that is?

Mr. LARSEN. I am not familiar with a study that looks at the impact of waivers.

Mr. MURPHY. The issue being that if someone is required to participate, then they are waived from that, I don't know what this actually means in terms of revenues spent, revenues locked in. We are trying to get a handle on what all this means and the whole financial analysis of this bill and not clear if anybody is doing that analysis.

Mr. LARSEN. Well, in the transition between now and 2014, I think these limited waivers are beneficial to all the stakeholders, to both—either the companies or the issuers or the States or the

beneficiaries so that they can continue the coverage between now and 2014.

Mr. MURPHY. Thank you very much.

Mr. STEARNS. The gentleman yields back the balance of his time. Mr. Green is recognized for 5 minutes.

Mr. GREEN. Thank you, Mr. Chairman. Annual limits or coverages we understand can be a pretty rotten deal if you are really ill for consumers. You pay premiums for many years and then all of a sudden you find out that your wife has cancer or maybe your child that was just born has some terrible illness that you have to have a lot of health care for, and your insurance company ends up paying a lot and then they end up hitting up against that annual limit and sometimes even a lifetime limit.

Unfortunately until health care law was implemented, will be implemented in 2014, there are some people who have a choice between a plan with low annual limits on coverage or no coverage at all, and Congress intended to make sure that people enrolled in these plans wouldn't see their premiums rise dramatically or see their options for coverage disappear while employers adjust to new consumer protection rules and the full range of health care reforms.

Mr. Larsen, am I correct that the waiver process that we are talking about today was envisioned by Congress and put into place to help consumers in these low-cost and low-benefit plans?

Mr. LARSEN. That is correct.

Mr. GREEN. It is my understanding that these waivers are temporary and that they only last for a year, and they won't be available in 2014, or after. Is that correct?

Mr. LARSEN. That is correct.

Mr. GREEN. Mr. Larsen, what are some of the benefits that will be available to low-wage workers once the annual limit ban becomes firm in 2014?

Mr. LARSEN. Well, the entire landscape changes to the benefit of the consumer. They will have access to an insurance marketplace; there will be increased competition, benefits will be fuller; there will be premium subsidies available for individuals who can't afford to purchase insurance; but, the insurance that they purchase will now have full coverage and not the restricted limits that, unfortunately, some people have today.

Mr. GREEN. OK, and the waiver process I know benefits businesses, too. Health and Human Services implementing the ban on annual limits incrementally, starting with the floor of $750,000 in coverage for central care annually and raising that floor gradually until annual limits are eventually prohibited. Business and health plans would see substantially higher exposure to claims under even this incremental approach can apply for short-term waivers.

What percentage of the businesses that have applied for these short-term waivers received them?

Mr. LARSEN. Well, we approved the vast majority of the applicants that came in. Some are Taft-Hartley Plan, some are self-insured businesses, some are issuers, but overall I think the approval rate is about 95 percent or so.

Mr. GREEN. That is what our staff has come up with, about 90 percent and these are requests from businesses who are asking for that short-term waiver so they can grow into the health care.

Mr. LARSEN. That is right.

Mr. GREEN. It seems to me the waiver process implemented is just the sort of thoughtful approach that we want in a health insurance reform plan. The President advocated the ban on annual limits is a critical consumer protection, and the waiver process allows the Administration to implement that protection with due regard to individual circumstances and individual particular consumers and businesses.

The prohibiting annual limits is important reform that responds to one of the worst features of our insurance market today, and, again, I served 20 years in the legislature, and I understand what happens in legislatures where you have very low-limit policies because you hope sometimes somebody has one, just has a policy.

Annual limits can leave consumers, particularly those with expensive and chronic conditions and those experiencing catastrophic medical limits, with enormous medical debt and without an ability to access the health care. Congress included a ban on annual limits in the Reform Bill, but it also gave HHS the authority to waive it.

It is my understanding this waiver process was necessary to ensure the small number of people in certain low-cost, low-benefit plans, often called mini-meds, which still have access to at least some coverage before health care reform is fully implemented. Is that your understanding, Mr. Larsen?

Mr. LARSEN. That is right.

Mr. GREEN. Since this waiver process does not represent a flaw in the health care law but rather a recognition that flexibility and accommodation of unique circumstances—you don't turn around a battleship or an aircraft carrier immediately just like you don't turn around our health care plan.

Under circumstances would be required we build towards full range of consumer protections, and benefits will be available to all Americans in 2014. Is that correct?

Mr. LARSEN. That is correct.

Mr. GREEN. In fact, the waiver process responds to an uncommon, relatively uncommon set of circumstances. What percentage of the people in private insurance plans, Mr. Larsen, are covered by plans that have received a waiver?

Mr. LARSEN. Well, again, the number is about 2½, so less than 2 percent of people that have employer-based coverage are in plans that have received a waiver.

Mr. GREEN. So we are addressing this problem, but less than 2 percent——

Mr. LARSEN. That is right.

Mr. GREEN [continuing]. Have requested or received a waiver. Compared to the number of people receiving protection against annual limits under the Affordable Care Act, I would call that number a very small amount. I wish we didn't have to issue any waivers from this important protection, but just over 1 or 2 percent seems fairly minor.

In addition, the annual limit restrictions are but one important part of the series of protections that have been implemented since

enactment. Young adults can now stay on their parents' policies until 26, lifetime limits have been eliminated, plans must cover preventative care for free.

Mr. Larsen, are any of these protections or any of those protections being waived?

Mr. LARSEN. No. No, sir.

Mr. GREEN. OK. So the core protections of the law continue to be implemented smoothly with benefits for families, employers in this area. Is that correct?

Mr. LARSEN. That is correct.

Mr. GREEN. OK. Thank you, Mr. Chairman. I will yield back my time.

Mr. STEARNS. All right. Thank the gentleman. The gentlelady, Mrs. Myrick, is recognized for 5 minutes.

Mrs. MYRICK. Thank you, Mr. Chairman. Thank you both for being here.

The center contains the Office of Insurance Programs, which will administer the temporary high-risk pool program called the Pre-Existing Condition Insurance Plan. The health care law created this program with $5 billion in funding. Correct? I guess these probably go to Mr. Larsen since you are the head of that right now. Correct?

Mr. LARSEN. I can speak somewhat, and Jay can as well.

Mrs. MYRICK. OK. Well, whoever wants to answer. Go ahead. OK. Is—the $5 billion is correct. Right?

Mr. ANGOFF. Yes.

Mrs. MYRICK. And HHS recently announced the enrollment in the program. What was the number?

Mr. ANGOFF. Approximately 12,000.

Mrs. MYRICK. Twelve thousand, which seems awfully low considering the fact that pre-existing conditions were used routinely as one of the reasons that we needed to have the law. So don't you think the health care law, an unprecedented intrusion into the health care sector, was probably oversold by continually referencing those who had pre-existing conditions?

Mr. ANGOFF. No, I don't think so, Congresswoman. And I don't think it is law. The program has only been up for a couple of months. It is a transitional mechanism. It is only necessary because, under current law, insurance companies are permitted to exclude people based on health status and to charge more based on that.

Mrs. MYRICK. Well, when the report was issued last April CMS's Chief Actuary said the creation of a national high-risk insurance pool will result in roughly 375,000 people getting coverage in 2010, and if only 12,000 have enrolled, it seems to me that that is an overestimate of about 360,000 people for last year.

Mr. ANGOFF. No question that prediction has proved to be inaccurate. There were fears that the program would be overrun, and that has not occurred.

Mrs. MYRICK. Well, the Washington Post did a story also at the end of 2010, in December, the open question was—this is what they said. It is an open question whether the $5 billion allotted by Congress to start up the plans will be sufficient. Do you think these high-risk pools will need additional funding?

Mr. ANGOFF. No, I don't.

Mrs. MYRICK. The same news article states New Hampshire's plan has only about 80 members, but they already have spent nearly double the $650,000 the State was allotted. Is this true?

Mr. ANGOFF. No, it is not. They spent more than the amount that was allotted for 1 year, but they are well under the amount that was allotted for the entire lifetime of the program.

Mrs. MYRICK. And how many people are they scheduled to enroll then in the program?

Mr. ANGOFF. I am sorry?

Mrs. MYRICK. How many people are they scheduled to enroll in the program based on what you are saying?

Mr. ANGOFF. I can't give you a projected number of people, but I do know that the projections are that they will not exceed the amount that they have been allotted for the entire lifetime of the program.

Mrs. MYRICK. Will States like New Hampshire be provided any more money then in case they do?

Mr. ANGOFF. There is a process pursuant to which money could be reallocated but——

Mrs. MYRICK. Does that mean reallocated from other States that aren't spending it or——

Mr. ANGOFF. Yes, but that is very unlikely because there is no State which has spent more than its allocation for the period of——

Mrs. MYRICK. At this point.

Mr. ANGOFF [continuing]. That the program would be in place, and as you pointed out, there is a lot of money left to insure a lot of people, and we are looking forward to doing that.

Mrs. MYRICK. The article also states that although they collect enrollment data monthly, they have decided—you have decided to report it on a quarterly basis. Can you commit to reporting it on a monthly basis instead of quarterly since the data is available?

Mr. LARSEN. I would have to go back and check with our systems folks.

Mrs. MYRICK. Would you do that?

Mr. LARSEN. Sure.

Mrs. MYRICK. Because it seems like, if it is overestimated enrollment that is still spending more than it was originally promised, if you wait on the quarterly data instead of doing it monthly, it just doesn't——

Mr. LARSEN. Sure.

Mrs. MYRICK [continuing]. Serve the purpose, and it technically kind of eliminates political damage.

Mr. LARSEN. Well, we can do that, and to Mr. Angoff's point, the initial period, the start-up, getting this set up was where the resources were devoted to, to make sure that the program was up and running.

Mrs. MYRICK. OK.

Mr. LARSEN. So we understand that there are estimates out there that are higher than the 12. We know, for example, that after we got the program up and running and we started the outreach, I think, in the last period, enrollment has increased 50 percent. So we are already seeing a very rapid rise in the enrollment of this,

and we fully expect that to grow as we now, having stood the program, have had the opportunity to get the work——

Mrs. MYRICK. Got one more question because I am running out of time. HHS recently announced that new resources will be available to increase awareness of the program. Correct?

Mr. LARSEN. Correct.

Mrs. MYRICK. And so some of those include working with the U.S. Social Security Administration on a comprehensive outreach campaign. Any idea on the cost of that?

Mr. LARSEN. I don't, sitting here today, but I will get that——

Mrs. MYRICK. If you will get it back to me.

Mr. LARSEN. Absolutely.

Mrs. MYRICK. I mean, there has already been so much discussion about this Health Care Bill, and there has been so much awareness, et cetera, during the long period we debated it that my concern is do we really need to spend more dollars right now on additional outreach? So——

Mr. LARSEN. Well, I think we——

Mrs. MYRICK [continuing]. Mr. Chairman—go ahead.

Mr. LARSEN [continuing]. Have learned that it really takes a lot of effort. Many of these people have had a tough time; they have medical conditions; they don't have coverage; so, we are going to work with hospitals and providers and other sources to make sure that they get what they need, and they are aware of this program.

Mrs. MYRICK. Thanks. I am out of time.

Mr. STEARNS. Thank the gentlelady. Ms. Schakowsky, recognized for 5 minutes.

Oh, Mr. Waxman. I didn't see you.

Mr. WAXMAN. Thank you very much, Mr. Chairman. Some of the Republicans on this committee and elsewhere have been relentless in their attacks on the Health Care Bill generally and on your Office's implementation of the bill in particular. One of the main allegations is that CCIIO has acted with bias in granting waivers to annual limits on essential benefits coverage.

Representative Gingrey alleged that the waiver process has been "highly political and selective," and that politics and insider status rather than objective criteria have been guiding this process. Others have suggested that an increase in waiver grants following the November, 2010, election reflects potential reward of political allies. Subcommittee Chairman Stearns said, "From December, 2010, to January, 2011, the number of waivers grew from 222 to over 700, and yes, a lot of those waivers are going to unions."

Mr. Larsen, before this hearing HHS turned over to the Committee detailed information on all approvals and denials of requests for waivers from the New Annual Limits Provisions of the Affordable Care Act. I would like to get your thoughts on what this information shows about the allegations of bias.

The information HHS has provided the committee shows that of applications by union plans or plans that serve union members 14 percent were denied waivers compared to denial rate of about 3 percent for all other applicants, so plans to serve union members are almost five times as likely to be denied waivers as other applicants.

Do you think this information supports allegations that CCIIO is showing favoritism toward unions?

Mr. LARSEN. No. It doesn't, and to be clear, we didn't solicit applications from any particular sector. We didn't favor applicants from any particular sector or type of applicant. I know it has been described in some cases as a high percentage of union approvals, but as I think the data show, and hopefully we have clarified for you all, those are generally the Taft-Hartley Plans, which, in fact, are employer-sponsored coverage. They are not union plans, and so as you point out, there is a very—a small percentage, in fact, of unions that have gotten waivers, a much higher percentage of employer-based coverage.

Mr. WAXMAN. I guess to say that unions are getting special treatment, which they are not, is a way to get people angry because they want to stir up hostility to unions, although the unions, unfortunately, are shrinking to less and less an important part of our economy.

Mr. Larsen, the information received from our committee indicates that there was a spike in waiver grants in January of this year. Can you explain why there was such an increase?

Mr. LARSEN. Yes. So we require applicants to submit their requests 30 days in advance of the plan year, the policy year for which the coverage takes effect, and because many plan and policy years begin on January 1, as you might expect, right around December 1 and the end of November we received an increase in the number of waiver applications to coincide with the large number of plans.

So there is kind of a bubble, and things have receded back down closer to the levels that we saw right before December.

Mr. WAXMAN. Well, let me be very specific. I want to ask you this question. Is political support for the Obama Administration a factor in any way for the CCIIO considering and evaluating applications for the waivers to annual limit?

Mr. LARSEN. No, not in any way.

Mr. WAXMAN. And can you assure this committee that your office has handled the waiver process in an unbiased fashion?

Mr. LARSEN. We handle the applications in an unbiased fashion.

Mr. WAXMAN. So when people make these charges, there is no basis for these charges. They are all political. It is all propaganda. It is just another attack on this Administration, another attack on the Health Care Bill.

I am a strong believer in effective oversight, but this redoric and tone surrounding the attacks on HHS implementation of the health care law has me very concerned. Opponents have hurled one accusation after another at HHS and at the Health Care Bill, and then when the facts emerge, the allegation turns out to be unfounded.

I hope that we are not going to do this in oversight on all the issues that we have before us. I just hear these statements that I know are untrue. The Republicans say that they had a bill that would have accomplished all the same things that the Democratic bill would have accomplished. It would have stopped the discrimination for pre-existing conditions, it would have stopped these discriminations by insurance companies. That isn't what they proposed at all, and they didn't propose anything that covered Ameri-

cans. Maybe $3 million, not the $30 million that the bill covered. I just get frustrated that we have to run after the falsehoods with truth.

I yield back the balance of my time.

Mr. STEARNS. Gentlelady from Tennessee is recognized for 5 minutes.

Mrs. BLACKBURN. Thank you, Mr. Chairman, and we are talking so much about the waivers that States are getting, including Tennessee, which came to you and asked for a waiver, and I have got their waiver letter with me. This came to you September 17, 2010. This was during the administration of Governor Bredesen, who has since left office, and we have Governor Haslam.

But talking about these waivers and our concern, our program in Tennessee, CoverTN, which is an innovative program that was put in place, and we are concerned about what is going to happen with these programs in the future, and I want to read for you page 6 of this letter that went to you. It says that absent a waiver, absent getting a waiver from you, from Obamacare, that the State would have to dis-enroll 20,000 Tennesseans, who were not served by the commercial market in Tennessee prior to their enrollment in CoverTN. It seems likely that the majority of these individuals would become uninsured, and finally, it goes on and states that insurance premiums would go up, get this, 86 percent. Eighty-six percent.

So would you agree with me that this would be a significant cost increase to individuals and the State?

Mr. ANGOFF. I would. I would just like to make one thing clear, though, that I don't think has been made clear, which is this. The waivers are not granted to States. They are granted for coverage that is mandated by States. I am not as familiar with Tennessee as I am with New Jersey where I was Deputy Commissioner, and in New Jersey, for example, New Jersey mandates that all carriers shall have certain coverage.

Mrs. BLACKBURN. That is right. You all had guaranteed issue in New Jersey, but we have a TennCare program that was put up as an executive order of the governor and then has been run under the purview of CMS. OK, but you all granted Tennessee a waiver for this program. Right?

Mr. ANGOFF. For that specific program.

Mrs. BLACKBURN. For the CoverTN Program. That is exactly right. The program that is working and providing coverage and is successful.

Mr. ANGOFF. Correct.

Mrs. BLACKBURN. Now, what is Tennessee and what are these Tennesseans going to do in 2014? Where are they going to go? What is going to happen? Because that program is not going to be there unless you give it another waiver.

Mr. ANGOFF. Well, I'll just say this. We have been very conscious of this—when a State mandates certain coverage, and I will refer to New Jersey again because I am most familiar with that, New Jersey mandates that carriers sell relatively limited coverage, and so when a State mandates certain coverage——

Mrs. BLACKBURN. Sir, I am going to interrupt you with that because I am not talking about guaranteed issue. I am talking about

an innovative program in Tennessee that is working and what is going to happen with that program. And, see, I think my State is a great example of what is wrong with your approach to this with Obamacare, because you are going to take away a program that is working and then people are going to be left to go through and try to find something through an exchange, and they are going to face higher rates, and they are going to face a cramped access to health care services. Their insurance cost goes up, and the delivery costs goes up. It goes up on two fronts, two separate fronts.

And I think that the letter—I was looking at page 3 of this where it defines the benefits. This is a State solution. CoverTN is a State solution to provide affordable basic health insurance for small businesses, the self-employed, and the recently unemployed that covers the most frequently-used services. This letter also explains to you that because of the way this program was set up, and the letter came to you from the Department of Finance and Administration from the State of Tennessee on behalf of the CoverTN Program, but it states this plan has seen enrollment climb because, number one, the plan is affordable, and the medical loss ratio for 2010 was 87 percent.

Now, under the current rules this plan would disappear in 2014. Is that correct?

Mr. LARSEN. Congresswoman, if I could respond, I actually think we are in agreement on many issues. The State of Tennessee, like other States, in response to the very broken marketplace that we are all trying to solve.

Mrs. BLACKBURN. Our marketplace was broken because of the implementation of TennCare that ate up 35.3 percent of the budget——

Mr. LARSEN. I can't speak to TennCare.

Mrs. BLACKBURN [continuing]. And saw hundreds of thousands of Tennesseans dis-enrolled from the program.

Mr. LARSEN. So Tennessee——

Mrs. BLACKBURN. You are correct. We were under the 1115 Waiver Program, and it did nearly bankrupt the State, and I would hope, I would like to move onto my last question.

Mr. LARSEN. If I could, ma'am.

Mrs. BLACKBURN. No, sir. I have got one last question that I am going to ask and because you all avoid it. If history is a guide, what in heaven's name are you going to do with escalating costs? TennCare's cost quadrupled. They quadrupled within about a 5-year period of time.

So if history is a guide and that happens with Obamacare, I would love to hear what is your plan for dealing with accelerated costs?

Mr. LARSEN. The Affordable Care Act, in fact, is full of provisions and its purpose is to lower the cost curve, and there is a series——

Mrs. BLACKBURN. Sir, history tells you that when you go into this premise of near-term expenses banking on long-term savings, it doesn't work. What is your plan B?

Mr. LARSEN. The plan is the Affordable Care Act. That is the plan, and it is going to work.

Mrs. BLACKBURN. Sir, there is no case in history in this country where this has worked.

Mr. LARSEN. This will work.

Mrs. BLACKBURN. None. It is——

Mr. STEARNS. I thank the gentlelady. The time has expired and will recognize——

Ms. DEGETTE. Mr. Chairman, I would like to ask unanimous consent to let Mr. Larsen answer the very important question that Ms. Blackburn asked.

Mr. STEARNS. Well, I think Mr. Larsen answered it. He said that the answer is Obamacare.

Ms. DEGETTE. No. The previous question that she asked.

Mr. STEARNS. Mr. Larsen, did you answer her previous question?

Mr. LARSEN. Well, the point, the only point I was trying to make about the State programs and the point that I think we were in agreement on, which was the market is broken. People can't get coverage, haven't been able to get affordable coverage. One response at the State level, these are the States that applied for waivers, was to set up programs that have limited benefits, and we understand that. We agree that those programs between now and 2014 should continue so that those people do have access to care. Then in 2014, they will have access to much better—

Mr. STEARNS. I would advise all members we are going to have a second round here, so if anybody wants to stay, they can go into it.

So Ms. Schakowsky.

Ms. SCHAKOWSKY. Well, let me explore that a little further. The waiver that is granted to States like Tennessee and Florida is to allow the mini-med plans. Talk about those plans for a minute that Ms. Blackburn has lauded as some really great coverage. What are we really talking about in terms of mini-med plans? Are they not limited coverage?

Mr. LARSEN. They are limited coverage. They are not all the same. Some have very low annual limits. Some have restrictions on other types of benefits, and that is the dilemma because they are not good coverage. They don't provide comprehensive coverage, but, nonetheless, today until the full reforms of the Affordable Care Act kick in, that is an option for people.

Ms. SCHAKOWSKY. Right.

Mr. LARSEN. And we want people to have that option, even though it is not necessarily full coverage.

Ms. SCHAKOWSKY. So we see that as a bridge——

Mr. LARSEN. As a bridge.

Ms. SCHAKOWSKY [continuing]. As you said to better coverage. Would you describe what happens to people who are in the mini-med programs now once the full implementation of the Affordable Care Act in 2014?

Mr. LARSEN. Well, they are going to get a much richer, fuller benefit package, and they are not going to have to worry about whether they spend 4 days in the hospital and run out of their inpatient coverage because there is an annual limit on their policy.

So consumers are going to be better off. The system is going to be better off because we are not going to have the levels of uncompensated care that we have today. So that is the world in 2014.

Ms. SCHAKOWSKY. I want to go back to the issue of the States for just a second, the overall policy, because, again, it was—it

seemed to be promoted by our Chairman as, again, something political about Florida or New York. What States, what is the feature in the States that would uniquely make them eligible for a waiver?

Mr. LARSEN. The feature is if they have a law or program that establishes a package of benefits that insurers have to issue, or insurers issue pursuant to a State program. So there is a small number of States that have these types of programs, one of which is——

Ms. SCHAKOWSKY. These are the limited-benefit programs.

Mr. LARSEN. That is right.

Ms. SCHAKOWSKY. Yes. So——

Mr. LARSEN. And, otherwise, we apply the same regulatory criteria that we apply to all applicants to the States that apply. So there has to be a significant increase in premiums or decrease in access to benefits if they had to comply with the law.

Ms. SCHAKOWSKY. OK. The other issue I wanted to deal with, there was a charge made somehow that there is skimming in order to create your office, and I wanted to talk a little bit about it.

Mr. Angoff, I wanted to ask you about the Secretary's authority to create the office. Implementing landmark health insurance reform, of course, is a huge job, and following the enactment of the Affordable Care Act, Secretary Sebelius established the Office for Consumer Information and Insurance Oversight.

So I think you talked a little bit about the responsibilities of the office, but I am more interested in getting to the question really of the authority because Representative Burgess questioned that authority. The committee looked into, the staff did some research and found that according to the Department's reorganization plan from 1953, the Secretary, "may from time to time make some provisions as the Secretary deems appropriate, authorizing the performance of any of the functions of the Secretary by any other officer or by any agency or employee of the Department."

So it looks, Mr. Angoff, like the Secretary has had that power for nearly 60 years.

Mr. ANGOFF. That is correct. There is no question about the Secretary's authority to create the Office. She has such authority.

Ms. SCHAKOWSKY. Now, I also want to clarify what you said. You were saying that there is money in the bill to implement the provisions and that a decision was made about a structure to do that, taking money already in the bill. Is that what you were saying? To create an appropriate structure.

Mr. ANGOFF. That is correct. There is $1 billion appropriated for the ACA as part of the Act, and then in addition there are specific provisions such as the provision authorizing the high-risk pools and the provision authorizing the Early Retiree Reinsurance Program, which carry independent funding with those provisions.

Ms. SCHAKOWSKY. Thank you. So I just want to end by saying words like skim, I think, are very loaded, they create a very negative feeling that, in fact, all of the money to create this Office to help implement the bill was appropriated and in the legislation. Thank you.

Mr. STEARNS. Thank the gentlelady. Does the word fungible work better?

Mr. Griffith, you are recognized for 5 minutes.

Mr. GRIFFITH. Thank you, Mr. Chairman. I am curious following up on that line, you were hired on February 16, but the legislation wasn't passed until March 23. Why not put a line in there that specifically stated that you all were going to have this office?

Mr. ANGOFF. That is not for me to answer.

Mr. GRIFFITH. It would have made things a lot clearer, would it not?

Mr. ANGOFF. No, I don't think so. I mean, I think the provisions which Congresswoman Schakowsky cited make it clear that there has never been any question about the Secretary's authority to delegate authority and manage her jurisdiction in the way she sees fit. So I just don't see any issue there.

Mr. GRIFFITH. Do you know how much money you all spent in this endeavor, 252 employees, and I understand you had offices in Maryland at one time?

Mr. ANGOFF. Yes. For fiscal year 2010, $33.4 million is the amount that comes out of the billion that was authorized, that was appropriated.

Mr. GRIFFITH. All right, and how much do you anticipate going forward?

Mr. GRIFFITH. That would be Mr. Larsen's area.

Mr. LARSEN. We are still working through the 2011 number, so I can't give you that number at this point. In the President's budget in 2012, we have got, I think $94 million for oversight and consumer assistance and functions like that in the President's budget.

Mr. GRIFFITH. And you indicated that—speaking to Mr. Larsen now, you indicated that you had an outreach program for folks to get into the programs regarding high risk or areas where people were——

Mr. LARSEN. We are starting that up now. We have not to date had a very vigorous outreach program, and I think that accounts for the lower-than-anticipated enrollment. So we are going to——

Mr. GRIFFITH. My question then would be do you also have an outreach program for micro-employers, people that have five or less employees? Do you have an outreach program to let them know about they can easily access the ability to get a waiver if they need one?

Mr. LARSEN. We don't have a specific program targeted to types of employers, but I would be happy to talk to you about ideas for doing that.

Mr. GRIFFITH. And as we go forward you don't anticipate there being any waivers after 2014?

Mr. LARSEN. We don't, because the law wouldn't allow for limited waivers or policies because the restrictions on the annual limits are complete at that point, and that is the point at which consumers have access to a full array of benefits.

Mr. GRIFFITH. And in regard to the minimum essential coverage penalty, you answered earlier your plan B was this is actually going to work and so forth, but how do you anticipate dealing with States like Virginia where it has been ruled unconstitutional because of that penalty and the 26 States that are in the Florida legislation——

Mr. LARSEN. Right.

Mr. GRIFFITH [continuing]. That, of course, got its own opinion? How do you all plan to deal with that? Are you going to continue to charge forward, notwithstanding the legal question which obviously is very serious with, I think, now 27 States having a ruling that says that that provision at least is unconstitutional. Now, the difference, of course, Virginia not only had a separate piece of legislation but had a separate suit from the others and focused entirely on that one part of it.

But how do you plan to go forward?

Mr. LARSEN. Yes. I guess I would answer in two ways. First, today, right now, we are proceeding with implementation of the law, but our lawyers at HHS are, as you can imagine, looking at the implications of the ruling and how we will be responding to that. So——

Mr. GRIFFITH. And I guess my question is what is the plan B if ultimately the 27 States that have already gotten a ruling that is unconstitutional prevail?

Mr. LARSEN. Yes. Well, that I can't speak to.

Mr. GRIFFITH. Does the plan work without mandatory purchase?

Mr. LARSEN. Well, I think as been discussed publicly, the individual responsibility provisions are an important part of the architecture of the ACA, but in terms of what happens, I can't get into——

Mr. GRIFFITH. Including the penalty provision?

Mr. LARSEN. I can't get into what happens in light of the pending litigation that we have.

Mr. GRIFFITH. So there is no plan B?

Mr. LARSEN. I am not saying there is or there isn't a plan B; but, in matters relating to the litigation that we have with the States, we are proceeding with implementation today as I sit here, and I will leave it to the lawyers to figure out——

Mr. GRIFFITH. Can you let me know when you develop a plan B?

Mr. LARSEN. We absolutely will.

Mr. GRIFFITH. Thank you.

Mr. STEARNS. Thank the gentleman. Mr. Scalise, the gentleman from Louisiana, is recognized for 5 minutes.

Mr. SCALISE. Thank you, Mr. Chairman. I appreciate you calling this hearing. Obviously we are trying to get as much information as we can about the impacts, unfortunately in many cases, the devastating impacts of President Obama's health care law that are now being felt.

I want to talk to you first about the child only policies. We have been being a number of companies that used to offer child only policies that are now getting out of the market because of this law.

Are you aware, first of all, of that problem of the companies that are just dropping this line of business altogether?

Mr. LARSEN. Well, the Affordable Care Act set up a system where, for the first time, insurance companies aren't going to be able to deny care for sick kids, and that was the goal of the Affordable Care Act, and it is unfortunate, frankly, that there are insurance companies that have decided that if they can—unless they can only insure healthy kids, they are not going to offer——

Mr. SCALISE. So what you are saying you are aware that there are companies now that just aren't offering these health care op-

tions to any parents who want to provide this for their children. Are you aware of this?

Mr. LARSEN. In the small segment of the market there are companies——

Mr. SCALISE. Can you tell me how many companies have gotten out of this line of business since——

Mr. LARSEN. I can't answer that exact question. I don't know.

Mr. SCALISE. You can't? I mean, I would understand it is your job, your Office's job to follow these effects on insurance injury and the ability for people to get access to health care. I would think it is your job, so I would think you would know how many.

Mr. LARSEN. Well, here is what we have done. We have provided guidance to States, Louisiana and other States, with a range of options to encourage them to take, in order to maintain a market for these carriers that otherwise don't want to insure sick kids. So, they are leaving the market because, unless they can just insure healthy people——

Mr. SCALISE. Right, and one of our concerns all along, and frankly it was discussed by those of us on this side of the aisle when this bill was being debated over the course of the last year and a half, that these kinds of mandates and laws that were included in Obamacare were going to deny access to people who had health care that they liked. And, of course, the President multiple times would say if you like what you have, you can keep it, and we pointed out in many cases that because of these changes, they were going to actually force a lot of people just out of the market altogether, which would deny coverage to many people who had health care that they liked. And so, you don't know the number of companies now. You are saying that. I would encourage you to go and find out how many there are and find out what things need to be done to unravel it unless, I guess, you all are more concerned about invoking a policy than actually improving access to people who want to get health care, because your policies that took effect.

I see in September of 2010 are what ran a lot of these people out of the market altogether, and there are articles that started coincidentally right after the law took effect that talk about all of these companies that were offering health care options to children that no longer are doing it. So now you have denied access to families, parents who had good health care for their kids that don't have that option today.

Mr. LARSEN. We have not. The insurance companies——

Mr. SCALISE. Well, the law did. You personally didn't do it, but Obamacare did, and since it is your job to track these things, I would encourage you to go back and take a look.

Mr. LARSEN. Well, we have worked with the States. We have sent guidance out and worked with the States to provide them with——

Mr. SCALISE. Well, with the States, you are on your own now because families don't have the same options. They have limited options, and I appreciate maybe you have a difference on the overall law. I will say, and I am glad that the Chairman is having this. I am a little surprised that some of our counterparts on the other side are criticizing us for having this hearing. There is a letter, and I would like to get the letter in the record, there is a letter that

a number of members of this committee wrote last year asking then Chairman Waxman to hold a hearing on these kind of problems, and for whatever reason Chairman then Waxman chose not to have any hearings, and maybe it is because they didn't want the American people to find out just how devastating this law, Obamacare, is on denying access to people today.

Now, one other area I want to get——

Mr. STEARNS. Do you want to put that in the record?

Mr. SCALISE. And I would like, yes, to ask unanimous consent to put that letter in the record, because I think——

Mr. STEARNS. Without objection, so ordered.

[The information appears in the exhibit binder at the conclusion of the hearing.]

Mr. SCALISE [continuing]. It is important to show we have been interested in this for a long time. Unfortunately, the folks on the other side when they were in charge didn't want to have these kind of oversight hearings where the American people could find out that people today are being denied health care that they liked because of this law.

Now let us get to these waivers. I think probably one of the biggest heights of hypocrisy is the fact that the President ran around touting how great this law was going to be, it is going to be wonderful for American people, it is going to reform health care problems. Of course, we pointed out back then all the problems it would created. I am surprised at how many people have asked and now, I am not surprised how many people have asked. Frankly I think everybody would like and should get a waiver from the entire law and hopefully the courts will take care of that, but I am surprised how many waivers have been granted.

Can you tell me how many waivers have been granted to companies that said we just, you know, we don't want to comply with some of these sections.

Mr. LARSEN. Sure. Through——

Mr. SCALISE. I am talking about the number. Do you know the number?

Mr. LARSEN. I believe the number that we gave you was 915.

Mr. SCALISE. OK. The 915. From what I am understanding about 60 companies have been denied that ability to get the waiver. Can you get us the list of those companies that have been denied, and even more specifically, I would ask you to submit to the committee matrix on the number of companies, the number of employees, if you don't want to include their name for other reasons, I can appreciate that, but at least get us the matrix on the number of companies, the number of employees, broken done by region, and also broken down by union versus non-union, because I think a lot of small businesses out there that would like to be exempted from this haven't been given that opportunity, you know, and maybe there is a line formed at the White House where you have to go and get it, but frankly, I think it is the public's right to know what that, what those matrix are and to get that data and who has been exempted from this——

Mr. LARSEN. We provided that to the committee.

Mr. SCALISE [continuing]. Was touted as a panacea and is, in fact, destroying access to health care for millions of Americans. Thanks. I yield back.

Mr. STEARNS. Thank the gentleman. We are going to go another round of questions. If you would engage us, I would appreciate your forbearance here.

The President kept saying during his campaign, if you like your health care, you can keep it. He kept saying that as a mantra, but wouldn't both of you agree that without a waiver these people that you gave a waiver, they couldn't keep their health care? Isn't that true, Mr. Angoff?

Mr. ANGOFF. We don't know whether those people liked their health care——

Mr. STEARNS. No, but, I mean, the fact is the President says you can keep it, you can keep your health care. If you like your health care, you can keep it, but without a waiver, they couldn't keep it. Isn't that true?

Mr. ANGOFF. They are keeping it. Keep in mind that in 2014——

Mr. STEARNS. Mr. Larsen, isn't that true, though, basically that without these waivers, McDonald's and these people, they couldn't provide?

Mr. LARSEN. I agree with Mr. Angoff. The fact is that they are keeping it, and the ACA contemplated setting up a system to ensure that people in these low annual limit policies could, in fact, keep——

Mr. STEARNS. Well, you know, the Democrats are continually trying to defend these waivers, but, you know, what the problem is the Administration health care, Obamacare, has created this problem, and now the Democrats are recommending a solution. If they didn't have this problem from the first place, we wouldn't need this solution, which is these waivers.

So, you know, our response on this side is the only reason you have the waiver is because of the new requirements, all these new requirements of Obamacare making insurance, providing insurance too expense.

For example, you indicated that you had 915 waivers. 2011, as I understand it, the ceiling per year is $750,000 a year. Isn't that true?

Mr. LARSEN. That is right.

Mr. STEARNS. OK, and does it go up to $1.25 million roughly in the year 2012?

Mr. LARSEN. That is correct.

Mr. STEARNS. And it goes up in 2013, to over $2 million. Is that roughly true?

Mr. LARSEN. Yes.

Mr. STEARNS. So if a person could not make it in 2011, like a McDonald's, aren't there going to be a lot more corporations that are going to come for waivers once they realize that the benefit is going to go up from $750,000 to $1.25 million? Don't you think more people will—just logically?

Mr. LARSEN. That is exactly why we set up a program where we are going to have a 1-year——

Mr. STEARNS. I understand, but all those people for 1 year are going to come back, and then more people are going to come. Then the year 2013, it goes to $2 million, and 2014, is unlimited. Right?

Mr. LARSEN. So what we are doing this year, to answer your question, is looking at the very question that you are asking, which is what is the best glide path for these types of policies between now and 2014, in light of the increasing annual limits that——

Mr. STEARNS. It goes to the heart of the whole question is the President said if you like your health care, you can keep it, but basically you can't keep it unless the government gives you waivers. Have you done an economic analysis, 2014, comes, right, all these companies you have given waivers now must comply. Have you done an economic analysis to see what it is going to cost these companies when they have to provide unlimited benefits every year for their employees?

Mr. LARSEN. Well——

Mr. STEARNS. I mean——

Mr. LARSEN [continuing]. Remember that this——

Mr. STEARNS [continuing]. We are seeing these waivers from 2011, 2012, 2013, 2014 unlimited. I mean, have you done any kind of economic analysis?

Mr. LARSEN. But the vast majority of employer-based coverage will, or already does, meet those annual limits. So we are only talking about a very small percentage of the marketplace that has to be on a glide path to 2014.

Mr. STEARNS. Well, I think that I would disagree with you because when you say to a corporation, a small corporation that you have got to provide unlimited benefits, I think it is going to make it more expensive, and this whole process is just going to be very dependent upon high costs at which the government is going to have to supplement and pay to cover these. And I think you have got the indication of the problem with these waivers from States, and if New York gets a waiver, has, I mean, at what point after you have given these waivers to large States do we actually see the realization that we can't afford this?

And so, I mean, we are just talking about escalating the number of waivers.

Mr. LARSEN. Well, I think that is the connection between today and 2014. We have a solution in 2014, and we need to make sure that this small part of the marketplace gets to 2014, and that those individuals as you suggest as the President wants, can continue their current coverage.

Mr. STEARNS. Well, I think for the benefit of acting on what the President says, if you like your health care, you can keep it, you should have some economic analysis, what is going to happen in 2014, based upon all these waivers you are anticipating that are going to increase.

Just a last question. How does a corporation know that he, his corporation, his benefit, his union can get a waiver? Do you tell people? I mean, how does a normal small business find out? How did Waffle House find out that they could even do a waiver? Because I think there are many people out there that don't know they can get a waiver, they don't have the steps to do it. I don't—are you advertising that you can get waivers?

Mr. LARSEN. When we put the waiver process in place, we put out a press release, and we posted the information on the Web site.

Mr. STEARNS. On your webpage.

Mr. LARSEN. A number of—that is right. Trade groups, law firms——

Mr. STEARNS. When did you do that?

Mr. LARSEN [continuing]. Consultants.

Mr. STEARNS. How long ago? Did you do it 2 months ago or——

Mr. LARSEN. Well, we set the program up in September, and then we have had subsequent——

Mr. STEARNS. OK.

Mr. LARSEN [continuing]. Guidance since then and——

Mr. STEARNS. So I could advise any corporation in the State that wants a waiver to go to your Web page, and they would understand how to fill out the forms and do it?

Mr. LARSEN. Yes.

Mr. STEARNS. OK. My time has expired. The gentlelady, Ms. DeGette.

Ms. DEGETTE. Thank you, Mr. Chairman. I just want to clarify a couple of things.

The first thing I want to clarify, Mr. Larsen, is Mr. Scalise asked you if the information on all of the waivers, the applications, the approvals, et cetera, was available, and it is available online. Correct?

Mr. LARSEN. It is on our Web site. Yes.

Ms. DEGETTE. So you guys aren't trying to hide any of that information. Right?

Mr. LARSEN. No, we are not in any way.

Ms. DEGETTE. Thank you.

Mr. LARSEN. We are very——

Ms. DEGETTE. The second question I have is, Mr. Scalise was talking quite a little bit about the insurance companies after the requirement that they couldn't drop children with pre-existing conditions were leaving the market, in fact, most children are the cheapest group of folks to insure if they are healthy. Correct?

Mr. LARSEN. Correct.

Ms. DEGETTE. And so really what these insurance companies are saying is we don't want to have to give insurance policies to children with pre-existing conditions or who are sick. Would that be a fair interpretation?

Mr. LARSEN. That is correct.

Ms. DEGETTE. And the Affordable Care Act as it is phasing in now says, you know what, if you are going to offer parents an insurance policy, you have to offer people like Diana DeGette, who has a child with Type I Diabetes, an insurance policy just like you have to offer everybody else an insurance policy. Isn't that right?

Mr. LARSEN. Right.

Ms. DEGETTE. Don't you think—well, never mind. I will say what I think. I think the parents of America would like to see sick children as well as well children insured.

Let me ask you another question which is I guess I am a little bit perplexed by some of these lines of questioning on the other side, because the reason you folks set up these waivers is so that States or—well, strike that. So that employers that were offering

these limited-benefit plans would be able to continue to offer those in the transition period before—between now and 2014. Right?

Mr. LARSEN. Correct.

Ms. DEGETTE. And if we didn't have these waivers, then those folks would be bumping up against the caps. Correct?

Mr. LARSEN. For the small percent of the market. Yes.

Ms. DEGETTE. For the 2 percent of the market that is getting the waivers. Right?

Mr. LARSEN. Correct.

Ms. DEGETTE. And so it seems to me that what you are doing is you are allowing this gap to be filled between now and 2014, for people who need those policies. Right?

Mr. LARSEN. That is correct.

Ms. DEGETTE. Now, I want to ask you this follows up on this last question, and the reason you are not going to need these waivers in 2014, is because there are many new tools that are coming on deck in 2014, that these employers will be able to have. Is that right?

Mr. LARSEN. That is correct.

Ms. DEGETTE. I am wondering if you can explain some of those tools that we will have and why we will no longer need those waivers for these limited number of employers in 2014, briefly.

Mr. LARSEN. Well, consumers are going to have a range of new options. First of all, there is going to be a ban on all pre-existing conditions for all issuers. Everyone can get coverage. Everyone can get full coverage. There will be an essential package of benefits. There will be options within the exchanges with richer benefits, and not as rich benefits, covering still the same set of essential benefits. There will be a competitive marketplace where people can shop. Competition will increase, and for those who are low-income individuals, there will be opportunities for premium subsidies to get better coverage that will be affordable for them.

Ms. DEGETTE. So, in fact, I don't know if you are aware but the non-partisan Congressional Budget Office made a projection, and what they said was Americans buying comparable health care plans to what they have today in the individual market would see their premiums fall after 2014, by 14 to 20 percent, which would save $732 on an individual policy and $1,975 for a family policy. Most Americans buying coverage on their own would qualify for these tax credits that would reduce their premiums by an average of 60 percent, even as they get better coverage as they have today.

And the CBO also estimated that small businesses would see premium reductions of 8 to 11 percent and would receive tax credits worth nearly $40 billion over the next decade to help pay for coverage.

Are you aware of the CBO analysis?

Mr. LARSEN. Generally, yes.

Ms. DEGETTE. And one last question. According to what you know are the benefits that people, that employers are going to have to offer after 2014, unlimited benefits?

Mr. LARSEN. They are not going to be able to have lifetime and annual limits on the policies that they issue.

Ms. DEGETTE. But the limits—are not unlimited. They are going to be——

Mr. LARSEN. Oh, that is right. That is right.

Ms. DEGETTE. Thank you.

Mr. STEARNS. Thank the gentlelady. Dr. Burgess is recognized for 5 minutes.

Dr. BURGESS. Thank you, Mr. Chairman. In the interest of brevity I am interested in the private sector experience that both of you have, and perhaps you could provide that to the committee at some point so we would be able to review that.

I want to just close the loop on a line of questioning that I was undertaking before, Mr. Angoff. So now we have the situation where OCIIO has become CCIIO, and it is located at CMS. Right?

Mr. ANGOFF. Yes, sir.

Dr. BURGESS. Just recapitulate and all the functions that I mentioned before are now under the direction of Administrator Dr. Don Berwick. Is that correct?

Mr. ANGOFF. Yes, sir.

Dr. BURGESS. So CMS, Center for Medicare and Medicaid Services oversees Medicare, Medicaid, SCHIP, and a very significant portion of the private insurance market over which it never had authority in the past. Is that a valid observation?

Mr. ANGOFF. Not entirely, in that much of Medicaid and Medicare now is actually run through the private insurance system.

Dr. BURGESS. But it is all directly—Dr. Berwick is directly responsible for all of those federal programs.

Mr. ANGOFF. yes.

Dr. BURGESS. So we have the public and private side by side as PPACA phases in. So, again, just to complete the story, we have an Administrator at CMS, who parenthetically has never been confirmed by the Senate because he was a recess appointment, so as much affection and respect that I have for Dr. Don Berwick, he has never come before the United States Senate to undergo the confirmation process. Maybe they will have an opportunity to do that before, but he is in charge of almost all insurance coverage in the United States of America as PPACA phases in, and it is all going to be led by this sub-organization of HHS, CCIIO, that is a follow on from OCIIO that was a non-directly appropriated, non-authorized center without clear authority who cannot provide his budget to the committee at this time. Is that a fair assessment of the landscape as we—as it exists today?

Mr. ANGOFF. I don't think it is fair because I think——

Dr. BURGESS. Of course it is. I went to great detail to, painstaking detail to outline it for you.

Mr. ANGOFF. And Congresswoman Schakowsky went into specific detail about the specific provisions which authorize the Secretary to delegate her authority, and as I said before, there is a delegation, and we will provide that to the committee.

Dr. BURGESS. And again, I have been working for several months. I would very much like to have that delegation of authority and the budgetary plan under which you have been working, Mr. Larsen, under which you intend to work going forward because I just think for an entirely new federal agency that is going to have this broad of power, and I went through those powers with you, this broad a scope and reach over—into the lives of every single man, woman, and child in this country, not just now but for the

next 3 decades, it is appropriate that this committee from time to time have some curiosity about just what is going on and kicking the tires on OCIIO or CCIIO or whatever it then becomes going forward.

The Governor of Utah was in town this week and spoke at several places. I know we have been talking about the waiver authority under the mini-med plans, but you are also responsible for setting up the State exchanges. Is that correct?

Mr. ANGOFF. That is correct.

Dr. BURGESS. And Governor Herbert had mentioned some difficulty that he was having getting an answer out of CMS or HHS on some flexibility that he wanted. Just the administrative flexibility of being able to do things electronically rather than on paper, that he estimated would save his State some $600 million a year, but he had been waiting from July until this week to get an answer.

Does that seem a little long?

Mr. LARSEN. Well, I apologize. I don't know the details of what he is looking for. I know that we have on ongoing dialogue with the States and the State Governors. I know Utah has an exchange as do one or two other States, and we look forward to working with the States. We view the States as our partners on the exchange process and——

Dr. BURGESS. Well, again, it just looks like July to the day after Valentine's Day seems like a long timeframe to get an answer on a relatively straightforward administrative simplification request that his State had with the expectation that it is going to save significant dollars for the State.

And after all, I mean, the gentlelady from Tennessee pointed out a big problem for all of us, you guys at the witness table but for us guys up here at the dais, in that what do you do going forward? All this stuff—you are granting the waivers, you are kind of doubling down on the population as it is coming in. 2014, hits, you flip the switch, and no light comes on. What do we do then?

Mr. LARSEN. Well, I think in 2014——

Dr. BURGESS. You are betting on all this stuff working.

Mr. LARSEN. I think we are going to flip the switch and the lights are going to go on, and it is going to be——

Dr. BURGESS. But, again, as the gentlelady from Tennessee pointed out, where is the plan B? What rational person looks at the demographics of the United States of America today with people my age who within a very short period of time will be entering Medicare, the advancing complexity of what we are able to do to alleviate suffering and treat disease, what rational person looks at that and says, you know what? In 2014, it is going to cost $500 billion less than it did the year before. I mean, that is crazy talk. That is not going to happen.

It is going to cost more to take care of the Medicare patients going forward, and other than waiting lists and rationing, I don't see that you have done anything that is going to be able to control costs going forward.

Mr. Chairman, I appreciate the indulgence on the time. I would be happy to hear the answer from either of our panelists if they would care to do so.

Mr. ANGOFF. Yes. I would just like to point out just one rule which really already is having an affect, and that is the medical loss ratio regulation. The trade press really is reporting that that is already having an effect of having companies reduce their rates and provide more generous benefit packages to their policyholders.

So there are already things that are being done, even though it has only been in effect for a short while, that are actually driving down costs.

Dr. BURGESS. Yes. With all due respect you were late getting that done and let us revisit that in a year's time and see what the story looks like.

Thank you, Mr. Chairman.

Mr. STEARNS. I thank the gentleman. The gentleman from Colorado, Mr. Gardner, is recognize for 5 minutes.

Mr. GARDNER. Thank you, Mr. Chairman, and Mr. Foster, in your opening statement that I was able to listen to you mentioned that you—it is your goal to allow people to keep the insurance that they currently have. That was something that you had said this Health Care Bill was attempting to do. Is that correct?

Mr. LARSEN. Yes. This bill and—yes.

Mr. GARDNER. And I believe that Mr. Foster, with the Medicare, in Medicare has testified before the House Budget Committee that that would not be the case, that people would not be able to keep the insurance they had. Is he wrong?

Mr. LARSEN. I have to confess that I am not familiar with the testimony that Mr. Foster gave I guess recently in front of the committee. I know that our view is absolutely people can keep the care that they have. They are doing it now. I think they will have in 2014.

Mr. GARDNER. So your Office is in charge of implementation in many of these things that we went through, and Mr. Burgess went through a long list with you, Mr. Angoff, of what responsibility your Office had. You don't communicate with the Chief Actuary of Medicare?

Mr. LARSEN. I am not saying that I do or don't. I am just not familiar with the testimony that he gave, and I apologize for this particular——

Mr. GARDNER. Has the Chief—had Medicare, has he expressed concern that—he actually made two statements. He said that it probably won't lower costs and that it will not allow people to keep their insurance. Have they expressed that to you?

Mr. LARSEN. I haven't heard that from Mr. Foster, but, again, we are 2 weeks into this transition so——

Mr. GARDNER. How long has your Office been open?

Mr. LARSEN. We have been in——

Mr. ANGOFF. Since April 19. Rick Foster is the Actuary for Medicare, not for the Office of Consumer Information and Insurance Oversight.

Mr. GARDNER. Right, but do you not communicate with Medicare in terms of what is happening with the Health Care Bill? That is the Chief Actuary who said that these two primary tenants of the Health Care Bill aren't going to come true. That is pretty significant, is it not? Yes or no?

Mr. LARSEN. Like I said, I apologize. I would be happy to go back and review his statements with regard to the area. As Jay said, he is the Medicare Actuary. We are the private health insurance market coming into CMS, so we will go back and read his testimony.

Mr. GARDNER. Mr. Angoff, that is a pretty significant difference of opinion, isn't it?

Mr. ANGOFF. Opinion is probably the right word. These actuaries make predictions. Sometimes they pan out, sometimes they don't.

Mr. GARDNER. And so you are just betting that he is wrong and you are right?

Mr. ANGOFF. Again, I haven't seen—I am unfamiliar with the specific testimony that you are referring to.

Mr. GARDNER. So do you think he is wrong, that people will get to keep the insurance that they currently have?

Mr. ANGOFF. Well, people are getting to keep the insurance they currently have. We have got to keep in mind there are 50 million people today without any insurance at all.

Mr. GARDNER. That is not what he said. He said that it is doubtful that they won't be able to keep the insurance that they have. That is his testimony before the House Budget Committee. Was he wrong?

Mr. LARSEN. I don't know. I have got to take a look at it.

Mr. GARDNER. Before you if you look into your document file, you will notice that there is a letter from the Aspen Skiing Company. It is in the document tab that you should have. The document states at the bottom that compliance with the PPACA would cause the cost to increase substantially, which would render the plans unaffordable. Is that correct?

Ms. VOICE. Document 20 I believe.

Mr. GARDNER. I am sorry. Yes. Document 20.

Mr. ANGOFF. I am sure it says what you say it says.

Mr. GARDNER. And this company did receive a waiver. Is that correct?

Mr. ANGOFF. I would have to look at the list. I can do that if you want.

Mr. GARDNER. Well, they did, and so there are seasonal employees at the Aspen Skiing Company. The letter states that 800 full and part-time employees during the summer go to 2,600 employees in the winter season——

Mr. ANGOFF. Yes.

Mr. GARDNER [continuing]. And that is what it talks about. So in 2014, what happens to the Aspen Skiing Company? They will go into the exchanges. Is that correct?

Mr. LARSEN. There will be a number of options for the employees of the company, and they will have an opportunity to get fuller health care coverage than they probably have today.

Mr. GARDNER. And do you believe that the ski resort knows what is best for their employees?

Mr. LARSEN. I don't understand your question.

Mr. GARDNER. I mean, do you think that the operator of a ski resort is better equipped to determine the health care needs of their employees than the Federal Government?

Mr. LARSEN. Well, I don't know who is best equipped to make that decision. I know that——

Mr. GARDNER. So the answer is, no, you think the government may be better equipped than the Aspen Skiing Company?

Mr. LARSEN. No. I don't think that is what I am saying. I think, what we want is, we want people to have full coverage, and my guess is that the employees of Aspen would like to have full coverage as compared to limited coverage.

Mr. GARDNER. So the letter says the plans are specifically designed to meet the needs of seasonal and part-time employees.

Mr. LARSEN. Right. That is typical of the applicants that we get for annual limits waivers. This is probably a very typical application. It is part-time coverage, seasonal coverage.

Mr. GARDNER. So they might be wrong, though? I mean, we think the Federal Government might know better how to provide coverage for those employees?

Mr. LARSEN. No. I don't think that is what we are saying.

Mr. STEARNS. The gentleman's time has expired.

Dr. Gingrey, you are recognized for 5 minutes.

Mr. GINGREY. Mr. Chairman, thank you, and to the witnesses let me apologize for not being here earlier. We have got concurrent subcommittee hearings, both extremely important, and this obviously is an extremely important hearing for me as a position member of the subcommittee and obviously the issue of the area which you have jurisdiction over regarding the Patient Protection Affordable Care Act is extremely important to all committee members.

I think I will focus my attention on the Class Act. I don't know whether that has come up in—from previous questions, but I am very concerned about the Class Act, particularly in reference to information that has come out recently in regard to the unsustainability, the non-viability of the program as it is designed in regard to the monthly premiums and the benefit package.

In testimony before the Finance Committee yesterday, in fact, Secretary Sebelius admitted that long-term care insurance program created by Obamacare called the Class Act, is totally unsustainable I think she put it. This statement mirrors similar remarks made by the Chief Actuary of CMS, Rick Foster, when he testified before the House Ways and Means Committee a couple of weeks ago. In fact, the President's Deficit Reduction Commission even cited the need to dramatically change or even repeal the Class Act because they also found the program completely unsustainable as currently proposed.

Mr. Larsen, the President's budget proposal asks for $13.4 million for an IT system and another $93.5 million for information, education in order to sign American workers up for the Class Act.

So yes or no, if you will. In light of the Secretary's statement and those posted on your Web site, do you believe the Administration should provide proof to the American people before your agency begins signing them up for the Class Program?

Mr. LARSEN. Well, if I could answer this way, and I hope you will accept my apology, the Class Act is not actually part of CCIIO or OCIIO, so we don't oversee the Class Act. In fact, I am aware of the issues that you raised, and I know the Secretary spoke about this yesterday, but it is not in the purview of the——

Mr. GINGREY. Do you have an opinion on that? Can you answer that question yes or no?

Mr. LARSEN. Well, I am not familiar with the issues surrounding——

Mr. GINGREY. All right. Mr. Angoff, do you have an opinion?

Mr. ANGOFF. No, I don't. The Class Act is part now of the Administration on Aging, and so it is under their jurisdiction.

Mr. GINGREY. Well, given the Secretary's dire warning and should the Secretary not listen to reason, will the Center for Consumer Information and Insurance Oversight, that is you. Right? Include a disclaimer in its education material to workers stating clearly that the Class Act is not sustainable? It is unsustainable?

Mr. LARSEN. I would be happy to look at whatever proposal there is on that.

Mr. GINGREY. Again, you are punting on this.

Mr. LARSEN. I am punting.

Mr. GINGREY. Mr. Angoff, would you like to take the ball and run with it?

Mr. ANGOFF. No, I wouldn't.

Mr. GINGREY. You are also a punter. Well, look, let me just comment then, Mr. Chairman, in the remaining time that I have left since these gentlemen have stated that this is not under their purview and they don't want to express an opinion, and I certainly will express an opinion.

Back in, I guess it was in the late '80s when we had the bill that was enacted, catastrophic coverage under Medicare forced on the American people, and the seniors just went nuts when they found out what it was going to cost them in regard to their part B premiums, and then Ross Stankowsky I think almost had his automobile destroyed in downtown Chicago with umbrellas over that bad piece of legislation.

This is the kind of thing that—why we feel so important to have the oversight on every aspect of this bill, all 2,400 pages of it, PPACA, Obamacare, however you want to call it, Patient Protection Affordable Care Act, but this is one I think that is very important, even though it is not under your authority specifically, that the committee, the subcommittee understands that something like the Class Act, it was just part of so much of this bill that was thrown together just to get it passed so that hopefully after people read the bill they would come to like it.

They are not going to come to like the Class Act, and hopefully we are not going to spend $100 million putting it into effect.

Mr. Chairman, I will yield back.

Mr. STEARNS. Thank the gentleman. The gentlelady from Tennessee is recognized for 5 minutes.

Mrs. BLACKBURN. Thank you, Mr. Chairman. I want to go back to Mr. Larsen's answer to Mr. DeGette.

You continue to talk about, well, come 2014, you are going to have all of these wonderful benefits, it is going to be better, it is going to be fuller coverage, and, sir, I just have to tell you this is our concern. We have lived through this in Tennessee, and it does not work. You cannot incentivize use, and there is no way to pay for it. Doing this investment on the front end and expecting to get savings on the back end, it doesn't work. And I have got plenty of charts here that show you what happened in our State.

Now, what you have not been able to define for me is how do you plan to pay for it? What is going to happen to these innovative plans like CoverTN when you get to 2014? How, you know, you talk about this exchange market, but I have to tell you, sir, unless you can point to a pilot project that has worked, the examples that are out there now do not work. You are speaking on theory. Is that not correct? Your statement to me was Obamacare would work. This plan would work, but you have no data to back it up. You have no analysis that says, we ran this program, and we looked at it, and this worked.

So, we are looking at this, and we are shaking our heads. In 2014, the CoverTN Program would cease to exist. Is that not correct?

Mr. LARSEN. If I can respond this way, we know the system prior to the passage of this bill was broken. Fifty million people without insurance. I think there were——

Mrs. BLACKBURN. Sir, I am not even going to—I am going to jump in, and it is not out of disrespect. It is just that you are talking apples and oranges. There are reforms that need to be placed. People want them to be in place as free market, patient-centered reforms. When you have tried a public option health care system, see, you are avoiding my question. You cannot give me an example of where public option health care has worked successfully, and that is because you don't got one.

Mr. LARSEN. Well——

Mrs. BLACKBURN. As they say in Tennessee. You just don't. Let me go onto something else.

When we are looking at the Center moving from HHS to CMS, when was that—why was the decision made? When was that decision made?

Mr. ANGOFF. I am sorry. When was it made?

Mrs. BLACKBURN. Why and then when?

Mr. ANGOFF. Oh. The reason it was made is that it made sense to have a separate organization reporting directly to the Secretary that had to do a lot of things quickly as an independent organization. Once all——

Mrs. BLACKBURN. OK. Who was involved in the decision making?

Mr. ANGOFF. Sorry?

Mrs. BLACKBURN. Who? Who was involved in the decision-making process, sir?

Mr. ANGOFF. Several people at HHS. I don't know.

Mrs. BLACKBURN. Several people at HHS. Would you please supply me with a list of those that were involved in that decision making?

Mr. ANGOFF. Yes, I will.

Mrs. BLACKBURN. Thank you very much. And why did you not start the Office in CMS?

Mr. ANGOFF. Because it was—we had a lot to get done in a very short time, we needed a mechanism to do it, we thought——

Mrs. BLACKBURN. OK.

Mr. ANGOFF [continuing]. The best way to do it would be to have an independent organization.

Mrs. BLACKBURN. OK.

Mr. ANGOFF. Now that it has matured and all the major regs——

Mrs. BLACKBURN. All right, and then when did you decide to move it?

Mr. ANGOFF. In December, late December.

Mrs. BLACKBURN. OK. Mr. Chairman, I would like to submit for the record the letter from Secretary Sebelius on January 5, 2011, writing to inform that they were moving it to CMS. I find that date to be a little bit curious.

Mr. STEARNS. Without objection, so ordered.

[The information appears in the document binder at the conclusion of the hearing.]

Mrs. BLACKBURN. Thank you, sir. Was any discussion had about the fact that by moving the Center into CMS where funding is directed for Medicare and Medicaid that it would either better protect or give less subject to oversight or be harder to de-fund that, and would it allow you to run that office more along the vein of the 1115 Waiver Program that Tennessee operated TennCare under which put the feds in control of how a State would deliver their program and basically took those State lawmakers out of the process, basically handed State lawmakers the bill, and said, here you go. The feds say you have to fund it.

You know, I find it so curious you did this, and then I look back at what has transpired in our State and when I was in the State Senate there, and we were trying to figure out how to pay for this program and then I went back and read the statement from our former Governor who said this would be the mother of all unfunded mandates, and you know what, I am beginning to think they are about right on that.

What was your decision for moving that?

Mr. ANGOFF. I am sorry. What was the question?

Mrs. BLACKBURN. What was your decision matrix for moving it? Why did you move it?

Mr. ANGOFF. There are efficiencies to be gained by merging the two organizations, functions such as——

Mrs. BLACKBURN. I thought you just told me you wanted it over there because it would be an independent organization and not tied to HHS.

Mr. ANGOFF. At the beginning.

Mrs. BLACKBURN. Did it have anything to do with funding?

Mr. ANGOFF. No.

Mrs. BLACKBURN. Could it easier to protect? Would it eliminate oversight? Would it tie the hands of State Legislators?

I yield back.

Mr. ANGOFF. No. It was a question of efficiencies. There are overlapping functions, budget, grants, personnel, external affairs, IT. Now that the regs have been adopted and the programs established, there are efficiencies to be gained by merging the two organizations.

Mr. STEARNS. I thank the gentlelady. The gentleman from Virginia is recognized for 5 minutes.

Ms. DEGETTE. Mr. Chairman, before the gentleman——

Mr. STEARNS. Sure. Point of——

Ms. DEGETTE [continuing]. I would just like to note—move to strike the last——

Mr. STEARNS. Right. Or a question of personal privilege.

Ms. DEGETTE. I just want to note that we have now had two rounds of questions——

Mr. STEARNS. That is correct.

Ms. DEGETTE [continuing]. And the Chairman is proceeding to the third round of questioning.

Mr. STEARNS. That is correct.

Ms. DEGETTE. I object to that because I believe these witnesses have thoroughly and adequately answered all of the questions put to them regarding their agency and the waivers that have been granted, and I think now what we are moving into is the majority is using this hearing as a way to attack the Affordable Care Act, and frankly, I think it is abusive to the witnesses.

Having registered that objection, you are the Chairman. You are going to do what you want, and I will reserve any time I have in this third round of questioning until the conclusion.

Mr. STEARNS. And I thank the gentlelady. You know, this is our first hearing really. We have only been here 2½ hours for this huge new government program, so I think Members having a chance for the first time to do this is very reasonable, and I think the witnesses are doing an adequate job as best they can to explain it, and I think it is worthwhile to Members who perhaps had not been able to ask questions, come back, and so we are going to continue.

So, Mr. Griffith.

Dr. BURGESS. Mr. Chairman, if I might——

Mr. STEARNS. Sure.

Dr. BURGESS. [continuing]. Just make a point of personal privilege——

Mr. STEARNS. Yes.

Dr. BURGESS. [continuing]. As well, it is far less abusive to not make the witnesses listen to opening statements from every member of the committee as we did during the last Congress.

I will yield.

Ms. DEGETTE. I will agree with that.

Mr. STEARNS. I think Ms. DeGette will agree with that.

The gentleman from Virginia.

Mr. GRIFFITH. Just to note, this is only my second time, but anyway—no, no. I was here. I just didn't get my first and second—I was here. This is just my second, though, and I am the last one, but it is only my second time.

We talked earlier, Mr. Angoff, about the $33.4 million in expenses and that that came out of the $1 billion appropriated or that was mentioned in the Act.

Mr. ANGOFF. Yes, sir.

Mr. GRIFFITH. And at one point in the questioning with someone else you indicated that there were three sources of money from which you could get your funds, the $1 billion in the Act, the high-risk area, and the early retirees. And when I asked the question, and I am not trying to make any accusation, I am just saying that you said there was $33.4. Did that include all the pots of money or just the billion?

Mr. ANGOFF. No. That $33.4 million is only out of the billion.

Mr. GRIFFITH. What monies came out of the other two sources?

Mr. ANGOFF. There is additional money coming out of those two sources, and I don't have that with me.

Mr. GRIFFITH. Can you get that for us?

Mr. ANGOFF. Absolutely.

Mr. GRIFFITH. OK, and I do appreciate that there were additional monies.

Now onto the $1 billion it is interesting because the waiver program, can you tell me how much just the waiver program costs?

Mr. ANGOFF. No, I can't.

Mr. LARSEN. I don't have that broken out by the staff that work on the waiver program compared to the entire $33 million. We can, you know, try and get that to you.

Mr. GRIFFITH. If you can do that for me, I would appreciate it, and here is the point, and I touched on this in my previous questioning. We have got this giant Act. Now, while it does have the catchall that the Secretary has the authority to, you know, implement, and it has the $1 billion in the back of it, it doesn't actually have waiver in here.

And I guess my problem is is that one of the things that I fear is is that part of the distrust that people have in general is that when you have a gigantic Act it is hard to figure it out, and then you can't find things, and it looks like to me what we have done is we have built a program based on the Secretary's authority to try to implement the law and then we have bootstrapped back in that she can use the $1 billion to implement the law, but we have got layer upon layer of interpretation, and that might be OK if this was a 5-page bill and you could say, well, we couldn't get it all in here, but I mean, we have got this, you know, it is a textbook in length. It is 1,000 pages this way. It was more than 2,000 pages when it was in bill form.

And so I just have great concerns that we are building assumptions on top of assumptions, and it may very well be the fault of Congress for not having been specific in past years going back not just during this bill but many other bills, but it seems to me that we are the ones that ought to be making the laws and that if there is something that is unclear, it ought to come back to the Legislative Branch. In this case that would be United States Congress.

And I just wonder if you had any comments on that.

Mr. ANGOFF. Just this. On the waiver issue there is language there that makes it clear that statutory language, not regulatory language, in the statute that says that the restricted annual limits should be interpreted in a way so that people can keep their coverage. Everything that we have done is done pursuant to specific language in the statute.

Mr. GRIFFITH. Well, and I guess the concern that I have is we are spending money to notify folks of part of the program, but we are not spending money yet to let folks know about the waivers, as I mentioned earlier, and while we have given McDonald's a waiver, I don't know how they work their system, but I have a letter from a constituent of mine who owns several Burger King establishments. He is panicked about how this is going to impact him, and I, of course, as soon as I get back to the office I will notify him of the waiver program. I am not sure he knows about that.

And so, that is what happens when you make things so complex, and you can't find it in the written word. You have to go to an assumption made on an assumption made by an attempt to try to implement something that apparently the legislation wasn't crafted as well as maybe it should have been. I wasn't here, so I didn't take part in that, but it just seems to me that there is an awful lot of confusion out there, and we are spending money on some things based on assumption what we are supposed to do, and we are not spending it on others. And it would seem to me that we would want consumers to be aware of the waivers as well as to be aware of knowing how they get into any of the other programs.

I yield back the remainder of my time, Mr. Chairman.

Mr. STEARNS. I thank the gentleman. I dare say that if you took an ad and put it in the Final Four basketball, announcing to the American public that they can receive waivers from the Obamacare, I think you would be offering waivers well in adjustment of 915, because I think as the gentleman from Virginia had indicated, a lot of people don't know that you can get these waivers, and they are not going to your Web site.

But lo and behold if you told all 50 States in a very clear manner and you told all the corporations in America that they could get a waiver, I think everybody would do that, and they would want to waiver every year, and they would want to waiver in 2014.

The ranking member mentioned about the new tools coming on in 2014, and Mr. Larsen consumed a little bit of time talking about the ranges of these new benefits, but I guess, Mr. Larsen, who is going to pay for those benefits? Because the benefits are all inclusive, and lo and behold, the taxpayers or the corporations are going to have to charge more money.

And she also indicated that she was concerned about recently that a lot of sick children were not being insured, but—before Obamacare, but the reason a lot of people now are pulling back is because, frankly because they are concerned about these benefits going from $750,000 up to $1.2 and $2.2. I mean, that is a little bit of a chilling factor for a lot of companies, so they are deciding that they don't want to insure, and I don't think they know about the waivers.

I guess I want to ask you a little bit of question, Mr. Larsen, about some of the spending here. How much money in total has HHS spent so far in setting up and operating your Office? Can you just give me an estimate? Just approximate.

Mr. LARSEN. Yes, and I think Jay touched on this earlier, of the $1 billion that was appropriated at the outset of the implementation of the ACA——

Mr. STEARNS. So it is about a billion dollars?

Mr. LARSEN. Well, that—no, no, no.

Mr. STEARNS. OK.

Mr. LARSEN. Thirty-three million is the answer——

Mr. STEARNS. OK.

Mr. LARSEN [continuing]. Spending to date for OCIIO, now CCIIO.

Mr. STEARNS. So $33 billion——

Mr. LARSEN. Million.

Mr. STEARNS [continuing]. From all sources.

Mr. LARSEN. I am sorry. Did I say billion?

Mr. STEARNS. Billion?

Mr. LARSEN. No, $33 million——

Mr. STEARNS. Thirty-three million.

Mr. LARSEN [continuing]. Out of the $1 billion.

Mr. STEARNS. All right. I respect that. OK. Now, I think our staff is a little non-plussed here because $33 million seems like a pretty small amount. Does this include all the sources of funding?

Mr. LARSEN. Well, that is essentially to operate the 252 and the programs. I think this was earlier——

Mr. STEARNS. Two hundred and fifty-two employees out of Bethesda?

Mr. LARSEN. Right.

Mr. STEARNS. Are they still out in Bethesda?

Mr. LARSEN. Yes.

Mr. STEARNS. OK. You seem a little puzzled. Have they moved since you left? You were a little puzzled.

Mr. LARSEN. I didn't know whether you knew something I didn't. No. They are still out there.

Mr. STEARNS. OK. How did HHS come up with $465 million for implementation of the President's budget for HHS? Do you know that?

Mr. LARSEN. Well, I know——

Mr. STEARNS. Either one of you know that?

Mr. LARSEN [continuing]. Generally, the breakdown, because I know which part is attributable to the CCIIO-related activities. There is about $94 million for oversight and consumer information, which includes the Healthcare.gov Web site, which is a fantastic consumer tool. People can go in today and find out what policies are available to them, what coverages, what options are available. So it includes that money. There is consumer assistance, setting up the appeals unit again, so consumers that have been denied, they are going to have an appeal process.

So there is $94 million associated with all of those activities and then, of the $400 million figure you mentioned, there are exchanges. We are now standing up the exchanges. We have got IT programs that we have got to get up and running.

Mr. STEARNS. Yes.

Mr. LARSEN. So I think that is the composition of the request in the President's budget.

Mr. STEARNS. You asserted that these waivers are necessary between now and 2014, to help people retain their coverage until they have access to comprehensive coverage through the exchange, but isn't it true that these plans and employers have access to comprehensive coverage now, but it is just too expensive and so that the employees themselves choose a lower-cost plan?

Mr. LARSEN. Well, it is a good question. It is not always clear why employers offer different levels of coverage and, certainly, in some cases, they are aware that their employees can only afford—because they may be part-time workers or seasonal workers, can only afford benefit packages that have limited benefits.

So, that is what we know today. There is a range of options——

Mr. STEARNS. Yes.

Mr. LARSEN [continuing]. But sometimes many of them aren't affordable. In 2014, I think we are going to have a better set of options available for employees and employers.

Mr. STEARNS. I guess the question is do you and perhaps Mr. Angoff think that the comprehensive coverage that we mandated in 2014, through the exchanges or offered by employers, do you think they will be less expensive and more affordable than it is today? Based upon what we are saying and all these waivers and——

Mr. LARSEN. Yes. You know, there are——

Mr. STEARNS. Don't you think——

Mr. LARSEN [continuing]. Offsetting factors at play because, when you bring, when you expand the insurance pool, you are going to bring down costs because now you have a full pool, and the exchanges also reduce administrative expenses because all the time and money that insurance companies spend today underwriting people and trying to figure out how not to provide coverage with the—without having the pre-existing condition, having a pre-existing condition exclusion ban, so there are a number of factors that help to bring the cost down in 2014. I think that was referenced even in the——

Mr. STEARNS. Mr. Larsen, in all deference to you, you say these based upon your opinion, that you think that it will bring the cost down and so forth, but if you look at countries that have a government universal health care plan, the costs have not come down, and in fact, the costs have gone up, and many countries now are trying to get from out—from underneath the universal government health care. And there is a long line.

So is there any study or any analysis that you have done to corroborate what you have just indicated that you think——

Mr. LARSEN. Well, I know——

Mr. STEARNS [continuing]. Through this universal magic wand that everybody is going to get cheaper and more coverage.

Mr. LARSEN [continuing]. Even—back to your earlier question——

Mr. STEARNS. Because, see, basically, in my opinion you are putting price controls by—people are asking for waivers because you are putting in price controllers. You are saying basically these people got to comply with this or else, and those people are saying we need waivers.

So it is a form of price control. You might not agree, but when you do that, then what happens is you don't have the opportunity for the market to bring it down because the government is putting all these mandates down.

So I am just philosophizing——

Mr. LARSEN. Well, I think——

Mr. STEARNS. So the question is, do you have an analysis to show, to back up, corroborate what your analysis is?

Mr. LARSEN. Well, here is what we do know.

Mr. STEARNS. Do you have an analysis?

Mr. LARSEN. Consulting firms like Hewitt and Mercer looked at the impact of the ACA on employer-based coverage and found the impact might be in the 1 to 2 percent range, because most coverage is meeting the requirements of the ACA, but we want to raise the bar for everyone——

Mr. STEARNS. OK.

Mr. LARSEN [continuing]. So the financial impact on premiums has been in the 1 to 2 percent range, and that is offset by the benefits that consumers get. They don't have cost sharing now for preventative services. So their out-of-pocket expenses are much less now than they were before the passage of the——

Mr. STEARNS. All right. My time has expired.

Dr. BURGESS. Thank you. Just a couple loose ends to tie up, and it may not even take the full time.

There was some discussion, Mr. Stearns, and you with Ranking Member DeGette about new tools versus new benefits. New tools, one thing, new benefits certainly are a cost driver, so when you flip the switch in 2014, and all the lights do come on on all the new benefits, it is—there is going to be increased cost.

So have you done an economic analysis on what is going to be the effect on companies that are having difficulty meeting the financial obligation today and require a waiver, they have got new tools or new benefits, which means new costs? Have you done an economic analysis, or can you point us toward a single study that shows how that is going to work?

Mr. LARSEN. I know it is subject to disagreement, but the CBO estimated that the bill is going to lower overall health care costs for many of the reasons that we have talked about.

Dr. BURGESS. Well, OK. So they did, and that is the point of some disagreement.

Actually, I had a resolution of inquiry the last Congress and had the Democratic Chairman accepted it, we could have had Mr. Foster in to talk about just that, because I was concerned that Congress voted on a bill without knowing the actual cost. Mr. Foster—Mr. Elmendorf had dramatically different cost estimates, about a $450 billion spread over 10 years as I recall, and that was pretty significant.

But we never got an opportunity to do that. Perhaps, Mr. Chairman, we will get to do that make up.

Now, Mr. Angoff, you actually said that I was mischaracterizing things when I said that the Office of Consumer Information and Insurance Oversight skimmed from the appropriations, the $1 billion for appropriations when you were setting up the Act. So let me rephrase my question so it won't be a mischaracterization.

Would it be inaccurate for anyone to say that, for example, $5 billion was set aside for subsidizing the high-risk pools?

Mr. ANGOFF. No. That is accurate.

Dr. BURGESS. But because you used some of that figure for your Office for start-up costs, then the entire $5 billion was not available, was it?

Mr. ANGOFF. And that is the intent because the language says $5 billion is authorized to carry out the provision.

Dr. BURGESS. Oftentimes we have a limiting amount that only 5 percent can be used for administrative function, but there was no such limitation in this case, was there?

Mr. ANGOFF. That is right.

Dr. BURGESS. So, again, I point to the fact that it would be great to have that budgetary information, that detailed budgetary information.

Now, you were hired a year ago as we have already established, and you were involved in the outline of the development of the creation of OCIIO, the predecessor of CCIIO or whatever it is. I get confused. Who appointed you?

Mr. ANGOFF. The Secretary.

Dr. BURGESS. And who advised the Secretary on the creation of the Office of Consumer Information and Insurance Oversight?

Mr. ANGOFF. I did not.

Dr. BURGESS. Do we know who?

Mr. ANGOFF. I don't know.

Dr. BURGESS. You had a Deputy at the time. Was the Deputy involved in providing that advise to the Secretary?

Mr. ANGOFF. My Deputy?

Dr. BURGESS. Yes.

Mr. ANGOFF. Not to my knowledge.

Dr. BURGESS. Well, who decided that it was a good idea to put it in the Secretary's office?

Mr. ANGOFF. I don't know.

Dr. BURGESS. Well, we have already established that there was a reason then to move it to CMS. Mr. Larsen, can you help us with that just a little bit more why it was so important to have it freely mobile within HHS at one point and then suddenly bring it under the control of CMS?

I got to tell you with all due respect it does look like we were trying to move things around, and it was because this committee indirectly started asking questions about what was happening and beginning to shine a little light on the activities, because I got to tell you, most members of Congress were blissfully unaware, Mr. Angoff, of your activities last fall.

Mr. LARSEN. I would characterize it this way. I hope this is helpful. It is kind of the difference between a startup and then running the operation. They had to start this thing up from scratch.

Dr. BURGESS. And I don't dispute that, but it is just interesting that after the questions started to get asked when the discussion was made——

Mr. LARSEN. They weren't connected. We concluded that——

Dr. BURGESS. Let me ask you this, Mr. Angoff. We had a nice discussion in November, and I was concerned, if I got a constituent back home that says, well, I want one of these waivers, how do I get one? And it actually wasn't available on the Web site that, at that time. It was shortly after our visit that that information did become available on the Web site, so I am greatly appreciative that you did that, but as you were developing this, why was there not more thought given to how do we get this out to just the regular guy on the street who may run a small business or a restaurant or may need this waiver?

Mr. ANGOFF. Well, we did give it some thought. As you said, it is on the Web site now. It is a transparent process, and we think it has worked well.

Dr. BURGESS. But, again, this was all in the works for some time, and it just strikes me as odd that you wouldn't have had that one simple feature out there early on to make this more accessible to more people. Obviously it is a very popular waiver program, very

popular, and many people want to participate in it, and again, I dare say they will still want to after 2014.

Mr. Chairman, I yield back.

Mr. STEARNS. All right. Mr. Griffith from Virginia is recognized for 5 minutes.

Mr. GRIFFITH. Thank you, Mr. Chairman. Let me ask you this in regard to the shift. I think I heard earlier that part of the reason for that was that there were would be efficiencies gained. I have also heard there were 252 employees. I am wondering how many employees have been let go or been transferred subsequent to the shifts in the attempt to make efficiencies.

Mr. LARSEN. Sure. Well, I guess a couple of answers. One, we are in a 60- to 90-day transition period. We have a transition team from CMS and a transition team from our shop working together to nail down these efficiencies. We don't anticipate laying people off, but as Jay mentioned there are certainly areas where we don't—we are not going to staff up in the future, for example, and we have got to figure out what exactly that staffing level is going forward.

So we are right in the middle of that process from a staffing perspective.

Mr. GRIFFITH. So you made the move for the efficiencies, but we don't know what—how much you are going to——

Mr. LARSEN. Well——

Mr. GRIFFITH [continuing]. How many employees you are going to be able to save, how many spots you are going to be able to reduce?

Mr. LARSEN. Well, let me rephrase that. We are not talking about necessarily reducing—meaning laying people off. I mean, we have told our people we are not laying people off, but as attrition comes in and as we get efficiencies with the budget people and with the legislative office and with the programs office, there is——

Mr. GRIFFITH. So you are planning to do it through attrition, but do you have any idea what your target—how many——

Mr. LARSEN. That is—no.

Mr. GRIFFITH [continuing]. Spots you wish to get of?

Mr. LARSEN. That is what we are working—we are, literally as we speak, working through the exact components.

Mr. GRIFFITH. And I am new to the Federal Government but wouldn't it make sense to have some idea of what—how many folks or how many spots you were going to eliminate if the reason for shifting was efficiencies——

Mr. LARSEN. Well, we didn't——

Mr. GRIFFITH [continuing]. Before you made the shift?

Mr. LARSEN [continuing]. Go in with a hard and fast number about what we want to save. We clearly understood as we were continuing to stand up OCIIO,and that we need to have functions here, and that CMS has those functions, and those——

Mr. GRIFFITH. Let me shift gears.

Mr. LARSEN. Sure.

Mr. GRIFFITH. Isn't it true that the employers' plans which have received these waivers are likely to drop coverage for their employees is no longer affordable in 2014, finding it cheaper to pay the penalty, if applicable?

Mr. LARSEN. I don't think so.

Mr. GRIFFITH. Well, the CBO estimates approximately three million employees will be dropped by their employers into the exchanges, and in that circumstance won't the individuals be forced to buy a more comprehensive plan at a greater cost to themselves and at a greater cost to the taxpayer if that premium then has to be subsidized through the exchange?

Mr. LARSEN. Well, they will have an option for better coverage, and if they meet the guidelines for subsidies, then they will have the opportunity to get that coverage, but that is paid through the various sources as you know, the funds, the Affordable Care Act.

Mr. GRIFFITH. But isn't it correct that if there are, in fact, three million employees that are dropped, that that is going to put some burden onto the exchanges and the subsidies?

Mr. LARSEN. Well, it means there would be more people there, but I think, as we have talked about, there are a number of aspects of the ACA that reduce costs overall, so I think those costs are going to be manageable and affordable for people in those policies.

Mr. GRIFFITH. But as Mr. Angoff said earlier when he didn't like somebody's opinion, actuaries just give you opinions and then you have to see if they are right. This would also be the case with what you have just said. We have to see whether or not those actuaries are right, and many times they are not. Isn't that correct?

Mr. LARSEN. Well, if you have two actuaries, there is always the possibility——

Mr. GRIFFITH. One of them is going to be wrong.

Mr. LARSEN. Right.

Mr. GRIFFITH. I yield back my time.

Mr. STEARNS. I thank the gentleman. Before I recognize the gentleman from New York for 5 minutes I ask unanimous consent to put this into the record, a letter from Kathleen Sebelius.

Without objection, so ordered, and it is dated January 5, 2011.

[The information appears in the exhibit binder at the conclusion of the hearing.]

Mr. STEARNS. The gentleman from New York is recognized for 5 minutes.

Mr. WEINER. Thank you, Mr. Chairman. I have been watching with some interest in—my office has been trying to do the appropriation bill on the floor at the same time.

I just want to try to set this up a little bit. You know, we have this tendency to believe that this debate is about health care, and to some degree it is, but what it is really about is how we pay for the health care we get. I mean, isn't it true, Mr. Larsen, that if someone is struck by lightening and they are lying on the street, that an ambulance will come and pick them up, that a doctor will try to resuscitate them, if they need surgery, they will probably get it, but the question becomes how it is we pay for that care and how we insure certain minimum standard of care.

Is that right, Mr. Larsen?

Mr. LARSEN. That is correct.

Mr. WEINER. And are there not really three possibilities? One is the employer-based model, which is we pay premiums to an insurance company, they set the rules, they set the standards, we go to them, we pay them, and they pass the money along to the hos-

pitals, to the doctors, to the ambulance driver, and then they take a certain amount of profit.

The second model is the one where basically you don't have a private company passing along costs. A government agency kind of does that. For example, Medicare is like that. No government officer, Mr. Larsen, is paid to be the doctor. It is just a matter of how we are paid for that care.

And then there is the third traunch of people which have no coverage whatsoever. They are the people that don't have any insurance whatsoever, and we hope and hope and hope they have money in their own pocket to pay for that care, but if they don't, isn't it true, Mr. Larsen, that what would wind up happening is we are stuck with some tough choices. We can say to the hospital doctor, tough. You got to suck it up, and sometimes hospitals go out of business. We lost 17 hospitals, Ms. DeGette, in New York just since the year 2000.

Or we can say, you know, let us come up with some kind of reimbursement program, own reimbursed care. Different States have different rules, the Federal Government has different rules. Or we can do this. We can say to the taxpayer, why don't you pay it, and we will figure out later on how we need to work that, and that is why States get stuck with such a large cost, localities get stuck with large costs.

When we had this discussion about how to come up with a system for dealing with those people that are uninsured, what did we do? We didn't go for the model that someone like I would have liked, which is let us say like Medicare, for more Americans, eventually covering all Americans. We went with basically a free-market model and said, let us try the employer-based system. Let us try to offer people both incentives, subsidies, and then if they don't do it, we are going to say to them, you know what? You can't pass your bills along to everyone else. You are going to have to pay a little extra if you are going to do that.

Wasn't it, in fact, the system that we set up a reliance upon the market-based model, the free-market model that says insurance companies, you go do this work? Wasn't that basically the path we followed here, Mr. Larsen?

Mr. LARSEN. Yes.

Mr. WEINER. And further, Mr. Larsen, do not insurance companies, and they are not venal people. They are in a business. They are in a free-market business. Do they not make the most profits if they take in the highest amount of premiums and pay out the least amount in care? Don't they then make the most profit?

Mr. LARSEN. Yes.

Mr. WEINER. And isn't the model today structured to incentivize them to do that? The problem is, Mr. Larsen, and Mr. Angoff, is that that model is not necessarily in the interest of our constituents or good care.

I will give you an example. What if they decide we don't want to cover preventative care, or we don't want to cover people for the entire life of their illness. We just want to cover the first couple of days. They are going to make more money. Their stockholders are going to do well. That company is going to do well, but it is not necessarily in the best interest of the American people, whether

you are in a Republican congressional district or a Democratic. Sometimes we want to say to them, you know what? We want to have some standards we want you to uphold. We don't want you to go out of business. We have socked it in on this process. We obviously want insurance companies to do well to make a healthy profit. We want them to be around for years to come.

But the question is should we say to them, maybe we should put basic requirements that if that guy is lying on the street, you can't look at him and say, oh, I don't think this guy is going to be a good deal and have the insurance company keep driving by. No, of course not. We got to be able to make coverage.

And you know what? They are doing remarkably well. Let us face it. If you bought insurance company stock at the beginning of the recent downfall, you would still be doing pretty well because people keep getting sick, people keep getting struck by lightning, people keep needing that care. They are doing OK. As a matter of fact, if you want to find the easiest, let us say $300 billion or so, you can take out, you can transfer in health care costs to better care and reduce taxes for people. You might want to look at the percentage of the health care budget that we put to insurance company profits.

So the idea that somehow government is coming in and imposing some government solution, there is not a single government doctor that has been hired, a single government nurse, a single government operator of an X-ray machine. But that doesn't mean we should simply say you are unfettered by any regulatory force.

For all of the talk about let us have transferring of being able to buy insurance policies over State lines, none of my Republican friends have said, let us get rid of State insurance commissioners and State insurance regulations because we acknowledge we need some basic regulations.

Mr. Larsen, is that basically in a broad form what your office has been spending part of its time doing?

Mr. LARSEN. Yes.

Mr. WEINER. Thank you, and I await a second round, Mr. Chairman.

Mr. STEARNS. All right. The gentleman has advocated strongly for Medicare as a solution, so he has made that argument all during our markups, and I think he—and I appreciate him coming down.

I think what we are going to do, we are finished the rounds. I thought the ranking member would have a chance to close, and then I would say a few——

Ms. DEGETTE. I would ask unanimous consent that——

Mr. STEARNS. Objection. Just let me just clarify. Generally when we do the rounds, a member has to be here. So—but if the member shows up in the beginning and then goes to the restroom and comes back, then that is OK, but if someone comes at the very end—I think your eloquent goes to the equivalent of three.

So at this point I think we are going to have—we have been here 3 hours, and we are going to let the ranking member conclude, and then I will say a few closing comments, and we appreciate the witnesses bearing through the rest of us.

Go ahead.

Ms. DEGETTE. Thank you so much, Mr. Chairman. I just have a couple of questions to clarify. I guess I would ask either one of you gentlemen, if this agency was moved because of any action that this Oversight and Investigations Committee or the Energy and Commerce Committee in general made?

Mr. ANGOFF. No, it was not.

Ms. DEGETTE. And why was it moved?

Mr. ANGOFF. It was moved because there are efficiencies to be gained, as we mentioned, in such functions as budget, personnel, external affairs, IT, and other front office functions. There are efficiencies to be gained.

Ms. DEGETTE. So it was actually done to make the program operate in a more efficient manner?

Mr. ANGOFF. That is correct.

Ms. DEGETTE. Now, there was some question about the agency's budget, and I just wanted to clarify. As I recall, the HHS overall budget request was about $79 billion, and from what I have heard is that your Office's budget, Mr. Larsen, is roughly about $330 million for 2012. Is that correct?

Mr. LARSEN. Yes.

Ms. DEGETTE. So of that amount that would—of the CMS budget, which, of course, is much smaller than the overall HHS budget, your budget request would be around $7.5 of the CMS budget request and less than one-half of 1 percent of the overall HHS discretionary budget request for 2012. Is that correct?

Mr. LARSEN. Correct.

Ms. DEGETTE. And what your agency is doing by giving these waivers, it is working with companies, both private companies and also group plans, to give them appropriate waiver so that they can give insurance to their employees during the gap between now and 2014, when those employees will be having more options. Is that correct?

Mr. LARSEN. That is correct.

Ms. DEGETTE. Mr. Chairman, I will yield my remaining 2 minutes to Mr. Weiner.

Mr. WEINER. While you are here, can you clear up a couple of things? I understand in the Health Care Act we hired 16,000 IRS officers. That is not true, is it?

Mr. LARSEN. I don't know.

Mr. WEINER. Yes. That was one of those made-up things. I actually wanted a couple of moments to tick off the made-up stories about the health care, but I realize 2 minutes and 48 seconds will barely tip the iceberg, but let me just—that is one of the stories that is made up,

Secondly, there is this notion about the Health Care Act that has been perpetuated widely that government is going and taking over health care, government takeover of health care is said over and over again.

Under the Act today, under the Act today, or under the Act when it is implemented, will there ever be a situation where there will be a government employee, a government employee telling a doctor what process or processes that they can offer to a patient?

Mr. LARSEN. Not to my knowledge.

Mr. WEINER. However, there still will be, because we have private insurance companies, still will be insurance companies that are going to have broad discretion to be jackasses with their customers. Right? You can't—there are still going to be people, they are still going to keep you on hold for hours. There is nothing in the bill that prevents that. Right?

Mr. LARSEN. If your question is does it preserve the private market for insurance companies, yes.

Mr. WEINER. Yes. You are much more delicate than I am, Mr. Larsen.

Let me ask you another question. There is this notion that we are paying a couple of years, we are paying 10 years of taxes for 6 years of service. Isn't it true that today as we speak that senior citizens have—that senior citizens are getting help reducing the cost for prescription drugs, the so-called donut hole? Isn't that true that that is true today, this second?

Mr. LARSEN. Yes.

Mr. WEINER. Is it also not true that under Medicare processes that used to be subject to a co-payment are now not covered—that now do not—or has that not taken affect yet?

Mr. ANGOFF. No, that is in effect.

Mr. WEINER. That has. That is today?

Mr. ANGOFF. Yes, sir.

Mr. WEINER. Year—basically year 1, week 1, month 1 of the new Health Care Act.

Let me finally ask you in the remaining 60 seconds about the idea of the death panel. What section or line is the death panel in? And just so you know, it was widely circulated by all kinds of media outlets and perpetuated by some members of this Congress that there was an effort going to be made in order to reduce end-of-life coverage. They were going to tell some people they could not get that coverage. Is that anywhere in the Act, anywhere in the regulation, or anywhere in the attempt of the law?

Mr. ANGOFF. No. I haven't been able to find it.

Mr. WEINER. Now, can I ask you this question. Is it also true that the way the private insurance model is supposed to work is that if you aggregate the cost on a wider population, meaning more people get private coverage, that in theory according to free-market principles that aggregation of cost means lower costs to the whole population?

Mr. ANGOFF. That is right. That is the fundamental principle of insurance. You spread the risk as widely as possible.

Mr. WEINER. Thank you very much, and I yield back what time is remaining.

Mr. STEARNS. All right. The gentlelady yields back, and we are going to conclude. I have, as Chairman I have the opportunity to offer a few closing comments.

I would say a question that, you don't have to answer but there is a competitive effectiveness for it which is part of this bill which is trying to determine efficiency of delivery, which is being construed by some as a case of cutting off certain services for, shall we say, medical practice.

But anytime you have a government mandate on insurance companies, you have a government mandate on employers and employ-

ees, that is considered a government-run system, and that is why in both the State of Virginia and the State of Florida they have ruled this mandate unconstitutional.

But I would just close with this comment. The New York Times recently reported on December 8, 2010, that you folks have leased an office in Bethesda and are, "paying almost double the market rate for the space." This is what the New York Times reported, and I assume that is true.

Mr. ANGOFF. No, it is not, Mr. Chairman.

Mr. STEARNS. It is not true. I will give you a chance to correct that——

Mr. ANGOFF. No, it is not.

Mr. STEARNS [continuing]. Because you think the New York Times is incorrect.

Mr. ANGOFF. In that case, yes, it is. The Bethesda office space was something that we didn't seek. We rented in Bethesda because the rates in Bethesda were lower, substantially lower than they were in Washington, DC, and in addition, there was the extra added bonus that the space there was already built out. We didn't want to go to Bethesda. We would much rather have preferred to be——

Mr. STEARNS. In Washington.

Mr. ANGOFF [continuing]. DC, but it was cheaper, and we could get it, get in there faster.

Mr. STEARNS. OK. So if I went to the landlord of that building you are in, they would lease it to me for the same amount that you are paying?

Mr. ANGOFF. I don't know what they would do.

Mr. STEARNS. So it is possible that you are paying, even though you are paying less than you would be in Washington, DC, you are paying more than the market rate for that Bethesda facility. I think that is what the New York Times——

Mr. ANGOFF. No, and I think——

Mr. LARSEN. I think that the error was that there is a difference between rentable space and usable space, and you get different rates based on whether it is, for example, ready to move in. So the market rate for rentable space, which is what my understanding is the GSA negotiated, was, in fact, the market rate for rental space.

Mr. STEARNS. Just giving you an opportunity. I just thought it ironic when we are trying to bring health care costs and the main core constituency that is deciding what the Health Care Bill should be is paying too high a market rate. So that is my only thought about it.

Let me just close by allowing all members to offer questions for a period of up to 10 days. If you have additional questions, you are welcome to offer those. I want to thank the witnesses for your participation, and without further ado, the Committee is adjourned.

[Whereupon, at 12:30 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

PREPARED STATEMENT OF HON. FRED UPTON

Thank you, Mr. Chairman, for convening our first oversight hearing on the Patient Protection and Affordable Care Act ("PPAC").

This oversight hearing is long overdue. The PPACA was enacted almost 1 year ago, and this is the first time this Committee has held an oversight hearing on the law. I know some may think we are moving too fast, or asking too many questions of the Department of Health and Human Services about the implementation of health care reform. But if you ask me, over the last year, this Committee didn't ask enough questions.

So today we begin our work. We will start by examining the Center for Consumer Information and Insurance Oversight. The Center is part of HHS and is responsible for implementing the PPACA. The current director of the Center, Mr. Steve Larsen, and its former director, Mr. Jay Angoff, are here to testify on behalf of HHS.

I think it is fair to say that this subcommittee has enough questions about the implementation of health care reform that we could keep Mr. Larsen and Mr. Angoff here testifying for the rest of the week. Today I am anxious to hear about the waivers the Center has been busy issuing to various health care plans offered by states, unions, and other employers. These waivers exempt those plans from the PPACA's requirements, in particular, the requirement that prohibits employers from imposing annual or lifetime limits on benefits. To date, the Center has issued over 900 waivers to health plans, and that number is rising every day.

This Committee has requested a number of documents about the waivers issued by the Center. We have some documents, but not all. The documents we do have show that complying with the PPACA would have forced hundreds of businesses to drop the health insurance plans they provide to their workers because the plans that Obamacare would have forced them to have would have been too expensive, and would have bankrupted those businesses.

What does it say about the feasibility of a law when you need to exempt over 900 health plans (so far)—or 2.5 million people—from complying with it? While I think it is a good thing that HHS recognized the significant problems posed by the PPACA—and exempted these health plans from a requirement that would have resulted in thousands of people losing their health insurance or having reduced benefits—I think it's a tacit admission that the PPACA is fundamentally flawed.

I also have questions for Mr. Angoff and Mr. Larsen about the Center's operations and its role, now that it has been moved from the Office of the Secretary of HHS to the Centers for Medicare and Medicaid Services ("CMS"). As the entity responsible for the massive changes being made to the private health care industry, I want to know what lessons the Center has learned as we approach the 1-year anniversary of the PPACA's enactment. I hope the witnesses will have some insights to share.

As Chairman of this Committee, I am committed to investigating the implementation of the PPACA. I think it is important that we uncover the facts about how this law is being implemented and what it means for the individuals and employers who have to live with its costly requirements. Only when we understand what worked and what didn't can this Congress enact meaningful healthcare reform that lets people keep their coverage and doesn't pass the bill to future generations.

I thank you, Mr. Chairman, and I yield back.

PREPARED STATEMENT OF HON. JOHN D. DINGELL

Thank you, Mr. Chairman.

The Department of Health and Human Services was tasked with the tremendous responsibility of implementing the Affordable Care Act, with the Center for Consumer Information and Insurance Oversight serving as one of the greatest consumer protections under this new law.

CCIIO has the critical responsibilities of providing consumers with comprehensive and accessible information about health plans, monitoring and ensuring compliance within the private insurance market, and overseeing the creation of state insurance exchanges. The success of CCIIO in these tasks is essential to providing consumers with affordable and quality health coverage now and when the health insurance exchanges are up and running.

In the time since the Affordable Care Act has been implemented, I believe that CCIIO used its authority appropriately to assist States, employers and insurers in complying with the law, while also ensuring that employers—both small and large—are not unnecessarily and negatively impacted by the Affordable Care Act. Their efforts at creating and providing transparency in implementing key provisions of the law have resulted in effective and efficient roll-outs of the Early Retiree Reinsurance Program and the Pre-existing Condition Insurance Plan.

Further, the development of the waiver process for annual limits has struck a delicate balance between protecting the access of millions of consumers in "minimed" plans to affordable coverage, while also assisting a diverse array of employers

and insurers with the information and tools necessary to navigate the application process.

The work CCIIO is doing now in the areas of annual limits, rate review, Early Retiree and PCIP all will lay a solid and necessary foundation for the creation of the health insurance exchanges, while ensuring uninterrupted care in the meantime. I commend CCIIO for their work done thus far, and I hope that today's hearing will serve as yet another opportunity for the American people to learn about how ACA is improving the quality of their health coverage.

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Michael Wilson

February 15, 2011

The Honorable Henry Waxman
Ranking Member
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

Dear Congressman Waxman:

On behalf of the American Heart Association (AHA), its American Stroke Association division, and more than 22 million volunteers and supporters nationwide, we appreciate the opportunity to comment on the Affordable Care Act's provision to eliminate annual dollar limits on essential benefits over time, beginning by limiting unreasonable annual limits.

When fully implemented by 2014, we believe that the ban on annual limits will be very helpful to patients living with heart disease and stroke. In a survey AHA commissioned that was released last year, 56 percent of patients reported that they had difficulty paying for health care services – and nearly half of those patients were insured.

Patients with chronic or serious cardiovascular conditions requiring extensive medical care can be left with significant out-of-pocket costs, even when insured, in part due to inadequate insurance coverage. For instance, the estimated average U.S. billed charges for the first year following a heart transplant were nearly $788,000 in 2008. Likewise, average first year billed charges for a heart-lung transplant were $1.1 million in 2008. As these costs illustrate, even patients with insurance coverage for their transplants can still face significant out-of-pocket costs. Perhaps, therefore, it is not surprising that cardiovascular disease is a leading cause of medical bankruptcy, and heart disease and stroke cause among the highest out-of-pocket expenses for those experiencing financial difficulties due to medical expenses, with stroke resulting in average out-of-pocket spending of $23,380 and heart disease $21,955 in 2007.

We look forward to the day when annual limits are completely banned in 2014. Until then, we strongly support the requiring of prominent warnings to consumers and employers when they are enrolled in or considering purchasing a health plan with an annual limit. Insurers or health plans should also be required to notify enrollees when they are close to reaching an allowed annual limit. Thank you for your consideration of our comments.

Sincerely,

Sue A. Nelson

Sue A. Nelson
Vice President, Federal Advocacy

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American Cancer Society
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February 15, 2011

The Honorable Diana DeGette, Ranking Member
Subcommittee on Oversight and Investigations
Energy and Commerce Committee
United States House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

Dear Representative DeGette:

We understand the House Committee on Energy and Commerce is undertaking a series of hearings on the insurance market reforms enacted as part of the Affordable Care Act. Speaking on behalf of millions of cancer patients, survivors and their families, the American Cancer Society Cancer Action Network strongly supports these reforms, including the elimination of lifetime and annual benefit limits on coverage.

One of the less visible but very significant problems among cancer patients is being "underinsured" – having insurance that offers too little coverage to fully address the needs of a serious medical condition like cancer. Cancer patients with inadequate coverage face devastating out-of-pocket costs for treatment, and thus face the additional stress of financial instability. A 2006 survey of cancer patients and their families found that one in five cancer patients with insurance used all or most of their savings when dealing with the financial costs of cancer.[1] Medical debt is an important cause of bankruptcy filing in the United States. Another study examined the causes of bankruptcy and found that 1.9 - 2.2 million Americans experienced bankruptcy medical related in 2001.[2] Among those with illnesses that led to bankruptcy, their out-of-pocket costs averaged less than $12,000, yet three-quarters had insurance at the time of their diagnosis – insurance that was simply inadequate to deal with catastrophic or chronic illness like cancer.

Last June, the U.S. Department of Health and Human Services issued an interim final regulation on the subject of annual coverage limits. The rule proposed a minimum limit of $750,000 for plans after September 23, 2010, with those limits rising annually, reaching $2 million by 2013, and with no limit after 2014. By eliminating arbitrary annual benefit limits the Affordable Care Act will make sure that cancer patients have access to health care and treatment when they become sick.

The regulation also recognized that some very inexpensive employer plans which have very low annual limits can not comply with the higher limit requirement and still remain affordable for the policy holders. While recognizing the complete inadequacy of such coverage for cancer patients and those with chronic disease, the rule recognized that for some people, inadequate protection may be better than none at all. Thus, these plans may request a waiver, and a waiver may be warranted in some situations. It should, however, come with some obligations on the part of the health insurance plans. In November, HHS issued guidance requiring plans to notify enrollees when they receive a waiver, including an explanation of the reason for it and the protection that the consumer would otherwise have had. This is a critical step toward consumer education and empowerment, and we commend HHS for taking it. We strongly believe the administration should be even more expansive in increasing disclosures and insurer transparency in the coming months and years.

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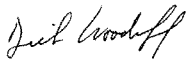
[1] *USA Today*, the Kaiser Family Foundation, the Harvard School of Public Health. National survey of households affected by cancer, August 1 – September 14, 2006.
[2] Himmelstein DB, Warren E, Thorne D, Woolhandler S. Illness and injury as contributors to bankruptcy. *Health Aff* 2005; Web exclusive: 63-73.

In the absence of insurance reform, adequate coverage at affordable prices is no longer attainable for many Americans. If we want all Americans to have meaningful access to quality health care, we need to change the insurance market rules, provide subsidies, streamline administrative processes and greatly increase transparency and accountability. The Affordable Care Act provides a solid framework for achieving these goals, and it is ACS CAN's intent to work with all interested parties to implement the law successfully so that the health system works for people with cancer and other serious medical conditions.

Sincerely,



Dick Woodruff
Vice President, Federal Relations and Strategic Alliances

Subcommittee on Oversight and Investigations
Health Care Issues Involving the Center for Consumer Information and Insurance Oversight
February 16, 2011

Exhibits Index

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4.	CMS, Office of the Actuary, *Estimated Financial Effects of the "Patient Protection and Affordable Care Act".*	April 22, 2010
5.	Federal Register, *Requirements for Group Health Plans.*	June 28, 2010
6.	Federal Register, *Pre-Existing Condition Insurance Plan Program.*	July 30, 2010
7.	Federal Register, *Medical Loss Ratio (MLR) Requirements.*	December 1, 2010
8.	U.S. Department of Health & Human Services, News Release, *HHS Secretary Sebelius' Statement on NAIC Recommendations on Medical Loss Ratio.*	October 21, 2010
9.	Politico Pulse, *OCIIO shows muscle at NAIC...Lobbying intensifies on credibility adjustments, broker fees...HHS releases Medicare ad budget...Layoffs strike at AHIP.*	October 20, 2010

10.	The Miami Herald, *As health care law rolls out, many insurers drop child-only policies.*	February 8, 2011
11.	The Washington Post, *Major health insurers to stop offering new child-only policies.*	September 20, 2010
12.	Hearing Request to Chairman Waxman.	October 8, 2010
13.	State of Tennessee, Department of Finance and Administration, Benefits Administration, *Waiver Request of the Annual Limits Requirement of PHS Section 2711.*	September 17, 2010
14.	Ohio Department of Insurance, *Waiver of Annual Limits Restriction for 2010.*	November 23, 2010
15.	HHS, Office of Consumer Information and Insurance Oversight, Office of Oversight, *Waiver Application for the Rice Food Markets, Inc. Group Health Plan, Part-Time Union Employees ("Plan").*	November 1, 2010
16.	Littler, *Ohio Conference of Teamsters & Industry Health & Welfare Fund/Application for Waiver from the Restricted Annual Limits Set Forth in the Interim Final Regulations.*	January 20, 2011
17.	Jamba Juice, *Request to Waive Annual Limits Requirements of PHS Act Section 2711.*	December 15, 2010
18.	Whelan Security Co, *Request for Waiver from Annual Limit Restrictions.*	September 21, 2010
19.	Nexion Health, *Application for Waiver of PHS Act Section 2711Restricted Annual Limits.*	October 19, 2010
20.	Aspen Snowmass, *PHSA Sec 2711-2011 Plan Year Waiver Application.*	September 20, 2010
21.	QK/DRD(Denny's) Policy Forms #358571 , *Waiver*	September 16, 2010

	Application Requests – Annual Limits Requirements of PHS Act Section 2711.	
22.	Johnson & Towers, *Application for Waiver of PHS Act Section 2711Restricted Annual Limits.*	December 22, 2010
23.	*Atlanta Plumbers & Steamfitters Fringe Benefit Funds, *Application for Waiver of PHS Act Section 2711 Restricted Annual Limits*	November 9, 2010
24.	Heating, Piping and Refrigeration, *Waiver Application.*	November 2, 2010
25.	Correspondence between HHS/OCIIO and Vestal Manufacturing Enterprises, Inc., *Application for the Waiver of the Annual Limits Requirements of the (PHS Act) Section 2711.*	December 8, 2010

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

January 5, 2011

The Honorable Harold Rogers
Chairman
Committee on Appropriations
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairman Rogers:

I am writing to inform you that the Department of Health and Human Services (HHS) plans to move the Office of Consumer Information and Insurance Oversight (OCIIO) out of the Office of the Secretary and into the Centers for Medicare & Medicaid Services (CMS). This proposal establishes the Center for Consumer Information and Insurance Oversight.

After the Affordable Care Act (ACA) was signed into law last March, HHS established the Office of Consumer Information and Insurance Oversight within the Office of the Secretary so that HHS senior leadership could ensure that early policy and program development could be achieved, bringing to bear the greatest expertise across the Department. Now that we are moving into an operational phase of ACA implementation, we believe an operating division such as CMS has the best resources, in terms of expertise and administrative processes, to achieve successful implementation. This reorganization will also result in administrative savings and organizational efficiencies. The Center for Consumer Information and Insurance Oversight will continue to fulfill the functions of OCIIO -- providing national leadership in setting and enforcing standards for health insurance that promote fair and reasonable practices to ensure affordable, quality health care coverage is available to all Americans. It will also provide consumers with comprehensive information on coverage options currently available so they may make informed health insurance choices.

CMS will be amending its section in the HHS Organization Manual through a *Federal Register* notice to reflect the reorganization. Enclosed please find the current CMS organization chart and the proposed CMS organization chart that reflects the changes.

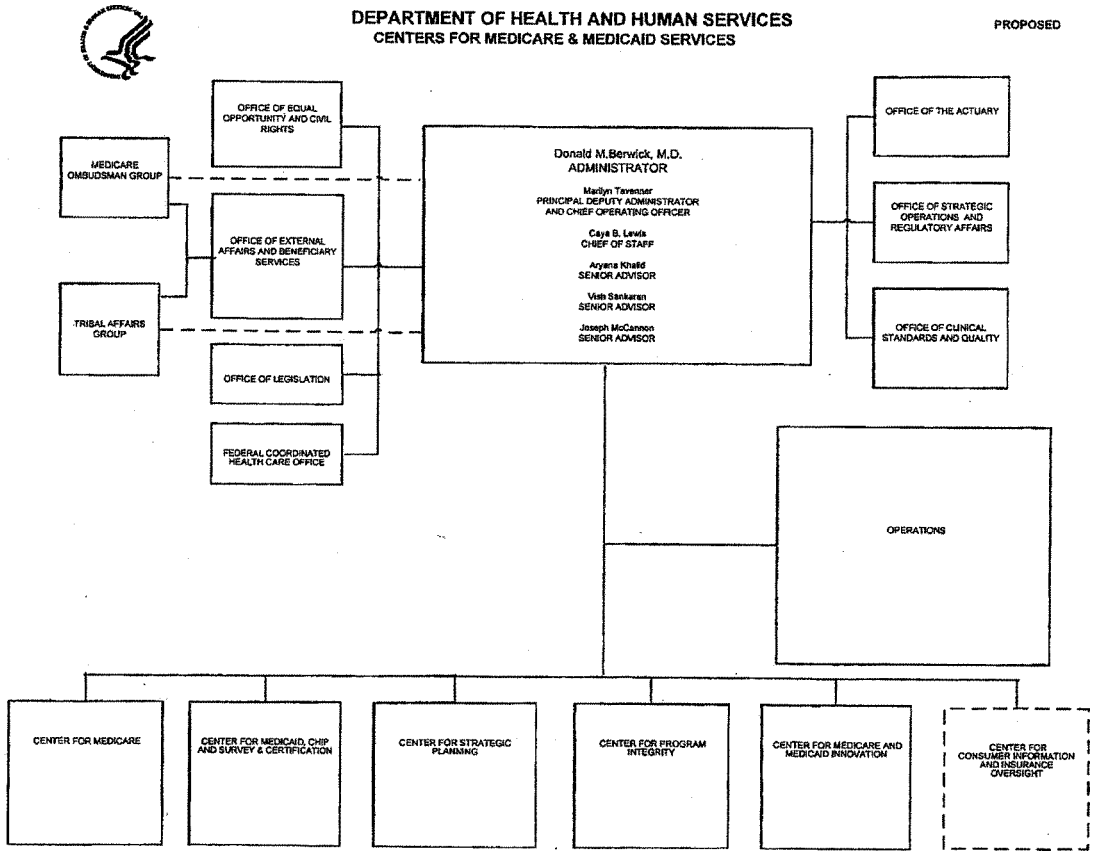
I appreciate the subcommittee's continued interest in and support of the activities of CMS, and I would be happy to answer any questions you or your staff may have.

Sincerely,

Kathleen Sebelius

Kathleen Sebelius

Enclosures (2)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TRIBAL AFFAIRS GROUP
OFFICE OF EQUAL OPPORTUNITY AND CIVIL RIGHTS
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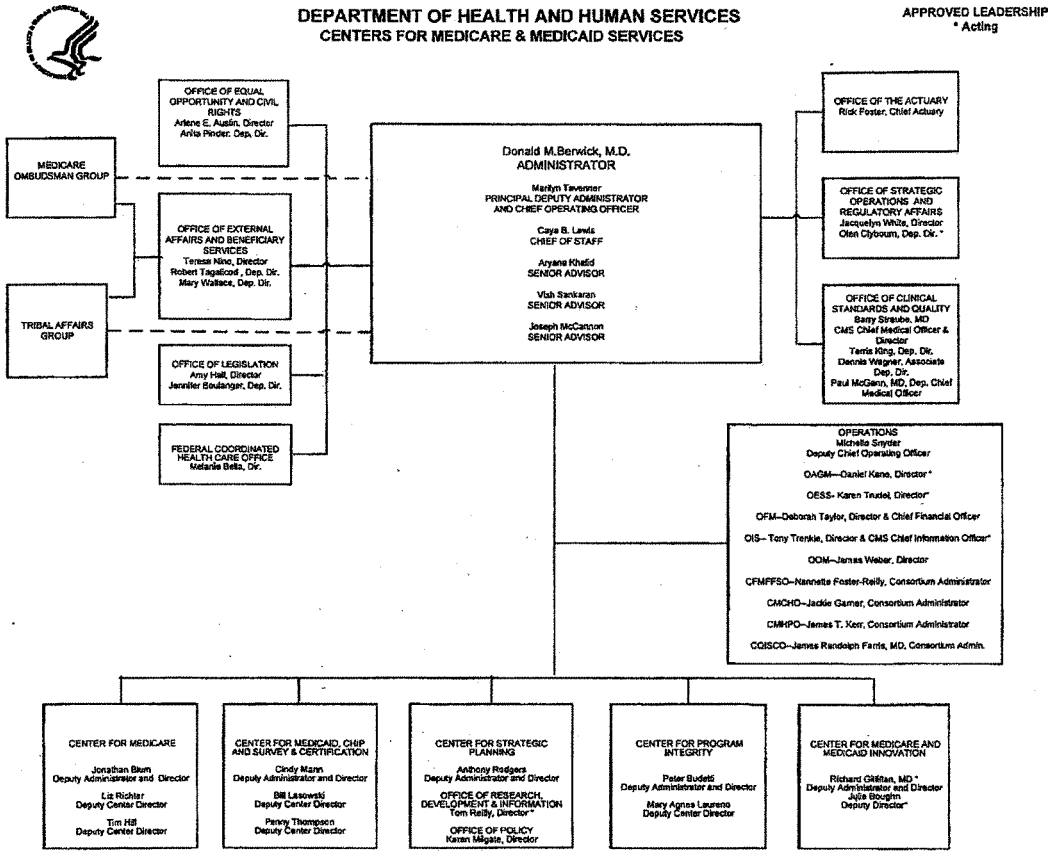
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Richard Gilfillan, MD *
Deputy Administrator and Director
Julie Bougdin
Deputy Director*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Consumer Information and Insurance Oversight
Washington, DC 20201

Date: October 2010

From: Steve Larsen, Director, Office of Oversight

Subject: Application for Waiver of the Annual Limits Requirements of PHS Act Section 2711

Dear Waiver Applicant:

Section 2711(a)(2) of the Public Health Service Act (PHS Act), as added by the Patient Protection and Affordable Care Act (Affordable Care Act), requires the Secretary to impose restrictions on the imposition of annual limits on the dollar value of essential health benefits (as defined in section 1302(b) of the Affordable Care Act) for any participant or beneficiary in a new or existing group health plan or a new policy in the individual market for plan or policy years beginning on or after September 23, 2010 and prior to January 1, 2014. Specifically, the Secretary is granted the authority to determine what constitutes a "restricted annual limit" that can still be imposed under such plans or policies prior to January 1, 2014.

The interim final regulations published on June 28, 2010 (codified at 26 CFR § 54.9815-2719T; 29 CFR § 2590.715-2719; and 45 CFR §147.126) established such restricted annual limits. The regulations also provided that these restricted annual limits may be waived by the Secretary of Health and Human Services (HHS) if compliance with the interim final regulations would result in a significant decrease in access to benefits or a significant increase in premiums. Pursuant to the regulation, HHS issued guidance on September 3 regarding the scope and process for applying for a waiver.

The Office of Consumer Information and Insurance Oversight, Office of Insurance Oversight received and processed your application for the plan(s) or policy(ies) year beginning January 1, 2011. We have determined that your application has met the criteria to obtain a waiver of the restricted annual limits requirements because compliance with the interim final regulations would result in a significant decrease in access to benefits for those currently covered by such plans or policies, or a significant increase in premiums paid by those covered by such plans or policies. To the extent you make any change to your benefit package after March 23, 2010, you must determine whether the change(s) will trigger loss of grandfathering status pursuant to 45 CFR §147.140(g)(1).

An approval of your request for waiver of the restricted annual limits requirements granted under this process applies only to the annual limit(s) provided in your application for the plan or policy year beginning between September 23, 2010 and September 23, 2011. This waiver only applies to the annual limits requirements in Section 2711 of the ACA and does not apply to any other requirement of the Affordable Care Act, ERISA, the IRS Code or the PHS Act. Further, a group

health plan or health insurance issuer must reapply for any subsequent plan or policy year prior to January 1, 2014 when this waiver expires in accordance with future guidance from HHS. HHS may modify this waiver approval process memorandum and other relevant information.

If you have any questions regarding this letter, please email OCIIOOversight@hhs.gov.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Consumer Information and
Insurance Oversight
Washington, DC 20201

Date: October 2010

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Subject: Application for Waiver of the Annual Limits Requirements of PHS Act Section 2711

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The Office of Consumer Information and Insurance Oversight, Office of Insurance Oversight received and processed your application for the plan(s) or policy(ies) year beginning January 1, 2011. We have determined that your application has not demonstrated that the requirement of the restricted annual limit would result in a significant decrease in access to benefits for those currently covered by such plans or policies, or a significant increase in premiums paid by those covered by such plans or policies. Please refer to the interim final regulations codified at 26 CFR § 54.9815-2719T; 29 CFR § 2590.715-2719; and 45 CFR §147.126 for the restricted annual limits, $750,000 for a plan year beginning on or after September 23, 2010, but before September 23, 2011.

If you have any questions regarding this letter, please email OCIIOOversight@hhs.gov.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop N3-01-21
Baltimore, Maryland 21244-1850

Office of the Actuary

DATE: April 22, 2010

FROM: Richard S. Foster
Chief Actuary

SUBJECT: Estimated Financial Effects of the "Patient Protection and Affordable Care Act," as Amended

The Office of the Actuary has prepared this memorandum in our longstanding capacity as an independent technical advisor to both the Administration and the Congress. The costs, savings, and coverage impacts shown herein represent our best estimates for the Patient Protection and Affordable Care Act. We offer this analysis in the hope that it will be of interest and value to policy makers and administrators as they implement and monitor these far-reaching national health care reforms. The statements, estimates, and other information provided in this memorandum are those of the Office of the Actuary and do not represent an official position of the Department of Health & Human Services or the Administration.

This memorandum summarizes the Office of the Actuary's estimates of the financial and coverage effects through fiscal year 2019 of selected provisions of the "Patient Protection and Affordable Care Act" (P.L. 111-148) as enacted on March 23, 2010 and amended by the "Health Care and Education Reconciliation Act of 2010" (P.L. 111-152) as enacted on March 30, 2010. For convenience, the health reform legislation, including amendments, will be referred to in this memorandum as the Patient Protection and Affordable Care Act, or PPACA.

Included are the estimated net Federal expenditures in support of expanded health insurance coverage, the associated numbers of people by insured status, the changes in Medicare and Medicaid expenditures and revenues, and the overall impact on total national health expenditures. Except where noted, we have not estimated the impact of the various tax and fee provisions or the impact on income and payroll taxes due to economic effects of the legislation. Similarly, the impact on Federal administrative expenses is excluded. A summary of the data, assumptions, and methodology underlying our national health reform estimates will be available in a forthcoming memorandum by the OACT Health Reform Modeling Team.

Summary

The table shown on page 2 presents financial impacts of the selected PPACA provisions on the Federal Budget in fiscal years 2010-2019. We have grouped the provisions of the legislation into six major categories:

(i) Coverage provisions, which include the mandated coverage for health insurance, a substantial expansion of Medicaid eligibility, and the additional funding for the Children's Health Insurance Program (CHIP);

(ii) Medicare provisions;

(iii) Medicaid and CHIP provisions other than the coverage expansion and CHIP funding;

(iv) Provisions aimed in part at changing the trend in health spending growth;

(v) The Community Living Assistance Services and Supports (CLASS) program; and

(vi) Immediate health insurance reforms.

The estimated costs and savings shown in the table are based on the effective dates specified in the law as enacted. Additionally, we assume that employers and individuals would take roughly 3 to 5 years to fully adapt to the new insurance coverage options and that the enrollment of additional individuals under the Medicaid coverage expansion would be completed by the third year of implementation. Because of these transition effects and the fact that most of the coverage provisions would be in effect for only 6 of the 10 years of the budget period, the cost estimates shown in this memorandum do not represent a full 10-year cost for the new legislation.

Estimated Federal Costs (+) or Savings (−) under Selected Provisions of the Patient Protection and Affordable Care Act as Enacted and Amended
(in billions)

	Fiscal Year										Total,
Provisions	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2010-19
Total*	$9.2	−$0.7	−$12.6	−$22.3	$16.8	$57.9	$63.1	$54.2	$47.2	$38.5	$251.3
Coverage†	3.3	4.6	4.9	5.2	82.9	119.2	138.2	146.6	157.6	165.8	828.2
Medicare	1.2	−4.7	−14.9	−26.3	−68.8	−60.3	−75.2	−92.1	−108.2	−125.7	−575.1
Medicaid/CHIP	−0.9	−0.9	0.8	4.5	8.6	5.1	4.6	3.4	1.3	1.7	28.3
Cost trend‡	—	—	—	—	−0.0	−0.1	−0.2	−0.4	−0.6	−0.9	−2.3
CLASS program	—	−2.8	−4.5	−5.6	−5.9	−6.0	−4.3	−3.4	−2.8	−2.4	−37.8
Immediate reforms	5.6	3.2	1.2	—	—	—	—	—	—	—	10.0

* Excludes Title IX revenue provisions except for sections 9008 and 9015, certain provisions with limited impacts, and Federal administrative costs.

† Includes expansion of Medicaid eligibility and additional funding for CHIP.

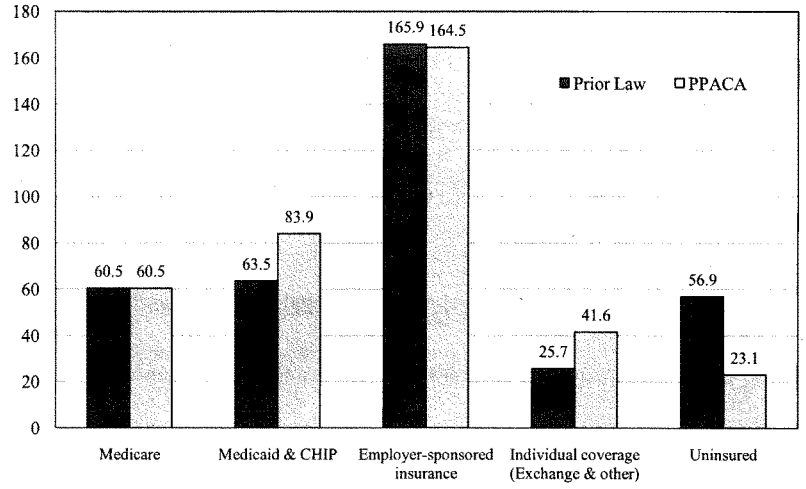
‡ Includes estimated non-Medicare Federal savings from provisions for comparative effectiveness research, prevention and wellness, fraud and abuse, and administrative simplification. Excludes impacts of other provisions that would affect cost growth rates, such as the productivity adjustments to Medicare payment rates (which are reflected in the Medicare line) and the section 9001 excise tax on high-cost employer plans.

As indicated in the table above, the provisions in support of expanding health insurance coverage (including the Medicaid eligibility changes and additional CHIP funding) are estimated to cost $828 billion through fiscal year 2019. The Medicare, Medicaid, growth-trend, CLASS, and immediate reform provisions are estimated to result in net savings of about $577 billion, leaving a net overall cost for this period of $251 billion before consideration of additional Federal administrative expenses and the increase in Federal revenues that would result from the excise tax on high-cost employer-sponsored health insurance coverage and other revenue provisions. (The additional Supplementary Medical Insurance revenues from fees on brand-name prescription drugs under section 9008 of the PPACA, and the additional Hospital Insurance payroll tax income under section 9015, are included in the estimated Medicare savings shown here.) The Congressional Budget Office and the Joint Committee on Taxation have estimated that the total net amount of Medicare savings and additional tax and other revenues would

somewhat more than offset the cost of the national coverage provisions, resulting in an overall reduction in the Federal deficit through 2019.

The following chart summarizes the estimated impacts of the PPACA on insurance coverage. The mandated coverage provisions, which include new responsibilities for both individuals and employers, and the creation of the American Health Benefit Exchanges (hereafter referred to as the "Exchanges"), would lead to shifts across coverage types and a substantial overall reduction in the number of uninsured, as many of these individuals become covered through their employers, Medicaid, or the Exchanges.

Estimated Effect of the Patient Protection and Affordable Care Act, as Enacted and Amended, on 2019 Enrollment by Insurance Coverage
(in millions)



Note: Totals across categories are not meaningful due to overlaps among categories (e.g., Medicare and Medicaid).

By calendar year 2019, the mandates, coupled with the Medicaid expansion, would reduce the number of uninsured from 57 million, as projected under prior law, to an estimated 23 million under the PPACA. The additional 34 million people who would become insured by 2019 reflect the net effect of several shifts. First, an estimated 18 million would gain primary Medicaid coverage as a result of the expansion of eligibility to all legal resident adults under 133 percent[1] of the Federal Poverty Level (FPL).[2] (In addition, roughly 2 million people with employer-

[1] The health reform legislation specifies an income threshold of 133 percent of the Federal Poverty Level but also requires States to apply an "income disregard" of 5 percent of the FPL in meeting the income test. Consequently, the *effective* income threshold is actually 138 percent of the FPL. For convenience, we refer to the statutory factor of 133 percent in this memorandum.

[2] This provision would extend eligibility to two significant groups: (i) individuals who would meet current Medicaid eligibility requirements, for example as disabled adults, but who have incomes in excess of the existing State thresholds but less than 133 percent of the FPL; and (ii) people who live in households with incomes below 133 percent of the FPL but who have no other qualifying factors that make them eligible for Medicaid under prior law, such as being under age 18, age 65 or older, disabled, pregnant, or parents of eligible children.

sponsored health insurance would enroll in Medicaid for supplemental coverage.) Another 16 million persons (most of whom are currently uninsured) would receive individual insurance coverage through the newly created Exchanges, with the majority of these qualifying for Federal premium and cost-sharing subsidies. Finally, we estimate that the number of individuals with employer-sponsored health insurance would decrease overall by about 1 million, reflecting both gains and losses in such coverage under the PPACA.

As described in more detail in a later section of this memorandum, we estimate that overall national health expenditures under the health reform act would increase by a total of $311 billion (0.9 percent) during calendar years 2010-2019, principally reflecting the net impact of (i) greater utilization of health care services by individuals becoming newly covered (or having more complete coverage), (ii) lower prices paid to health providers for the subset of those individuals who become covered by Medicaid, (but with net Medicaid costs from provisions other than the coverage expansion), and (iii) lower payments and payment updates for Medicare services. Although several provisions would help to reduce health care cost growth, their impact would be more than offset through 2019 by the higher health expenditures resulting from the coverage expansions.

The actual future impacts of the PPACA on health expenditures, insured status, individual decisions, and employer behavior are very uncertain. The legislation would result in numerous changes in the way that health care insurance is provided and paid for in the U.S., and the scope and magnitude of these changes are such that few precedents exist for use in estimation. Consequently, the estimates presented here are subject to a substantially greater degree of uncertainty than is usually the case with more routine health care legislation.

The balance of this memorandum discusses these financial and coverage estimates—and their limitations—in greater detail.

Effects of Coverage Provisions on Federal Expenditures and Health Insurance Coverage

Federal Expenditure Impacts

The estimated Federal costs of the coverage provisions in the PPACA are provided in table 1, attached, for fiscal years 2010 through 2019. We estimate that Federal expenditures would increase by a net total of $251 billion during this period as a result of the selected PPACA provisions—a combination of $828 billion in net costs associated with coverage provisions, $575 billion in net savings for the Medicare provisions, a net cost of $28 billion for the Medicaid/CHIP provisions (excluding the expansion of Medicaid eligibility and the additional CHIP funding), $2 billion in savings from provisions intended to help reduce the rate of growth in health spending, $38 billion in net savings from the CLASS program, and $10 billion in costs for the immediate insurance reforms. These latter five impact categories are discussed in subsequent sections of this memorandum.

Of the estimated $828 billion net increase in Federal expenditures related to the coverage provisions of the PPACA, about one-half ($410 billion) can be attributed to expanding Medicaid coverage for all adults who live in households with incomes below 133 percent of the FPL. This cost reflects the fact that newly eligible persons would be covered with a Federal Medical Assistance Percentage (FMAP) of over 99 percent for the first 3 years, declining to 93 percent by the sixth year; that is, the Federal government would bear a significantly greater proportion of

the cost of the newly eligible enrollees than is the case for current Medicaid beneficiaries.[3] Also included in this cost is the additional funding for the CHIP program for 2014 and 2015, which would increase such expenditures by an estimated $29 billion. The remaining costs of the coverage provisions arise from the refundable tax credits and reduced cost-sharing requirements for low-to-middle-income enrollees purchasing health insurance through the Exchanges ($507 billion) and credits for small employers who choose to offer insurance coverage ($31 billion). The increases in Federal expenditures would be partially offset by the penalties paid by affected individuals who choose to remain uninsured and employers who opt not to offer coverage; such penalties total $120 billion through fiscal year 2019, reflecting the relatively low per-person penalty amounts specified in the legislation.[4]

The refundable premium tax credits in section 1401 of the PPACA (as amended by section 1001 of the Reconciliation Act) would limit the premiums paid by individuals with incomes up to 400 percent of the FPL to a range of 2.0 to 9.5 percent of their income and would cost an estimated $451 billion through 2019. An estimated 25 million Exchange enrollees (79 percent) would receive these Federal premium subsidies. The cost-sharing credits would reimburse individuals and families with incomes up to 400 percent of the FPL for a portion of the amounts they pay out-of-pocket for health services, as specified in section 1402, as amended. These credits are estimated to cost $55 billion through 2019.

The PPACA establishes the Exchange premium subsidies during 2014-2018 in such a way that the reduced premiums payable by those with incomes below 400 percent of FPL would maintain the same share of total premiums over time. As a result, the Federal premium subsidies for a qualifying individual would grow at the same pace as per capita health care costs during this period. Because the cost-sharing assistance is based on a percentage of health care costs incurred by qualifying individuals and families, average Federal expenditures for this assistance would also increase at the same rate as per capita health care costs. After 2018, if the Federal cost of the premium and cost-sharing subsidies exceeded 0.504 percent of GDP, then the share of Exchange health insurance premiums paid by enrollees below 400 percent of the FPL would increase such that the Federal cost would stay at approximately 0.504 percent of GDP. We estimate that the subsidy costs in 2018 would represent about 0.518 percent of GDP, with the result that the enrollee share of the total premium would generally increase in 2019 and later.

As noted previously, the Federal costs for the coverage expansion provisions are somewhat offset by the individual and employer penalties stipulated by the PPACA. We estimate that individual penalties would provide $33 billion in revenue to the Federal government in fiscal years 2014-2019, taking into account the time lag associated with collecting the penalty amounts through the Federal income tax system. (A discussion of the estimated number of individuals who would choose to remain uninsured is provided below.) Additionally, for firms that do not

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[3] For the newly eligible enrollees, the FMAP for fiscal year 2020 and later will be 90 percent, compared to an average of 57 percent for the previously eligible enrollee population. In addition, the estimated cost includes new Medicaid enrollments by previously eligible individuals as a result of the publicity, enrollment assistance through the Exchanges, and reduced stigma associated with Federal assistance for health care. Also included here are the Medicaid costs for the provision to extend Medicaid coverage to individuals up to age 26 who were previously in foster care.

[4] Employer penalties would be $2,000 per employee in 2014, generally, which is substantially less than the cost of providing health insurance coverage. The relationship between penalties and premiums is much more complicated for individuals than for employers; still, for many individuals the applicable penalty would be considerably smaller than the cost of coverage.

offer health insurance and are subject to the "play or pay" penalties, we estimate that the penalties would total $87 billion in 2014-2019.

The penalty amounts for noncovered individuals will be indexed over time by the CPI (or, in certain instances, by growth in income) and would normally increase more slowly than health care costs. As a result, penalty revenues for nonparticipating individuals are estimated to grow more slowly than the Federal expenditures for the premium assistance credits. Penalties for employers who do not offer health insurance will be indexed by premium levels and will thus keep pace with health care cost growth.

The health reform act specifies maximum out-of-pocket limits in 2014 equal to the corresponding maximums as defined in the Internal Revenue Code for high-deductible health plans. We estimate that these limits would be $6,645 for an individual and $13,290 for a family with qualified creditable coverage (including employer-sponsored health insurance). For future years, the limits are indexed to the growth in the average health insurance premium in the U.S. Under this approach, the proportion of health care costs above the out-of-pocket maximum would be relatively stable over time. For the basic "bronze" benefit plan for individuals, with an actuarial value of 60 percent, we estimate that the cost-sharing percentage applicable before the out-of-pocket maximum is reached would average about 76 percent in 2014 and later. The corresponding cost-sharing rate for family coverage is 64 percent. For the "silver" benefit package, the individual and family cost-sharing rates below the out-of-pocket maximums would average about 47 percent and 40 percent, respectively. For the more comprehensive "gold" and "platinum" benefit packages authorized through the Exchanges, these initial cost-sharing levels would be significantly lower.

Health Insurance Coverage Impacts

The estimated effects of the PPACA on health insurance coverage are provided in table 2, attached. As summarized earlier, we believe that these effects will be quite significant. By calendar year 2019, the individual mandate, Medicaid expansion, and other provisions are estimated to reduce the number of uninsured from 57 million under prior law to 23 million after the PPACA. The percentage of the U.S. population with health insurance coverage is estimated to increase from 83 percent under the prior-law baseline to 93 percent after the changes have become fully effective.

Of the additional 34 million people who are estimated to be insured in 2019 as a result of the PPACA, a little more than one-half (18 million) would receive Medicaid coverage due to the expansion of eligibility to adults under 133 percent of the FPL. (Included in the total are an estimated 50,000 individuals who would gain Medicaid coverage as former children in foster care programs and who could be covered up to age 26 under the new law.) We anticipate that the intended enrollment facilitation under the PPACA—i.e., that the Health Benefits Exchanges help people determine which insurance plans are available and identify whether individuals qualify for Medicaid coverage, premium subsidies, etc.—would result in a high percentage of eligible persons becoming enrolled in Medicaid. We further believe that the great majority of such persons (15 million) would become covered in the first year, 2014, with the rest covered by 2016. About 2 million people who currently have employer-sponsored health insurance are estimated to enroll in Medicaid as a supplement to their existing coverage.

We estimate that 16 million people would receive health coverage in 2019 through the newly created Exchanges under the PPACA. (Another 15 million, who currently have individual health insurance policies, are also expected to switch to Exchange plans.) We modeled the choice to purchase coverage from the Exchanges as a function of individuals' and families' expected health expenditures relative to the cost of coverage if they were insured (taking into account applicable premium subsidies). We also considered the required penalty associated with the individual mandate if they chose to remain uninsured, along with other factors.[5] Our model indicated that roughly 63 percent of those eligible for the Exchanges would choose to take such coverage, with the principal incentive being the level of premium assistance available. For many individuals, the penalty amounts for not having insurance coverage were not sufficiently large to have a sizable impact on the coverage decision. Also, in this regard, individuals or families would not be subject to a penalty for failing to enroll in an Exchange plan if the "bronze" premium level (reduced by the premium tax credit, if applicable) would exceed 8 percent of income. We estimate that this provision would exempt individuals and families with incomes between about 400 percent and 542 percent of the FPL, representing about 16 percent of the non-aged population.

The new legislation would require the Office of Personnel Management to arrange for at least two private, multi-State health plans to be offered through each health insurance Exchange. The multi-State plans would generally meet the same benefit, cost-sharing, network, and other requirements applicable to private Exchange plans and would negotiate payment rates with providers. (A State could enact a requirement for additional benefits in the multi-State plans, beyond the essential benefits specified for a qualified plan, but would have to make payments on behalf of eligible individuals to defray the cost of the additional benefits.) We estimate that the multi-State plans would have costs that were very similar to those for other Exchange plans.

Employer-sponsored health insurance has traditionally been the largest source of coverage in the U.S., and we anticipate that it would continue to be so under the PPACA. By 2019, an estimated 13 million workers and family members would become newly covered as a result of additional employers offering health coverage, a greater proportion of workers enrolling in employer plans, and an extension of dependent coverage up to age 26. However, a number of workers who currently have employer coverage would likely become enrolled in the expanded Medicaid program or receive subsidized coverage through the Exchanges. For example, some smaller employers would be inclined to terminate their existing coverage, and companies with low average salaries might find it to their—and their employees'—advantage to end their plans, thereby allowing their workers to qualify for heavily subsidized coverage through the Exchanges. Somewhat similarly, many part-time workers could obtain coverage more inexpensively through the Exchanges or by enrolling in the expanded Medicaid program. Finally, as mentioned previously, the per-worker penalties assessed on nonparticipating employers are relatively low compared to prevailing health insurance costs. As a result, the penalties would not be a substantial deterrent to dropping or forgoing coverage. We estimate that such actions would collectively reduce the number of people with employer-sponsored health coverage by about 14 million, or slightly more than the number newly covered through

[5] Such other factors include age, gender of head of household, race, children, marital status, health status, and employment status (for both the head of household and the spouse), as well as adjustments to reflect the availability of health insurance on a guaranteed-issue basis and at community-rated, group insurance premium rates. Finally, we also considered the general desire to comply with the intent of the law, even in the significant number of cases in which the penalty amount would be small or would not apply.

existing and new employer plans under the PPACA. As indicated in table 2, the total number of persons with employer coverage in 2019 is estimated to be 1 million lower under the reform legislation than under the prior law.

For the estimated 23 million people who would remain uninsured in 2019, roughly 5 million are undocumented aliens who would be ineligible for Medicaid or the Exchange coverage subsidies under the health reform legislation. The balance of 18 million would choose not to be insured and to pay the penalty (if applicable) associated with the individual mandate. For the most part, these would be individuals with relatively low health care expenses for whom the individual or family insurance premium would be significantly in excess of any penalty and their anticipated health benefit value. In other instances, as happens currently, some people would not enroll in their employer plans or take advantage of the Exchange opportunities even though it would be in their best financial interest to do so.

Impact on Medicare and Medicaid

Medicare

The estimated financial impacts of the Medicare provisions in the PPACA are provided in detail in table 3, attached, which is organized by section of the legislation.[6] Net Medicare savings are estimated to total $575 billion for fiscal years 2010-2019. Substantial savings are attributable to provisions that would, among other changes, reduce Part A and Part B payment levels and adjust future "market basket" payment updates for productivity improvements ($233 billion); eliminate the Medicare Improvement Fund ($27 billion); reduce disproportionate share hospital (DSH) payments ($50 billion); reduce Medicare Advantage payment benchmarks and permanently extend the authority to adjust for coding intensity ($145 billion); freeze the income thresholds for the Part B income-related premium for 9 years ($8 billion); implement an Independent Payment Advisory Board together with strict Medicare expenditure growth rate targets ($24 billion); and increase the HI payroll tax rate by 0.9 percentage point for individuals with incomes above $200,000 and families above $250,000 ($63 billion). Other provisions would generate relatively smaller amounts of savings, through such means as reporting physician quality measures, reducing payments in cases involving hospital-acquired infections, reducing readmissions, refining imaging payments, increasing Part D premiums for higher-income beneficiaries, and implementing evidence-based coverage of preventive services.

These savings are slightly offset by the costs of closing the Part D coverage gap ($12 billion); reducing the growth in the Part D out-of-pocket cost threshold ($1 billion); extending a number of special payment provisions scheduled to expire, such as the postponement of therapy caps ($5 billion); and by the costs for improving preventive health services and access to primary care ($6 billion).

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[6] For ease of interpretation, we have incorporated the Medicare and Medicaid provisions of the managers' amendments, as specified in Title X of the PPACA, into the corresponding provisions of Titles II through VII and Title IX. For example, the savings shown for section 3403 (Independent Payment Advisory Board) represent the impact of this provision from the original bill as amended by Senate managers' amendment section 10320. Similarly, any further amendments introduced by the Reconciliation Act and managers' amendments to the Reconciliation Act have also been included with the corresponding title of the PPACA. For example, the costs under section 1101 of the Reconciliation Act, to close the Part D coverage gap or "donut hole," are included with the Part D provisions of PPACA, as are the costs of slowing the growth in the enrollee out-of-pocket cost threshold, as added by the managers' amendments to the Reconciliation Act.

The Reconciliation Act amendments introduced a new 3.8-percent "unearned income Medicare contribution" on income from interest, dividends, annuities, and other non-earnings sources for individual taxpayers with incomes above $200,000 and couples filing joint returns with incomes above $250,000. Despite the title of this tax, this provision is unrelated to Medicare; in particular, the revenues generated by the tax on unearned income are not allocated to the Medicare trust funds (and thus are not shown in table 3).

Conversely, the revenues from fees on manufacturers and importers of brand-name prescription drugs under section 9008 of the PPACA are earmarked for the Part B account in the Medicare Supplementary Medical Insurance trust fund. From the standpoint of the Federal Budget, these amounts are new receipts and serve to reduce the Budget deficit. From a trust fund perspective, however, the situation is more complicated. No changes were made in the existing statutory provisions for Part B beneficiary premiums and general revenue matching amounts, which by law are set each year at a level adequate to finance Part B expenditures. With no change to the existing financing, the additional revenues under section 9008 would result in an excessive level of financing for Part B and an unnecessary accumulation of account assets. It would be reasonable to establish a negative "premium margin" to maintain Part B assets at an appropriate contingency level, which would reduce beneficiary premium rates and matching general revenues by an amount equal to the new revenues from prescription drug fees. The estimated savings amounts shown in table 3 for section 9008 represent the net Budget impact (additional fee receipts less the reduction in beneficiary premiums). In practice, there would be no net impact on the operations of the Part B trust fund account.

Based on the estimated savings for Part A of Medicare, the assets of the Hospital Insurance trust fund would be exhausted in 2029 compared to 2017 under the prior law—an extension of 12 years. The combination of lower Part A costs and higher tax revenues results in a lower Federal deficit based on budget accounting rules. However, trust fund accounting considers the same lower expenditures and additional revenues as extending the exhaustion date of the HI trust fund. In practice, the improved HI financing cannot be simultaneously used to finance other Federal outlays (such as the coverage expansions) and to extend the trust fund, despite the appearance of this result from the respective accounting conventions.

It is important to note that the estimated savings shown in this memorandum for one category of Medicare provisions may be unrealistic. The PPACA introduces permanent annual productivity adjustments to price updates for most providers (such as hospitals, skilled nursing facilities, and home health agencies), using a 10-year moving average of economy-wide private, non-farm productivity gains. While such payment update reductions will create a strong incentive for providers to maximize efficiency, it is doubtful that many will be able to improve their own productivity to the degree achieved by the economy at large.[7] Over time, a sustained reduction in payment updates, based on productivity expectations that are difficult to attain, would cause Medicare payment rates to grow more slowly than, and in a way that was unrelated to, the

[7] The provision of most health services tends to be very labor-intensive. Economy-wide productivity gains reflect relatively modest improvements in the service sector together with much larger improvements in manufacturing. Except in the case of physician services, we are not aware of any empirical evidence demonstrating the medical community's ability to achieve productivity improvements equal to those of the overall economy. The Office of the Actuary's most recent analysis of hospital productivity highlights the difficulties in measurement but suggests that such productivity has been small or negligible during 1981 to 2005.
(See http://www.cms.hhs.gov/HealthCareFinancingReview/downloads/07-08Winterpg49.pdf.)

providers' costs of furnishing services to beneficiaries. Thus, providers for whom Medicare constitutes a substantive portion of their business could find it difficult to remain profitable and, absent legislative intervention, might end their participation in the program (possibly jeopardizing access to care for beneficiaries). Simulations by the Office of the Actuary suggest that roughly 15 percent of Part A providers would become unprofitable within the 10-year projection period as a result of the productivity adjustments.[8] Although this policy could be monitored over time to avoid such an outcome, changes would likely result in smaller actual savings than shown here for these provisions.

A related concern is posed by the requirements that will be placed on the Independent Payment Advisory Board. The Board will be charged with recommending changes to certain Medicare payment categories in an effort to prevent per-beneficiary Medicare costs from increasing faster than the average of the CPI and the CPI-medical for "implementation years" 2015 through 2019.[9] The Secretary of HHS is required to implement the Board's recommendations unless the statutory process is overridden by new legislation.

Average Medicare costs per beneficiary usually increase over time as a function of (i) medical-specific price growth, (ii) more utilization of services by beneficiaries, and (iii) greater "intensity" or average complexity of these services. In general, limiting cost growth to a level below medical price inflation alone would represent an exceedingly difficult challenge. Actual Medicare cost growth per beneficiary was below the target level in only 4 of the last 25 years, with 3 of those years immediately following the Balanced Budget Act of 1997; the impact of the BBA prompted Congress to pass legislation in 1999 and 2000 moderating many of the BBA provisions. As an additional comparison, during the last 25 years the average increase in the target growth rate has been 0.33 percent per year below the average increase in nominal GDP per capita—which is approximately the target level for the physician sustainable growth rate (SGR) payment system. Congress has overridden the SGR-based payment reductions for each of the last 7 years (and, to date, for the first 5 months of 2010).

The Board's efforts would be further complicated by provisions that prohibit increases in cost-sharing requirements and that exempt certain categories of Medicare expenditures from consideration. We have estimated the savings for section 3403 under the assumption that the provision will be implemented as specified; in particular, we have not assumed that Congress would pass subsequent legislation to prevent implementation of the Board's recommendations. Although the savings from the other Medicare provisions in the PPACA are quite substantial, they would not be sufficient to meet the growth rate targets specified in conjunction with the Advisory Board. We estimate that meeting the growth rate targets in 2015-2019 would require changes that would reduce Medicare growth rates by another 0.3 percent per year, on average, in addition to the impacts of the productivity adjustments, MA and DSH reductions, and other provisions in the PPACA.

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[8] The simulations were based on actual fiscal year 2007 Medicare and total facility margin distributions for hospitals, skilled nursing facilities, and home health agencies. Provider revenues and expenditures were projected using representative growth rates and the Office of the Actuary's best estimates of achievable productivity gains for each provider type, and holding all other factors constant. A sensitivity analysis suggested that the conclusions drawn from the simulations would not change significantly under different provider behavior assumptions.

[9] Maximum growth rate reductions of 0.5, 1.0, and 1.25 percentage points would apply to 2015, 2016, and 2017, respectively, and the maximum would be 1.5 percentage points thereafter. After implementation year 2019, the target growth amount would be based on the increase in per capita GDP plus 1 percentage point.

After 2019, further Advisory Board recommendations for growth rate reductions would generally not be required. The other Medicare savings provisions, if permitted to continue, would normally reduce expenditure growth rates to slightly below the post-2019 target level based on per capita GDP growth plus 1 percent. Even if Medicare growth rates exceeded the targets, recommendations might not be required if the projected Medicare growth rate were less than that for overall national health expenditures on a per capita basis—as would tend to be the case, given the continuing Medicare savings. (This exemption from the requirement to make recommendations could not be applied in 2 successive years.) Although the Advisory Board process would have no impact after 2019 based on the specific assumptions underlying these estimates, it would still serve as a brake during any periods of unusually rapid spending growth.

Under the prior law, Medicare Advantage payment benchmarks were generally in the range of 100 to 140 percent of fee-for-service costs. Section 1102 of reconciliation amendments sets the 2011 MA benchmarks equal to the benchmarks for 2010 and specifies that, ultimately, the benchmarks will equal a percentage (95, 100, 107.5, or 115 percent) of the fee-for-service rate in each county. During a transition period, the benchmarks will be based on a blend of the prior ratebook approach and the ultimate percentages. The phase-in schedule for the new benchmarks will occur over 2 to 6 years, with the longer transitions for counties with the larger benchmark decreases under the new method.

The PPACA, as amended, also introduces MA bonuses and rebate levels that are tied to the plans' quality ratings. Beginning in 2012, benchmarks will be increased for plans that receive a 4-star or higher rating on a 5-star quality rating system. The bonuses will be 1.5 percent in 2012, 3.0 percent in 2013, and 5.0 percent in 2014 and later. An additional county bonus, which is equal to the plan bonus, will be provided on behalf of beneficiaries residing in specified counties. The percentage of the "benchmark minus bid" savings provided as a rebate, which historically has been 75 percent, will also be tied to a plan's quality rating. In 2014, when the provision is fully phased in, the rebate share will be 50 percent for plans with a quality rating of less than 3.5 stars; 65 percent for a quality rating of 3.5 to 4.49; and 70 percent for a quality rating of 4.5 or greater.

The new provisions will generally reduce MA rebates to plans and thereby result in less generous benefit packages.[10] We estimate that in 2017, when the MA provisions will be fully phased in, enrollment in MA plans will be lower by about 50 percent (from its projected level of 14.8 million under the prior law to 7.4 million under the new law).

Medicaid/CHIP

The estimated Federal financial effects of the Medicaid and CHIP provisions in the PPACA are shown in table 4, attached. As noted earlier, the costs associated with the expansion of Medicaid eligibility to individuals and families with incomes below 133 percent of the FPL and to children previously in foster care are included with the national coverage provisions shown in table 1. The additional funding for the CHIP program is also included in table 1 with the other coverage provisions.

[10] MA plans use rebate revenues to reduce Medicare coinsurance requirements, add extra benefits such as vision or dental care, and/or reduce enrollee premiums for Part B or Part D of Medicare. The new law also requires adjustments to offset the impact of excess "coding intensity" in determining plan risk scores. These adjustments would prevent increases in future payments to MA plans as a result of such coding.

The total net Federal cost of the other Medicaid and CHIP provisions is estimated to be $28 billion in fiscal years 2010-2019 and reflects numerous cost increases and decreases under the individual provisions. Those with significant Federal savings include various provisions increasing the level of Medicaid prescription drug rebates ($24 billion) and reductions in Medicaid DSH expenditures ($14 billion). Interactions between the different sections of the legislation, such as the lower Medicare Part B premiums under the PPACA, contribute an additional $9 billion in reduced Medicaid outlays.

The key provisions that would increase Federal Medicaid and CHIP costs are the Medicaid "Community First Choice Option" and other changes to encourage home and community-based services ($29 billion), higher Federal matching rates for States with existing childless-adult coverage expansions ($24 billion), a temporary increase in payments to primary care physicians ($11 billion), and increased payments to the territories ($7 billion). (The net impact of the Medicaid and CHIP provisions on State Medicaid costs is a reduction totaling $33 billion through fiscal year 2019. These savings result in part because certain of the provisions reallocate costs from States to the Federal government.)

Impact of Provisions on the Rate of Growth in Health Care Costs

The PPACA includes a number of provisions that are intended, in part, to help control health care costs and to change the overall trend in health spending growth. Many of these are specific to the Medicare program, and their estimated financial effects are shown in table 3. While some of the Medicare provisions would have a largely one-time impact on the *level* of expenditures (for example, the reduction in MA benchmarks), others would have an effect on expenditure *growth rates*. Examples of the latter include the productivity adjustments to Medicare payment updates for most categories of providers, which would reduce overall Medicare cost growth by roughly 0.6 to 0.7 percent per year, and the Independent Payment Advisory Board process, which would further reduce Medicare growth rates during 2015-2019 by about 0.3 percent per year. As discussed previously, however, the growth rate reductions from productivity adjustments are unlikely to be sustainable on a permanent annual basis, and meeting the CPI-based target growth rates prior to 2020 will be very challenging as well.

The Independent Payment Advisory Board will also be required to periodically submit recommendations to Congress and the President regarding methods of slowing the growth of non-Federal health care programs. In many cases, Federal or State legislation would need to be enacted to implement these recommendations. In other cases, they could be adopted voluntarily by private health insurance plans or by health providers or introduced administratively by government entities. Because the nature of these broader recommendations is not known and there is no mandate to adopt them, we have not estimated an explicit impact on health care spending growth.

Another provision that would tend to moderate health care cost growth rates is the excise tax on high-cost employer-sponsored health insurance coverage (section 9001), which is described in more detail in the section of this memorandum on national health expenditures. In reaction to the tax, which would take effect in 2018, many employers would reduce the scope of their health benefits. The resulting reductions in covered services and/or increases in employee cost-sharing requirements would induce workers to use fewer services. Because plan benefit values will generally increase faster than the threshold amounts for defining high-cost plans (which, after

2019, are indexed by the CPI), additional plans would become subject to the excise tax over time, prompting many of those employers to scale back coverage. This continuing cycle would have a moderate impact on the overall growth of expenditures for employer-sponsored insurance. It should be noted, however, that an estimated 12 percent of insured workers in 2019 would be in employer plans with benefit values in excess of the thresholds (before changes to reduce benefits) and that this percentage would increase rapidly thereafter. The effect of the excise tax on reducing health care cost growth would depend on its ongoing application to an expanding share of employer plans and on an increasing scope of benefit reductions for affected plans. Since this provision is characterized as affecting high-cost employer plans, its broader and deeper impact could become an issue.

Certain other provisions of the PPACA are also intended to help control health care costs more generally, through promotion of comparative effectiveness research, greater use of prevention and wellness measures, administrative simplification, and augmented fraud and abuse enforcement. For fiscal years 2010 through 2019, we estimate a relatively small reduction in non-Medicare Federal health care expenditures of $2 billion for these provisions, all of which is associated with comparative effectiveness research.

Comparative Effectiveness Research

We reviewed literature and consulted experts to determine the potential cost savings that could be derived from comparative effectiveness research (CER). We found that the magnitude of potential savings varies widely depending upon the scope and influence of comparative effectiveness efforts. Small savings could be achieved through the wide availability of non-binding research, while substantial savings could be generated by a comparative effectiveness board with authority over payment and coverage policies.

Our interpretation of the CER provisions in the PPACA, which allow the Secretary of HHS to use evidence and findings from CER within defined limits in making coverage determinations under Medicare, is consistent with a low level of influence, translating into an estimated total reduction in national health expenditures of $8 billion for calendar years 2010 through 2019, and Federal savings of about $4 billion for fiscal years 2010 through 2019 (including Medicare). We anticipate that such savings would develop gradually, as changes in provider practice and culture evolved over time. Expert input on this subject suggests that the full impact of comparative effectiveness research, together with dissemination and application of its results, would take many years to develop.

Other Provisions

We show a negligible financial impact over the next 10 years for the other provisions intended to help control future health care cost growth. There is no consensus in the available literature or among experts that prevention and wellness efforts result in lower costs. Several prominent studies conclude that such provisions—while improving the quality of individuals' lives in important ways—generally increase costs overall. For example, while it is possible that savings can be achieved for many people by diagnosing diseases in early stages and promoting lifestyle

and behavioral changes that reduce the risk for serious and costly illnesses, additional costs are incurred as a result of increased screenings, preventive care, and extended years of life.[11]

Regarding the general fraud and abuse and administrative simplification provisions (that is, excluding the Medicare and Medicaid provisions), we find that the language is not sufficiently specific to provide estimates.

CLASS Program

Title VIII of the health reform act establishes a new, voluntary, Federal insurance program providing a cash benefit if a participant is unable to perform at least two or three activities of daily living or has substantial cognitive impairment. The program will be financed by participant premiums, with no Federal subsidy. Participants will have to meet certain modest work requirements during a 5-year vesting period before becoming eligible for benefits. Benefits are intended to be used to help purchase community living assistance services and supports (CLASS) that would help qualifying beneficiaries maintain their personal and financial independence and continue living in the community. Benefits can also be used to help cover the cost of institutional long-term care.

As shown in the table on page 2, we estimate a net Federal savings for the CLASS program of $38 billion during the first 9 years of operations—the first 5 of which are prior to the commencement of benefit payments. After 2015, as benefits are paid, the net savings from this program will decline; in 2025 and later, projected benefits exceed premium revenues, resulting in a net Federal cost in the longer term.[12]

We estimate that roughly 2.8 million persons will participate in the program by the third year. This level represents about 2 percent of potential participants, compared to a participation rate of 4 percent for private long-term care insurance offered through employers. Factors affecting participation in CLASS include the program's voluntary nature, the lack of a Federal subsidy, a minimal premium for students and individuals with incomes under 100 percent of the FPL (initially $5 per month), a relatively high premium for all other participants as a result of adverse selection and the effect of subsidizing participants paying the $5 premium, a new and unfamiliar benefit, and the availability of lower-priced private long-term care insurance for many.

Compounding this situation will be the probable participation of a significant number of individuals who already meet the functional limitation requirements to qualify for benefits. In the sixth year of the program (2016), these participants would begin to receive benefits, along with others who had developed such limitations in the interim. We estimate that an initial

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[11] Title IV in the PPACA creates a Prevention and Public Health Fund and authorizes the appropriation of $15 billion for these purposes. We consider these expenditures to be primarily administrative in nature and thus have not included them as program costs in this memorandum.

[12] The CLASS program is intended to be financed on a long-range, 75-year basis through participant premiums that would fully fund benefits and administrative expenses. If this goal can be achieved, despite anticipated serious adverse selection problems (described subsequently), then annual expenditures would be met through a combination of premium income and interest earnings on the assets of the CLASS trust fund. The Federal Budget impact would be the net difference between premium receipts and program outlays. Thus, the trust fund would be adequately financed in this scenario, but the Federal Budget would have a net savings each year prior to 2025 and a net cost each year thereafter.

average premium level of about $240 per month would be required to adequately fund CLASS program costs for this level of enrollment, adverse selection, and premium inadequacy for students and low-income participants. (Except for those paying the $5 premium, individuals enrolling in a given year will pay a constant premium amount throughout their participation, unless trust fund deficits necessitate a premium increase. Premiums will vary by age at enrollment and by year of enrollment.)

In general, voluntary, unsubsidized, and non-underwritten insurance programs such as CLASS face a significant risk of failure as a result of adverse selection by participants. Individuals with health problems or who anticipate a greater risk of functional limitation would be more likely to participate than those in better-than-average health. Setting the premium at a rate sufficient to cover the costs for such a group further discourages persons in better health from participating, thereby leading to additional premium increases. This effect has been termed the "classic assessment spiral" or "insurance death spiral." The problem of adverse selection is intensified by requiring participants to subsidize the $5 premiums for students and low-income enrollees. Although Title VIII includes modest work requirements in lieu of underwriting and specifies that the program is to be "actuarially sound" and based on "an actuarial analysis of the 75-year costs of the program that ensures solvency throughout such 75-year period," there is a very serious risk that the problem of adverse selection will make the CLASS program unsustainable.[13]

Immediate Insurance Reforms

A number of provisions in the PPACA have an immediate effect on insurance coverage. Most of these provisions, however, do not have a direct impact on Federal expenditures. (A discussion of their impact on national health expenditures is included in the following section of this memorandum.) Section 1101 of the PPACA authorizes the expenditure of up to $5 billion in support of a temporary national insurance pool for high-risk individuals without other health insurance. Section 1102 requires the Secretary of HHS to establish a Federal reinsurance program in 2010-2013 for early retirees and their families in employer-sponsored health plans. Participation by employers is optional, and the law authorizes up to $5 billion in Federal financing for the reinsurance costs. No other financing is provided, and reinsurance claims would be paid only as long as the authorized amount lasts. We estimate that the full amount of the authorizations for sections 1101 and 1102 would be expended during the first 1 to 3 calendar years of operation.

National Health Expenditure Impacts

The estimated effects of the PPACA on overall national health expenditures (NHE) are shown in table 5. In aggregate, we estimate that for calendar years 2010 through 2019, NHE would increase by $311 billion, or 0.9 percent, over the updated baseline projection that was released on June 29, 2009.[14] Year by year, the relative increases are largest in 2016, when the coverage expansions would be fully phased in (2.0 percent), and gradually decline thereafter to 1.0 percent

[13] An analysis of the potential adverse selection problems for the CLASS program was performed by a nonpartisan, joint workgroup of the American Academy of Actuaries and the Society of Actuaries. Their report was issued on July 22, 2009 and is available at http://www.actuary.org/pdf/health/class_july09.pdf .

[14] R. Foster and S. Heffler, "Updated and Extended National Health Expenditure Projections, 2010-2019." Memorandum dated June 29, 2009. Available online at http://www.cms.hhs.gov/NationalHealthExpendData/Downloads/NHE_Extended_Projections.pdf.

in 2019, as the effects of the Medicare market basket reductions compound and as the excise tax on high-cost employer health plans becomes effective. The NHE share of GDP is projected to be 21.0 percent in 2019, compared to 20.8 percent under prior law.

The increase in total NHE is estimated to occur primarily as a net result of the substantial expansions in coverage under the PPACA, together with the expenditure reductions for Medicare. Numerous studies have demonstrated that individuals and families with health insurance use more health services than otherwise-similar persons without insurance. Under the health reform legislation, as noted above, an estimated 34 million currently uninsured people would gain comprehensive coverage through the health insurance Exchanges, their employers, or Medicaid. The availability of coverage would typically result in a fairly substantial increase in the utilization of health care services, with a corresponding impact on total health expenditures. These higher costs would be partially offset by the sizable discounts imposed on providers by State Medicaid payment rules and by the significant discounts negotiated by private health insurance plans. We estimate that the net effect of the utilization increases and price reductions arising from the coverage provisions of the PPACA would increase NHE in 2019 by about 3.4 percent.

The PPACA will also affect aggregate NHE through the Medicare savings provisions. We estimate that these impacts would reduce NHE by roughly 2.4 percent in 2019, assuming that the productivity adjustments to Medicare payment updates and the impacts of the Independent Payment Advisory Board can be sustained through this period. The legislation would have only a slight impact on the utilization of health care services by Medicare beneficiaries (subject to the caveat mentioned previously regarding possible access issues under the provision to permanently reduce annual provider payment updates by economy-wide productivity gains). Medicaid outlays for health care would increase under some provisions and decrease under others; excluding the coverage expansion, the overall higher level of such costs would lower total U.S. health expenditures in 2019 by about 0.1 percent.

The immediate insurance reforms in Title I will affect national health expenditures as well, although by relatively small amounts. We estimate that the creation of a national high-risk insurance pool will result in roughly 375,000 people gaining coverage in 2010, increasing national health spending by $4 billion. By 2011 and 2012 the initial $5 billion in Federal funding for this program would be exhausted, resulting in substantial premium increases to sustain the program; we anticipate that such increases would limit further participation. An estimated 2.7 million retirees and dependents would be affected by the Federal reinsurance program for early retirees with employer-sponsored insurance. Although the reinsurance program would increase Federal costs by the allotted $5 billion, we estimate that the impact on total national health expenditures would be negligible.

Beginning in 2010, qualified child dependents below age 26 who are uninsured will be allowed to enroll under dependent coverage. An estimated 485,000 dependent children will gain insurance coverage through their parents' private group health plans, increasing national health spending by $0.9 billion. These impacts are expected to persist through 2013. Additionally, because this provision would not expire when the Medicaid expansion, individual mandate, and Exchanges start in 2014, we anticipate that these individuals would continue to remain covered as dependents even though they may be newly eligible for other coverage. Finally, we did not estimate NHE coverage or cost impacts for the other immediate reform provisions, such as prohibiting limitations on pre-existing conditions or elimination of lifetime aggregate benefit

limits. We believe that each of these provisions would have only a relatively minor upward impact on national health spending.

Section 9001 of the PPACA places an excise tax on employer-sponsored health insurance coverage with a benefit value above specified levels (generally $10,200 for individuals and $27,500 for families in 2018, adjusted in 2019 by growth in the CPI plus 1 percentage point and by growth in the CPI thereafter).[15] The tax is 40 percent of the excess benefit value above these thresholds. We estimate that, in aggregate, affected employers will reduce their benefit packages in such a way as to eliminate about three-quarters of the excess benefit value. The resulting higher cost-sharing requirements for employees would have an initial impact on the overall level of health expenditures, reducing total NHE by an estimated 0.1 percent in 2019. Moreover, because health care costs will generally increase faster than the CPI, we anticipate additional, incremental benefit coverage reductions in future years to prevent an increase in the share of employer coverage subject to the excise tax. These further adjustments would contribute to a small reduction in the growth in total health care costs (but an increase in out-of-pocket costs) for affected employees in 2019 and later.[16] As mentioned earlier, the proportion of workers experiencing reductions in their employer-sponsored health coverage as a result of the excise tax is estimated to increase rapidly after 2019.

The health reform legislation, as enacted, imposes collective annual fees on manufacturers and importers of brand-name prescription drugs and on health insurance plans. In addition, the PPACA establishes an excise tax on non-personal-use retail sales by manufacturers and importers of medical devices. For manufacturers and importers of brand-name prescription drugs, the fee is $2.5 billion in 2011, increasing to a maximum of $4.1 billion by 2018, and then is set at $2.8 billion per year in 2019 and beyond.[17] For insurers, the annual fee is set at $8.0 billion starting in 2014 and rises to $14.3 billion by 2018; thereafter, the fee increases by the rate of premium growth. In each case, the total annual fee amount would be assessed on the specified industry as a whole; the share of the fee payable by any given firm in that industry would be determined based on sales (for manufacturers and importers of drugs) and on net premiums (in the case of insurers), with some limited exemptions. The excise tax on medical device sales is effective in 2011 and is set at 2.3 percent of first sales in each year. We anticipate that these fees and the excise tax would generally be passed through to health consumers in the form of higher drug and device prices and higher insurance premiums, with an associated increase in overall national health expenditures ranging from $2.1 billion in 2011 to $18.2 billion in 2018 and $17.8 billion in 2019.

Although, compared to prior law, the *level* of total national health expenditures is estimated to be higher through 2019 under the PPACA, two particular provisions of the legislation would help reduce NHE *growth rates* after 2016. Specifically, the productivity adjustments to most Medicare payment updates would reduce NHE growth by about 0.10 to 0.15 percent per year. In addition, the excise tax on high-cost employer health plans (with benefit thresholds indexed by the CPI plus 1 percent for 2019 and by the CPI thereafter) would exert a further decrease in NHE

[15] Higher thresholds apply in the case of qualified retirees and individuals in high-risk occupations. Additionally, a higher threshold applies for employers with above-average proportions of older and/or female workers.

[16] We have not included the excise taxes under this provision in the estimated financial effects of the PPACA shown in this memorandum. Similarly, the indirect impacts on Federal income taxes and social insurance payroll taxes are not shown.

[17] These fees are allocated to the Part B account of the Medicare Supplementary Medical Insurance trust fund.

growth rates of an estimated 0.05 percent in 2019 and slightly more than that for some years after. Although these growth rate differentials are not large, over time they would have a noticeable downward effect on the level of national health expenditures. Such an outcome, however, would depend critically on the sustainability of both provisions. As discussed previously, the Medicare productivity adjustments could become unsustainable even within the next 10 years, and over time the reductions in the scope of employer-sponsored health insurance could also become an issue. For these reasons, the estimated reductions in NHE growth rates after 2016 may not be fully achievable.

Underlying the overall moderate effects of the PPACA on NHE will be various changes by payer. Based on the net impact of (i) the substantial coverage expansions, (ii) the significant cost-sharing subsidies for low-to-middle-income persons, (iii) the maximum out-of-pocket limitations associated with the qualified health benefit, and (iv) the increases in workers' cost-sharing obligations in plans affected by the excise tax on high-cost employer-sponsored health insurance coverage, we estimate that overall out-of-pocket spending would be reduced significantly by the PPACA (a net total decline of $237 billion in calendar years 2010-2019).

Public spending would increase under the PPACA as a result of the expansion of the Medicaid program and additional CHIP funding but would be reduced by the net Medicare savings from the legislation. Private expenditures would decrease somewhat because of the net reduction in the number of persons with employer-sponsored health insurance and the reduced benefits for plans affected by the excise tax on high-cost employer coverage. The sizable growth in health insurance coverage through Exchange plans would also affect NHE amounts by payer. Prior to the PPACA, public expenditures (principally Medicare and Medicaid) were estimated to represent 52 percent of total NHE in 2019. Under the PPACA, the public share would be roughly 51 percent if health expenditures by Exchange plans are classified as private spending.[18]

Caveats and Limitations of Estimates

The Federal costs and savings, changes in health insurance coverage, and effects on total national health expenditures presented in this memorandum represent the Office of the Actuary's best estimates for the PPACA. Although we believe that these estimates are reasonable and fairly portray the likely future effects of this comprehensive package of health care reforms, they are

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[18] The allocation of NHE *by payer* is based on the entity that is responsible for establishing the coverage and benefit provisions and that has the primary responsibility to ensure that payment is made for health care services. (Auxiliary analyses of NHE *by sponsor* are also prepared, based on the financing of health expenditures in the U.S.) Because all Exchange plans will be private plans, under the traditional NHE classification approach these expenditures would be considered private health insurance spending. However, the classification of health expenditures made by Exchange plans is complicated by three factors:

(i) The Exchanges will be government entities, with a role in setting minimum benefit standards, but they will not directly provide health insurance coverage. The same situation applies to the multi-State Exchange plans arranged by the Office of Personnel Management.

(ii) The Federal government, through the refundable tax credits and cost-sharing reductions, will subsidize a significant portion of Exchange plan premiums and cost-sharing liabilities.

(iii) The premium subsidies will vary between zero and 100 percent from one person to another, and the cost-sharing subsidies from zero to 80 percent on an insurance-value basis.

A more precise determination of the appropriate classification of the Exchange plan expenditures based on national health expenditure accounting principles will be conducted in the future.

subject to much greater uncertainty than normal. The following caveats should be noted, and the estimates should be interpreted cautiously in view of their limitations.

- These financial and coverage impacts are based on the provisions of the PPACA as enacted on March 23, 2010 and amended on March 30 by the Health Care and Education Reconciliation Act of 2010.

- Many of the provisions, particularly the coverage expansions, are unprecedented or have been implemented only on a smaller scale (for example, at the State level). Consequently, little historical experience is available with which to estimate the potential impacts.

- The behavioral responses to changes introduced by national health reform legislation are impossible to predict with certainty. In particular, the responses of individuals, employers, insurance companies, and Exchange administrators to the new coverage mandates, Exchange options, and insurance reforms could differ significantly from the assumptions underlying the estimates presented here.

- The nominal dollar amounts of costs and savings under national health reform are sensitive to the assumed trajectory of future health cost trends. Relative measures, such as the cost as a percentage of GDP, are less sensitive.

- Due to the very substantial challenges inherent in modeling national health reform legislation, our estimates will vary from those of other experts and agencies. Differences in results from one estimating entity to another may tend to cause confusion among policy makers. These differences, however, provide a useful reminder that all such estimates are uncertain and that actual future impacts could differ significantly from the estimates of any given organization. Indeed, the future costs and coverage effects could lie outside of the range of estimates provided by the various estimators.

- The existing number of uninsured persons in the U.S. is difficult to measure, and the number of uninsured persons who are undocumented aliens is considerably more uncertain. Medicaid coverage and Exchange premium subsidies under the PPACA are not available to undocumented aliens. As a result of these measurement difficulties, the actual costs under the PPACA and the reduction in the number of uninsured persons may be somewhat higher or lower than estimated in this memorandum.

- Certain Federal costs and savings were not included in our estimates if (i) a provision would have no, or only a minor, impact; (ii) the legislative language did not provide sufficient detail with which to estimate a provision's impact; or (iii) the estimates are outside of the scope of the Office of the Actuary's expertise and will be prepared by other agencies. In particular, we did not include any Federal savings pertaining to the excise tax on high-cost employer-sponsored health insurance coverage, the fees on insurance plans, the excise tax on devices, and other non-Medicare revenue provisions of the PPACA, as those estimates are provided by the Department of the Treasury. (In contrast, the impacts of these provisions on national health expenditures are reflected.) Similarly, Federal administrative expenses associated with the PPACA are not included here and will be estimated separately. The Congressional Budget Office and the Joint Committee on Taxation have estimated that the total amount of Medicare savings and additional excise tax and other revenues would somewhat more than offset the cost of the national coverage provisions, resulting in an overall small reduction in the Federal

deficit through 2019, and for the following 10 years as well, if all of the provisions continued to be fully implemented.

- In estimating the financial impacts of the PPACA, we assumed that the increased demand for health care services could be met without market disruptions. In practice, supply constraints might initially interfere with providing the services desired by the additional 34 million insured persons. Price reactions—that is, providers successfully negotiating higher fees in response to the greater demand—could result in higher total expenditures or in some of this demand being unsatisfied. Alternatively, providers might tend to accept more patients who have private insurance (with relatively attractive payment rates) and fewer Medicare or Medicaid patients, exacerbating existing access problems for Medicaid enrollees. Either outcome (or a combination of both) should be considered plausible and even probable initially.

  The latter possibility is especially likely in the case of the substantially higher volume of Medicaid services, for which provider payment rates are well below average. Therefore, it is reasonable to expect that a significant portion of the increased demand for Medicaid would be difficult to meet, particularly over the first few years.

  We have not attempted to model that impact or other plausible supply and price effects, such as supplier entry and exit or cost-shifting towards private payers. A specific estimate of these potential outcomes is impracticable at this time, given the uncertainty associated with both the magnitude of these effects and the interrelationships among these market dynamics. We may incorporate such factors in future estimates, should we determine that they can be estimated with a reasonable degree of confidence. For now, we believe that consideration should be given to the potential consequences of a significant increase in demand for health care meeting a relatively fixed supply of health care providers and services.

- As stated in the section on Medicare estimates, reductions in payment updates to health care providers, based on economy-wide productivity gains, are unlikely to be sustainable on a permanent annual basis. If these reductions were to prove unworkable within the 10-year period 2010-2019 (as appears probable for significant numbers of hospitals, skilled nursing facilities, and home health agencies), then the actual Medicare savings from these provisions would be less than shown in this memorandum. Similarly, the further reductions in Medicare growth rates mandated for 2015 through 2019 through the Independent Payment Advisory Board may be difficult to achieve in practice.

- In estimating the financial impact of the Medicaid eligibility expansion, we assumed that existing and new Medicaid enrollees would be appropriately classified for FMAP purposes.

- As discussed in the section on the CLASS program, we believe that there is a very serious risk that the program, as currently specified, will not be sustainable because of adverse selection.

Conclusions

The national health care reform provisions in the Patient Protection and Affordable Care Act, as amended, make far-reaching changes to the health sector, including mandated coverage for most people, required payments by most employers not offering insurance, expanded eligibility for Medicaid, Federal premium and cost-sharing subsidies for many individuals and families, a new system of health benefits Exchanges for facilitating coverage, and a new Federal insurance

program in support of long-term care. Additional provisions will reduce Medicare outlays, make other Medicaid modifications, provide more funding for the CHIP program, add certain benefit enhancements for these programs, and combat fraud and abuse. Federal revenues will be increased through an excise tax on high-cost insurance plans; fees or excise taxes on drugs, devices, and health plans; higher Hospital Insurance payroll taxes for high-income taxpayers; a new tax on investment revenues and other unearned income; and other provisions.

The Office of the Actuary at CMS has estimated the effects of the non-tax provisions of the PPACA on Federal outlays, overall national health expenditures, and health insurance coverage in the U.S. Our estimates are based on available data sources and what we believe are reasonable assumptions regarding individual, employer, and health plan responses to the legislation, together with analyses of the likely changes in the cost and use of health care services. Our primary estimates for the PPACA are as follows:

- The total Federal cost of the national insurance coverage provisions would be about $828 billion during fiscal years 2010 through 2019.
- By 2019, an additional 34 million U.S. citizens and other legal residents would have health insurance coverage meeting the essential-benefit requirements.
- Total net savings in 2010-2019 from Medicare provisions would offset about $575 billion of the Federal costs for the national coverage provisions. The Medicaid and CHIP provisions, excluding the expansion of Medicaid and increased CHIP funding, would raise costs by $28 billion. Additional Federal revenues would further offset the coverage costs; however, the Office of the Actuary does not have the expertise necessary to estimate all such impacts. The Congressional Budget Office and the Joint Committee on Taxation have estimated an overall reduction in the Federal Budget deficit through 2019 under the PPACA.
- The new Community Living Assistance Services and Supports (CLASS) insurance program would produce an estimated total net savings of $38 billion through fiscal year 2019. This effect, however, is due to the initial 5-year period during which no benefits would be paid. Over the longer term, expenditures would exceed premium receipts, and there is a very serious risk that the program would become unsustainable as a result of adverse selection by participants.
- Total national health expenditures in the U.S. during 2010-2019 would increase by about 0.9 percent. The additional demand for health services could be difficult to meet initially with existing health provider resources and could lead to price increases, cost-shifting, and/or changes in providers' willingness to treat patients with low-reimbursement health coverage.
- The mandated reductions in Medicare payment updates for providers, the actions of the Independent Payment Advisory Board, and the excise tax on high-cost employer-sponsored health insurance would have a downward impact on future health care cost growth rates. During 2010-2019, however, these effects would be outweighed by the increased costs associated with the expansions of health insurance coverage. Also, the longer-term viability of the Medicare update reductions is doubtful. Other provisions, such as comparative effectiveness research, are estimated to have a relatively small effect on expenditure growth rates.

We hope that the information presented here will be of value to policy makers and administrators as they endeavor to implement and monitor the health reform act.

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Chief Actuary

Attachments: 5

Table 1 — Estimated Federal Costs (+) or Savings (-) under the Patient Protection and Affordable Care Act, as Enacted and Amended, in billions

	Fiscal Year										Total, FY
Provisions	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2010-2019
Total*	$9.2	-$0.7	-$12.6	-$22.3	$16.8	$57.9	$63.1	$54.2	$47.2	$38.5	$251.3
Coverage Provisions:	3.3	4.6	4.9	5.2	82.9	119.2	138.2	146.6	157.6	165.8	828.2
Medicaid Expansion and CHIP Funding	—	—	—	—	38.8	62.9	78.7	72.2	76.3	81.2	410.3
Credits:	3.3	4.6	4.9	5.2	49.6	67.6	77.9	99.1	110.3	115.5	537.9
Individual Exchange Subsidies:	—	—	—	—	43.9	61.4	76.3	99.1	110.3	115.5	506.5
Refundable Premium Tax Credits	—	—	—	—	38.4	54.2	68.3	88.6	98.7	103.0	451.1
Reduced Cost-Sharing Requirements	—	—	—	—	5.5	7.2	8.0	10.5	11.6	12.5	55.4
Small Employer Credits	3.3	4.6	4.9	5.2	5.7	6.2	1.6	0.0	0.0	0.0	31.4
Penalties:	—	—	—	—	-5.5	-11.3	-18.4	-24.7	-29.0	-30.9	-119.9
Individual Penalties	—	—	—	—	0.0	-2.4	-5.3	-7.6	-8.6	-9.2	-33.1
Employer Penalties	—	—	—	—	-5.5	-9.0	-13.0	-17.1	-20.4	-21.8	-86.8
Medicare	1.2	-4.7	-14.9	-26.3	-68.8	-60.3	-75.2	-92.1	-108.2	-125.7	-575.1
Medicaid/CHIP (Excluding Coverage Expansions)	-0.9	-0.9	0.8	4.5	8.6	5.1	4.6	3.4	1.3	1.7	28.3
Cost Trend Proposals:	—	—	—	—	0.0	-0.1	-0.2	-0.4	-0.6	-0.9	-2.3
Comparative Effectiveness Research†	—	—	—	—	0.0	-0.1	-0.2	-0.4	-0.6	-0.9	-2.3
Prevention and Wellness	—	—	—	—	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Fraud and Abuse	—	—	—	—	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Administrative Simplification	—	—	—	—	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Additional Proposals:	5.6	0.4	-3.3	-5.6	-5.9	-6.0	-4.3	-3.4	-2.8	-2.4	-27.8
CLASS Program	—	-2.8	-4.5	-5.6	-5.9	-6.0	-4.3	-3.4	-2.8	-2.4	-37.8
Immediate Reforms	5.6	3.2	1.2	—	—	—	—	—	—	—	10.0

* Excludes Title IX revenue provisions except for sections 9008 (fees on manufacturers and importers of brand-name prescription drugs) and 9015 (additional HI payroll tax). Also excludes certain provisions with limited impacts and Federal administrative costs.

† Excludes the Medicare impact of CER, which is included in the Medicare savings total.

Source: Centers for Medicare & Medicaid Services, Office of the Actuary.

April 22, 2010

Table 2 — Estimated Effects of the Patient Protection and Affordable Care Act, as Enacted and Amended, on Enrollment by Insurance Coverage, in millions

	Calendar Year									
Prior Law Baseline	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
Medicare	46.9	48.0	49.4	50.9	52.4	53.9	55.4	57.1	58.7	60.5
Medicaid/CHIP	59.2	60.5	61.6	62.0	60.6	60.3	61.1	61.9	62.7	63.5
Other Public	12.3	12.6	12.9	13.2	13.6	13.9	14.2	14.6	14.9	15.2
Employer-Sponsored Private Health Insurance	163.8	163.2	164.5	165.0	166.1	166.6	166.4	166.2	166.0	165.9
Other Private Health Insurance*	26.1	25.3	25.5	25.6	25.8	25.8	25.8	25.8	25.8	25.7
Uninsured	48.3	48.6	47.9	48.1	50.0	51.7	53.1	54.4	55.6	56.9
Insured Share of US Population†	84.4%	84.5%	84.8%	84.9%	84.4%	84.0%	83.8%	83.5%	83.3%	83.0%

	Calendar Year									
New Law — PPACA	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
Medicare	46.9	48.0	49.4	50.9	52.4	53.9	55.4	57.1	58.7	60.5
Medicaid/CHIP	59.2	60.5	61.6	62.0	83.6	84.6	84.1	82.1	82.9	83.9
Other Public	12.6	12.6	12.9	13.2	13.6	13.9	14.2	14.6	14.9	15.2
Employer-sponsored Private Health Insurance	164.3	163.7	164.9	165.5	168.1	169.0	166.6	164.7	163.7	164.5
Other Private Health Insurance*	26.1	25.3	25.5	25.6	12.6	12.2	11.5	10.9	10.4	10.0
Exchanges	—	—	—	—	16.9	18.6	24.8	29.8	31.4	31.6
Uninsured	47.5	48.1	47.4	47.6	23.8	22.2	21.0	22.0	22.8	23.1
Insured Share of US Population†	84.7%	84.6%	85.0%	85.0%	92.6%	93.2%	93.6%	93.3%	93.1%	93.1%

	Calendar Year									
Impact of PPACA	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019
Medicare	—	—	—	—	—	—	—	—	—	—
Medicaid/CHIP	—	—	—	—	23.0	24.3	23.1	20.2	20.2	20.4
Other Public	0.4	—	—	—	—	—	—	—	—	—
Employer-sponsored Private Health Insurance	0.5	0.5	0.5	0.5	2.0	2.5	0.2	-1.5	-2.4	-1.4
Other Private Health Insurance*	—	—	—	—	-13.2	-13.7	-14.3	-14.9	-15.3	-15.7
Exchanges	—	—	—	—	16.9	18.6	24.8	29.8	31.4	31.6
Uninsured	-0.9	-0.5	-0.5	-0.5	-26.2	-29.5	-32.1	-32.4	-32.9	-33.8
Insured Share of US Population†	0.3%	0.2%	0.2%	0.2%	8.2%	9.1%	9.8%	9.8%	9.9%	10.1%

* In the prior-law baseline, other private health insurance includes private Medicare supplemental coverage and individual coverage. In the new-law estimates, other private health insurance includes only those with Medicare supplemental coverage.

† Calculated as a proportion of total U.S. population, including unauthorized immigrants.

Source: Centers for Medicare & Medicaid Services, Office of the Actuary.

April 22, 2010

Table 3—Estimated Medicare Costs (+) or Savings (–) under the Patient Protection and Affordable Care Act, as Enacted and Amended
(Amounts in millions)

Sec.	Provision	Fiscal year 2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	Total, 2010-14	2010-19
	TITLE III-IMPROVING THE QUALITY AND EFFICIENCY OF HEALTH CARE												
	SUBTITLE A-TRANSFORMING THE HEALTH CARE DELIVERY SYSTEM												
	PART I-LINKING PAYMENT TO QUALITY OUTCOMES IN THE MEDICARE PROGRAM												
3001	Hospital Value-Based Purchasing	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
3002	Physician Quality Reporting Initiative	0	0	0	210	120	-190	-390	-580	-560	-530	330	-1,920
3003	Expansion of Physician Feedback Program	0	0	0	0	0	0	0	0	0	0	0	0
3004	Quality Reporting for Long-Term Care Hospitals, Inpatient Rehabilitation Hospitals, and Hospice Programs	0	0	0	0	-30	-30	-30	-30	-20	-20	-30	-160
3005	Quality Reporting for PPS-exempt Cancer Hospitals	0	0	0	0	0	0	0	0	0	0	0	0
3006	Value-based Purchasing for SNF, HHA, & ASC	0	0	0	0	0	0	0	0	0	0	0	0
3007	Value-based Payment Modifer under Physician Fee Schedule	0	0	0	0	0	0	0	0	0	0	0	0
3008	Payment Adjustment for Conditions Acquired in Hospitals	0	0	0	0	0	-520	-610	-660	-700	-750	0	-3,240
	PART II-NATIONAL STRATEGY TO IMPROVE HEALTH CARE QUALITY												
3011	National Strategy	0	0	0	0	0	0	0	0	0	0	0	0
3012	Interagency Working Group on Health Care Quality	0	0	0	0	0	0	0	0	0	0	0	0
3013	Quality Measure Development	0	0	0	0	0	0	0	0	0	0	0	0
3014	Quality and Efficiency Measurement	0	0	0	0	0	0	0	0	0	0	0	0
3015	Data Collection; Public Reporting	0	0	0	0	0	0	0	0	0	0	0	0
	PART III-ENCOURAGING DEVELOPMENT OF THE NEW PATIENT CARE MODELS												
3021	CMS Innovation Center	0	0	0	0	0	0	0	0	0	0	0	0
3022	Medicare Shared Savings Program	0	0	0	0	0	0	0	0	0	0	0	0
3023	National Pilot Program on Payment Bundling	0	0	0	0	0	0	0	0	0	0	0	0
3024	Independence at Home Demonstration Program	0	0	0	0	0	0	0	0	0	0	0	0
3025	Hospital Readmissions Reduction Program	0	0	0	-530	-630	-1,180	-1,320	-1,410	-1,510	-1,620	-1,160	-8,200
3026	Community-Based Care Transitions Program												
	Part A	0	100	100	100	100	100	0	0	0	0	400	500
	Part B	0	0	0	0	0	0	0	0	0	0	0	0
3027	Extension of Gainsharing Demonstration	0	0	0	0	0	0	0	0	0	0	0	0
	SUBTITLE B-IMPROVING MEDICARE FOR PATIENTS AND PROVIDERS												
	PART I-ENSURING BENEFICIARY ACCESS TO PHYSICIAN CARE AND OTHER SERVICES												
3101	Increase in Physician Payment Update	0	0	0	0	0	0	0	0	0	0	0	0
3102	Extension of Floor on Medicare Work Geographic Adjustment	510	780	290	0	0	0	0	0	0	0	1,580	1,580
3103	Extension of Exceptions for Therapy Caps	520	1,160	500	10	10	20	20	20	20	20	2,200	2,300
3104	Extension of Treatment of Certain Physician Pathology Services	40	80	40	0	0	0	0	0	0	0	160	160
3105	Extension of Ambulance Add-ons	20	10	0	0	0	0	0	0	0	0	30	30
3106	Extension of Long-Term Care Hospital Provisions	30	440	530	140	10	0	0	0	0	0	1,150	1,150
3107	Extension of Physician Fee Schedule Mental Health Add-on	40	20	0	0	0	0	0	0	0	0	60	60
3108	Permitting Physician Assistants to Order Post-Hospital Extended Care Services	0	0	0	0	0	0	0	0	0	0	0	0
3109	Exemption of Certain Pharmacies from Accreditation Requirements	0	0	0	0	0	0	0	0	0	0	0	0
3110	Part B Special Enrollment for Disabled TRICARE	0	10	20	30	40	40	40	40	50	50	100	320

Table 3—Estimated Medicare Costs (+) or Savings (–) under the Patient Protection and Affordable Care Act, as Enacted and Amended
(Amounts in millions)

		Fiscal year										Total,	
Sec.	Provision	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2010-14	2010-19
3111	Bone Density Tests	20	40	20	0	0	0	0	0	0	0	80	80
3112	Revision to Medicare Improvement Fund												
	Part A	0	0	0	0	-15,350	0	0	0	0	0	-15,350	-15,350
	Part B	0	0	0	0	-11,890	0	0	0	0	0	-11,890	-11,890
3113	Treatment of Certain Complex Diagnostic Lab Tests	0	0	0	0	0	0	0	0	0	0	0	0
3114	Improved Access for Certified Midwife Services	0	0	0	0	0	0	0	0	0	0	0	0
	PART II-RURAL PROTECTIONS												
3121	Extend of Outpatient Hold Harmless Provision	50	20	0	0	0	0	0	0	0	0	70	70
3122	Extend Reasonable Cost Reimbursement for Laboratory Services in Small Rural Hospitals	0	0	0	0	0	0	0	0	0	0	0	0
3123	Extend Rural Community Hospital Demonstration Program	0	0	0	0	0	0	0	0	0	0	0	0
3124	Extend Medicare Dependent Hospital Program	0	0	100	10	0	0	0	0	0	0	110	110
3125	Improvements to Hospital Payments for Low-volume Hospitals	0	100	110	10	0	0	0	0	0	0	220	220
3126	Demonstration Project on Community Health Integration Models	0	0	0	0	0	0	0	0	0	0	0	0
3127	MEDPAC Study on Payments in Rural Areas	0	0	0	0	0	0	0	0	0	0	0	0
3128	Technical Correction to Critical Access Hospital Services	0	0	0	0	0	0	0	0	0	0	0	0
3129	Medicare Rural Hospital Flexibilty Program	0	0	0	0	0	0	0	0	0	0	0	0
	PART III-IMPROVING PAYMENT ACCURACY												
3131	Payment Adjustment for Home Health Care												
	Part A	20	-220	-370	-410	-690	-1,140	-1,710	-2,340	-2,700	-2,900	-1,670	-12,460
	Part B	20	-260	-450	-510	-860	-1,410	-2,120	-2,900	-3,350	-3,600	-2,060	-15,440
3132	Hospice Reform	0	0	0	0	0	0	0	0	0	0	0	0
3133	Improvement to Medicare DSH Payments	0	0	0	0	-110	-7,100	-9,170	-10,610	-11,180	-11,760	-110	-49,930
3134	Misvalued Codes under Physician Fee Schedule	0	0	0	0	0	0	0	0	0	0	0	0
3135	Equipment Utilization Factor for Advanced Imaging Services	0	-110	-170	-200	-210	-230	-240	-260	-270	-290	-690	-1,980
3136	Revision of Payment for Power Wheelchairs	0	-40	-50	-50	-50	-60	-70	-70	-80	-80	-190	-550
3137	Hospital Wage Index Improvement	260	30	0	0	0	0	0	0	0	0	290	290
3138	Treatment of Certain Cancer Hospitals	0	0	0	0	0	0	0	0	0	0	0	0
3139	Payment for Biosimilar Biological Products												
	Part B	0	0	0	10	20	-350	-810	-960	-1,150	-1,360	30	-4,600
	Part D	0	0	0	10	-20	-80	-130	-150	-180	-220	-10	-770
3140	Hospice Concurrent Care Demonstration	0	0	0	0	0	0	0	0	0	0	0	0
3141	Budget Neutrality in Calculation of Hospital Wage Index Floor	0	0	0	0	0	0	0	0	0	0	0	0
3142	Study on Urban Medicare-dependent Hospitals	0	0	0	0	0	0	0	0	0	0	0	0
	SUBTITLE C-PROVISIONS RELATING TO PART C												
3201	Medicare Advantage Payment												
	Part A	0	-3,170	-5,170	-7,170	-9,000	-10,160	-11,350	-12,480	-13,270	-14,190	-24,510	-85,960
	Part B	0	-2,090	-3,400	-4,720	-5,840	-6,700	-7,700	-8,670	-9,560	-10,390	-16,050	-59,070
3202	Benefit Protection and Simplification	0	0	0	0	0	0	0	0	0	0	0	0
3203	Coding Intensity Adjustment During MA Payment Transition	0	0	0	0	0	0	0	0	0	0	0	0
3204	Simplification of Annual Beneficiary Election Periods	0	0	0	0	0	0	0	0	0	0	0	0
3205	Specialized MA Plans for Special Needs Individuals	0	0	0	0	0	0	0	0	0	0	0	0
3206	Extension of Reasonable Cost Contracts	0	0	0	0	0	0	0	0	0	0	0	0

Table 3—Estimated Medicare Costs (+) or Savings (–) under the Patient Protection and Affordable Care Act, as Enacted and Amended
(Amounts in millions)

Sec.	Provision	Fiscal year 2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	Total, 2010-14	2010-19
3207	Technical Correction to MA Private FFS Plans	0	0	0	0	0	0	0	0	0	0	0	0
3208	Making Senior Housing Facility Demonstration Permanent	0	0	0	0	0	0	0	0	0	0	0	0
3209	Authority to Deny Plan Bids	0	0	0	0	0	0	0	0	0	0	0	0
3210	Development of New Standards for Certain Medigap Plans												
	Part A	0	0	0	0	0	0	0	0	0	0	0	0
	Part B	0	0	0	0	0	-50	-70	-80	-90	-90	0	-380
1103	Savings from limits on MA adminstrative costs	0	0	0	0	0	0	0	0	0	0	0	0
	SUBTITLE D-MEDICARE PART D IMPROVEMENTS FOR PRESCRIPTION DRUG PLANS AND MA-PD PLANS												
3301	Medicare Coverage Gap Discount Program	0	110	140	160	180	200	240	250	250	310	590	1,840
3302	Improving the Determination of Part D Low-Income Benchmarks	0	90	120	130	140	140	150	170	180	190	480	1,310
3303	Voluntary De Minimus Policy for Low-Income Subsidy Plans	0	20	20	20	20	30	30	30	30	30	80	230
3304	Special Rule for Widows and Widowers Regarding Eligibility for Low-Income Assistance	0	0	0	0	0	0	0	0	0	0	0	0
3305	Improved Information for Subsidy Eligible Individuals	0	0	0	0	0	0	0	0	0	0	0	0
3306	Funding Outreach and Assistance of Low-Income Programs	45	45	45	0	0	0	0	0	0	0	135	135
3307	Improving Formularies with Respect to Certain Categories or Classes of Drugs	0	0	0	0	0	0	0	0	0	0	0	0
3308	Reducing the Part D Premium Subsidy for High-Income Beneficiaries	0	-390	-590	-670	-760	-860	-980	-1,110	-1,260	-1,430	-2,410	-8,050
3309	Elimination of Cost Sharing for Certain Dual Eligible Individuals	0	0	0	0	0	0	0	0	0	0	0	0
3310	Reducing Wasteful Dispensing of Outpatient Prescription Drugs	0	0	0	0	0	0	0	0	0	0	0	0
3311	Improved Plan Complaint System	0	0	0	0	0	0	0	0	0	0	0	0
3312	Uniform Exception and Appeals Process	0	0	0	0	0	0	0	0	0	0	0	0
3313	OIG Studies and Reports	0	0	0	0	0	0	0	0	0	0	0	0
3314	Cost Incurred by AIDS Drug Assistance and HIS	0	50	70	70	80	90	100	110	120	130	270	820
9012	Elimination of deduction for Medicare Part D subsidy	0	0	0	40	100	130	170	190	190	200	140	1,020
1101	Closing the Medicare presription drug "donut hole"	0	990	170	380	560	860	1,250	1,760	2,340	3,470	2,100	11,780
—	Reducing growth rate of out-of-pocket threshold	0	0	0	0	40	70	170	240	320	480	40	1,320
1206	Drug rebates for new formulations of existing drugs	0	0	0	0	0	0	0	0	0	0	0	0
	SUBTITLE E-ENSURING MEDICARE SUSTAINABILITY												
3401	Market Basket Revisions and Productivity Adjustments												
	Skilled Nursing Faciltities	0	-30	-440	-1,000	-1,560	-2,160	-2,920	-3,700	-4,530	-5,660	-3,030	-22,000
	Long-Term Care Hospitals	-10	-50	-120	-220	-340	-450	-590	-780	-980	-1,250	-740	-4,790
	Inpatient Rehabilitation Facilities	-10	-40	-130	-250	-390	-530	-700	-930	-1,180	-1,510	-820	-5,670
	Hospitals Paid Under the Inpatient Prospective Payment System	-140	-870	-2,670	-4,940	-7,630	-10,360	-13,940	-18,550	-23,510	-29,990	-16,250	-112,600
	Inpatient Psychiatric Facilities--Productivity Adjustments	-10	-30	-100	-190	-290	-400	-530	-700	-890	-1,130	-620	-4,270
	Inpatient Psychiatric Facilities--Quality Reporting	0	0	0	0	-10	-10	-10	-10	-10	0	-10	-50
	Hospice	0	0	0	-220	-450	-690	-980	-1,330	-1,700	-2,120	-670	-7,490
	Hospital Outpatient Services	0	0	-820	-1,280	-1,850	-2,460	-3,180	-4,210	-5,490	-6,970	-3,950	-26,260
	Durable Medical Equipment	0	-20	-50	-80	-110	-140	-180	-230	-280	-330	-260	-1,420
	All Other Part B Fee Schedules, Except Physicians' Services	0	-100	-300	-520	-750	-1,010	-1,310	-1,680	-2,100	-2,600	-1,670	-10,370
	Home Health--Part A	0	-60	-160	-290	-350	-440	-610	-780	-970	-1,230	-860	-4,890
	Home Health--Part B	0	-70	-180	-320	-380	-490	-680	-870	-1,080	-1,370	-950	-5,440

Table 3—Estimated Medicare Costs (+) or Savings (–) under the Patient Protection and Affordable Care Act, as Enacted and Amended
(Amounts in millions)

		Fiscal year										Total,	
Sec.	Provision	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2010-14	2010-19
3402	Temporary Adjustment to Calculation of Part B Premiums												
	Part B Income (additional premiums)	0	-70	-190	-320	-510	-740	-990	-1,320	-1,700	-2,300	-1,090	-8,140
	Part B Benefits	0	0	0	-10	-10	-10	-20	-20	-50	-70	-20	-190
3403	Independent Payment Advisory Board												
	Part A	0	0	0	0	0	-370	-710	-1,200	-2,010	-3,000	0	-7,290
	Part B	0	0	0	0	0	-440	-830	-1,430	-2,420	-3,680	0	-8,800
	Part D	0	0	0	0	0	-330	-670	-1,190	-2,090	-3,290	0	-7,570
10323	Hazards												
	Part A	10	10	10	10	10	20	20	20	20	20	50	150
	Part B	0	10	10	10	10	10	10	10	10	20	40	100
10324	Protection for Frontier States												
	Part A	0	190	230	250	260	280	300	320	340	370	930	2,540
	Part B	0	80	150	170	170	190	200	230	240	280	570	1,710
10325	Delay Implementation of RUG-IV	0	0	0	0	0	0	0	0	0	0	0	0
10326	Pilot Testing for Pay-for-Performance	0	0	0	0	0	0	0	0	0	0	0	0
10327	Improvments to Physician Quality Reporting System	0	0	0	110	120	140	160	0	0	0	230	530
10328	Improvments to Part D Medication Therapy Management	0	0	0	0	0	0	0	0	0	0	0	0
10329	Methodology to Assess Health Plan Value	0	0	0	0	0	0	0	0	0	0	0	0
10330	Modernizing CMS Computer and Data System	0	0	0	0	0	0	0	0	0	0	0	0
10331	Public Reporting of Performance Information	0	0	0	0	0	0	0	0	0	0	0	0
10332	Availability of Medicare Data for Perfomance Measurement	0	0	0	0	0	0	0	0	0	0	0	0
10333	Community Based Collaborative Care Networks	0	0	0	0	0	0	0	0	0	0	0	0
10334	Minority Health	0	0	0	0	0	0	0	0	0	0	0	0
10335	Technical Correction to Hospital Value-based Purchasing	0	0	0	0	0	0	0	0	0	0	0	0
10336	Report on Access to High-quality Dialysis Services	0	0	0	0	0	0	0	0	0	0	0	0
	SUBTITLE F-HEALTH CARE QUALITY IMPROVEMENTS												
3501	Health Care Delivery System Research	0	0	0	0	0	0	0	0	0	0	0	0
3502	Support Patient-Sentered Medical Home	0	0	0	0	0	0	0	0	0	0	0	0
3503	Medication Management Services	0	0	0	0	0	0	0	0	0	0	0	0
3504	Regionalized Systems for Emergency Care	0	0	0	0	0	0	0	0	0	0	0	0
3505	Trauma Care Centers	0	0	0	0	0	0	0	0	0	0	0	0
3506	Shared Decisionmaking	0	0	0	0	0	0	0	0	0	0	0	0
3507	Prescription Drug Benefit and Risk Information	0	0	0	0	0	0	0	0	0	0	0	0
3508	Demonstration to Integrate Quality Care and Patient Safety	0	0	0	0	0	0	0	0	0	0	0	0
3509	Improving Woman's Health	0	0	0	0	0	0	0	0	0	0	0	0
3510	Patient Navigator Program	0	0	0	0	0	0	0	0	0	0	0	0
3511	Authorization of Appropriations	0	0	0	0	0	0	0	0	0	0	0	0
TOTAL, TITLE III		1,415	-3,235	-12,685	-22,020	-58,080	-48,770	-62,690	-77,850	-92,760	-110,160	-94,605	-486,835

Table 3—Estimated Medicare Costs (+) or Savings (–) under the Patient Protection and Affordable Care Act, as Enacted and Amended
(Amounts in millions)

Sec.	Provision	Fiscal year 2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	Total, 2010-14	2010-19
	TITLE IV-PREVENTION OF CHRONIC DISEASE AND IMPROVING PUBLIC HEALTH												
	SUBTITLE A-MODERNINZING DISEASE PREVENTION AND PUBLIC HEALTH SYSTEMS												
4001-4004		0	0	0	0	0	0	0	0	0	0	0	0
	SUBTITLE B-INCREASING ACCESS TO CLINICAL PREVENTIVE SERVICES												
4103	Annual Wellness Visit Providing a Personalized Plan	0	230	380	380	390	420	470	530	590	650	1,380	4,040
4104	Removing Barriers to Preventive Services	0	110	190	200	210	230	250	270	300	330	710	2,090
4105	Evidence-Based Coverage of Preventive Services	-60	-140	-160	-170	-170	-180	-200	-220	-240	-260	-700	-1,800
	SUBTITLE C-CREATING HEALTHIER COMMUNITIES												
4201-4207		0	0	0	0	0	0	0	0	0	0	0	0
	SUBTITLE D-SUPPORT FOR PREVENTION AND PUBLIC HEALTH INNOVATION												
4301-4306		0	0	0	0	0	0	0	0	0	0	0	0
	Additional Provisions	0	0	0	0	0	0	0	0	0	0	0	0
	SUBTITLE E-MISCELLENEOUS PROVISIONS												
4401-4402		0	0	0	0	0	0	0	0	0	0	0	0
TOTAL, TITLE IV		-60	200	410	410	430	470	520	580	650	720	1,390	4,330
	TITLE V-HEALTH CARE WORKFORCE												
	SUBTITLE A-PURPOSE AND DEFINITIONS												
5001-5002		0	0	0	0	0	0	0	0	0	0	0	0
	SUBTITLE B-INNOVATIONS IN HEALTH CARE WORKFORCE												
5101-5103		0	0	0	0	0	0	0	0	0	0	0	0
	SUBTITLE C- INCREASING THE SUPPLY OF THE HEALTH CARE WORKFORCE												
5201-5210		0	0	0	0	0	0	0	0	0	0	0	0
	SUBTITLE D-EHANCING HEALTH CARE WORKFORCE EDUCATION AND TRAINING												
5301-5315		0	0	0	0	0	0	0	0	0	0	0	0
	SUBTITLE E-SUPPORTING THE EXISTING HEALTH CARE WORKFORCE												
5401-5405		0	0	0	0	0	0	0	0	0	0	0	0
	SUBTITLE F-STRENGTHENING PRIMARY CARE AND OTHER WORKFORCE IMPROVEMENTS												
5501	Expanding Access to Primary Care/General Surgery Services	0	170	260	260	260	270	110	0	0	0	950	1,330
5502	Medicare Federally Qualified Health Center Improvements	0	10	10	20	20	70	90	100	100	110	60	530
5503	Distribution of Additional Residency Positions	0	0	0	0	0	0	0	0	0	0	0	0
5504	Counting Resident Time in Outpatient Setting	0	0	0	0	0	0	0	0	0	0	0	0
5505	Rules for Counting Resident Time for Didactic/Scholarly Activities	0	0	0	0	0	0	0	0	0	0	0	0
5506	Preservation of Resident Cap Positions	0	0	0	0	0	0	0	0	0	0	0	0
5507	Demonstration to Address Health Professions Workforce Needs	0	0	0	0	0	0	0	0	0	0	0	0
5508	Increasing Teaching Capacity	0	0	0	0	0	0	0	0	0	0	0	0
5509	Graduate Nurse Education Demonstration Program	0	0	0	0	0	0	0	0	0	0	0	0

Table 3—Estimated Medicare Costs (+) or Savings (–) under the Patient Protection and Affordable Care Act, as Enacted and Amended
(Amounts in millions)

Sec.	Provision	Fiscal year 2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	Total, 2010-14	2010-19
	SUBTITLE G-IMPROVING ACCESS TO HEALTH CARE SERVICES												
5601-5605		0	0	0	0	0	0	0	0	0	0	0	0
	SUBTITLE H-GENERAL PROVISIONS												
5701	Reports	0	0	0	0	0	0	0	0	0	0	0	0
TOTAL, TITLE V		0	180	270	280	280	340	200	100	100	110	1,010	1,860
	TITLE VI-TRANSPARENCY AND PROGRAM INTEGRITY												
	SUBTITLE A-PHYSICIAN OWNERSHIP AND OTHER TRANSPARENCY												
6001	Limitation on Medicare Exception to the Prohibition on Certain Physician Referrals for Hospitals	0	0	0	0	0	0	0	0	0	0	0	0
6002	Transparency Reports on Physician Ownership	0	0	0	0	0	0	0	0	0	0	0	0
6003	Disclosure Requirements for in-Office Ancillary Services	0	0	0	0	0	0	0	0	0	0	0	0
6004	Prescription Drug Sample Transparency	0	0	0	0	0	0	0	0	0	0	0	0
6005	Pharmacy Benefit Managers Transparency Requirements	0	0	0	0	0	0	0	0	0	0	0	0
	SUBTITLE B-NURSING HOME TRANSPARENCY AND IMPROVEMENT												
6101-6121		0	0	0	0	0	0	0	0	0	0	0	0
	SUBTITLE C-NATIONWIDE PROGRAM FOR BACKGROUND CHECKS ON DIRECT PATIENT ACCESS EMPLOYEES OF LONG-TERM CARE FACILITIES AND PROVIDERS												
6201	Nationwide Program for Background Checks	0	0	0	0	0	0	0	0	0	0	0	0
	SUBTITLE D-PATIENT CENTERED OUTCOMES RESEARCH												
6301	Patient Centered Outcomes Research	0	0	0	0	0	0	0	0	0	0	0	0
6302	Federal Coordinating Council for CER	0	0	0	0	0	0	0	0	0	0	0	0
	SUBTITLE E-MEDICARE, MEDICAID, AND CHIP PROGRAM INTEGRITY												
6401	Provider Screening and Other Enrollment Requirements												
	Part A	0	0	0	0	0	0	0	0	0	0	0	0
	Part B	-10	-20	-20	-30	-30	-30	-30	-30	-40	-40	-110	-280
6402	Enhanced Program Integrity Provisions												
	Part A	0	0	-10	-20	-30	-30	-30	-40	-40	-40	-60	-240
	Part B	0	0	-10	-10	-20	-20	-20	-20	-20	-20	-40	-140
6403	Elimination of Duplication between Data Banks												
	Part A	0	0	0	0	0	0	0	0	0	0	0	0
	Part B	0	0	0	0	0	0	0	0	0	0	0	0
6404	Maximum Period for Submission of Medicare Claims to Not More Than 12 Months												
	Part A	0	60	70	70	80	80	90	100	100	110	280	760
	Part B	0	50	50	50	50	60	60	70	70	80	200	540
6405	Physicians Required to Be Enrolled Physicians												
	Part A	-10	-20	-20	-20	-30	-30	-30	-30	-30	-40	-100	-260
	Part B	-30	-50	-50	-50	-60	-60	-60	-70	-70	-80	-240	-580

Table 3—Estimated Medicare Costs (+) or Savings (–) under the Patient Protection and Affordable Care Act, as Enacted and Amended
(Amounts in millions)

Sec.	Provision	Fiscal year 2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	Total, 2010-14	2010-19
6406	Documentaion on Referrals to Programs at High Risk of Waste and Abuse												
	Part A	0	0	0	0	0	0	0	0	0	0	0	0
	Part B	0	0	0	0	0	0	0	0	0	0	0	0
6407	Face to Face Encounter with Patient Required Before Physician May Certify for HHA or DME												
	Part A	-50	-70	-70	-80	-80	-90	-100	-100	-110	-120	-350	-870
	Part B	-70	-110	-120	-130	-140	-150	-160	-170	-180	-190	-570	-1,420
6408	Enhanced Penalties												
	Part A	0	0	0	0	0	0	0	0	0	0	0	0
	Part B	0	0	0	0	0	0	0	0	0	0	0	0
6409	Medicare Self-referral Disclosure Protocal												
	Part A	0	0	0	0	0	0	0	0	0	0	0	0
	Part B	0	0	0	0	0	0	0	0	0	0	0	0
	Adjustments to DME, Prosthetics, Orthotics, and Supplies												
6410	Competitive Acquisition Program												
	Part A	0	0	0	0	0	0	0	0	0	0	0	0
	Part B	0	-10	-20	-20	-20	-20	-80	-120	-130	-140	-70	-560
6411	Expansion of Recovery Audit Contractor (RAC) program												
	Part A	0	-20	-30	-40	-40	-40	-50	-50	-50	-60	-130	-380
	Part B	0	0	-10	-10	-10	-10	-10	-10	-10	-10	-30	-80
	Part D	0	-10	-20	-30	-30	-30	-30	-40	-40	-50	-90	-280
1301	Limit MH Center Providers												
	Part A	0	0	0	0	0	0	0	0	0	0	0	0
	Part B	0	0	-10	-10	-20	-20	-20	-20	-20	-30	-40	-150
1302	Repeal Limits on Claims Review												
	Part A	0	0	0	0	0	0	0	0	0	0	0	0
	Part B	0	0	0	0	0	-10	-10	-10	-10	-10	0	-50
1303	CMS-IRS Data Match to Find Fraudulent Providers												
	Part A	0	0	0	0	0	-10	-10	-10	-10	-10	0	-50
	Part B	0	0	0	-20	-60	-110	-130	-140	-150	-160	-80	-770
1304	Funding for Fraud and Abuse Activities												
	Part A	0	0	0	0	0	0	0	0	0	0	0	0
	Part B	0	0	0	0	0	0	0	0	0	0	0	0
1305	Enhanced Claims Review of New DME Providers												
	Part A	0	0	0	0	0	0	0	0	0	0	0	0
	Part B	0	0	-10	-10	-10	-10	-10	-20	-20	-20	-30	-110
	SUBTITLE G-ADDITIONAL PROGRAM INTEGRITY PROVISIONS												
6601	Prohibition on false Statements and Representations	0	0	0	0	0	0	0	0	0	0	0	0
6602	Clarifying Definition	0	0	0	0	0	0	0	0	0	0	0	0
6603	Development of Model Uniform Report Form	0	0	0	0	0	0	0	0	0	0	0	0
6604	Applicability of State Law to Combat Fraud and Abuse	0	0	0	0	0	0	0	0	0	0	0	0
6605	Administrative Summary Cease and Desist Orders	0	0	0	0	0	0	0	0	0	0	0	0

Table 3—Estimated Medicare Costs (+) or Savings (–) under the Patient Protection and Affordable Care Act, as Enacted and Amended
(Amounts in millions)

Sec.	Provision	Fiscal year 2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	Total, 2010-14	2010-19
6606	MEWA Plan Registration	0	0	0	0	0	0	0	0	0	0	0	0
6607	Permitting Evidentiary Privilege and Confidential Communications	0	0	0	0	0	0	0	0	0	0	0	0
	Additional Provisions	0	0	0	0	0	0	0	0	0	0	0	0
	SUBTITLE H-ELDER JUSTICE ACT												
6701	Short Title of Subtitle	0	0	0	0	0	0	0	0	0	0	0	0
6702	Definitions	0	0	0	0	0	0	0	0	0	0	0	0
6703	Elder Justice	0	0	0	0	0	0	0	0	0	0	0	0
	SUBTITLE I-SENSE OF THE SENATE REGARDING MEDICAL MALPRACTICE												
6801	Sense of the Senate Regarding Medical Malpractice	0	0	0	0	0	0	0	0	0	0	0	0
TOTAL, TITLE VI		-170	-200	-280	-360	-450	-530	-630	-710	-760	-830	-1,460	-4,920
	TITLE IX-REVENUE PROVISIONS												
9008	Fees on Brand-Name Pharmaceutical Manufacturers & Importers	0	-1,650	-2,590	-2,720	-2,850	-2,900	-2,900	-3,640	-3,970	-3,060	-9,810	-26,280
9015	Additional hospital insurance tax on high-income taxpayers[1]	0	0	0	-1,936	-8,090	-8,901	-9,735	-10,580	-11,504	-12,484	-10,026	-63,230
TOTAL, TITLE IX		0	-1,650	-2,590	-4,656	-10,940	-11,801	-12,635	-14,220	-15,474	-15,544	-19,836	-89,510
	TOTAL IMPACT, III-VI and IX	1,185	-4,705	-14,875	-26,346	-68,760	-60,291	-75,235	-92,100	-108,244	-125,704	-113,501	-575,075

[1] Estimates prepared by the Office of the Chief Actuary, Social Security Administration.

Notes: The effects of the managers' amendments, in Title X of P.L. 111-148 and in P.L. 111-152, on provisions in other titles have been incorporated with the estimates shown for those titles.
New proposals included in Title X have been grouped with the corresponding category of proposal in the estimates shown for earlier titles.
The estimates for provisions affecting Medicare Part B are net of premium offset.
The estimates for Medicare provisions that affect fee-for-service benefits also reflect interactions with payments to managed care plans.

Table 4— Estimated Federal Medicaid and CHIP Costs (+) or Savings (–) under the Patient Protection and Affordable Care Act, as Enacted and Amended, in millions

Sec.	Provision	Fiscal Year 2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	Total, 2010-14	2010-19
	Patient Protection and Affordable Care Act (P.L. 111-148)												
	TITLE II—ROLE OF PUBLIC PROGRAMS												
	Subtitle A—Improved Access to Medicaid												
2001	Medicaid coverage for the lowest income populations	1/	1/	1/	1/	1/	1/	1/	1/	1/	1/	1/	1/
	Impact of sections not affecting Medicaid expansion	$0	$0	$0	$30	$1,760	$3,010	$3,800	$4,180	$4,960	$5,780	$1,790	$23,520
2002	Income eligibility for nonelderly determined using modified gross income	1/	1/	1/	1/	1/	1/	1/	1/	1/	1/	1/	1/
2003	Requirement to offer premium assistance for employer-sponsored insurance	1/	1/	1/	1/	1/	1/	1/	1/	1/	1/	1/	1/
2004	Medicaid coverage for former foster care children	1/	1/	1/	1/	1/	1/	1/	1/	1/	1/	1/	1/
2005	Payments to territories	0	191	764	764	930	930	930	930	930	930	2,648	7,300
2006	Special adjustment to FMAP for major disaster recovery	0	255	90	0	0	0	0	0	0	0	345	345
2007	Medicaid Improvement Fund rescission	0	0	0	0	-100	-150	-150	-150	-150	0	-100	-700
	Subtitle B—Enhanced Support for CHIP												
2101	Additional federal financial participation for CHIP	1/	1/	1/	1/	1/	1/	1/	1/	1/	1/	1/	1/
2102	Technical corrections	0	0	0	0	0	0	0	0	0	0	0	0
	Subtitle C—Enrollment Simplification												
2201	Enrollment simplificiation and coordination with State health insurance exchanges	1/	1/	1/	1/	1/	1/	1/	1/	1/	1/	1/	1/
2202	Permitting hospitals to make presumptive eligibility determinations for all Medicaid eligible populations	1/	1/	1/	1/	1/	1/	1/	1/	1/	1/	1/	1/
	Subtitle D—Improvements to Medicaid services												
2301	Coverage for freestanding birth center services	0	0	0	0	0	0	0	0	0	0	0	0
2302	Concurrent care for children	15	15	15	15	20	20	20	25	25	25	80	195
2303	State eligibility option for family planning services	1	0	0	-2	-4	-6	-9	-12	-15	-18	-5	-65
2304	Clarification of definition of medical assistance	0	0	0	0	0	0	0	0	0	0	0	0
	Subtitle E—New State Options for Long-term Services & Supports												
2401	Community First Choice Option	0	0	820	1,060	1,815	2,585	3,520	3,940	4,630	5,210	3,695	23,580
2402	Removal of barriers to providing home and community-based services	25	50	80	120	170	190	215	240	270	300	445	1,660
2403	Money Follows the Person Rebalancing Demonstration	0	0	450	450	450	450	450	0	0	0	1,350	2,250
2404	Protection for recipients of home and community-based services against spousal impoverishment	0	0	0	0	125	190	215	240	270	75	125	1,115
2405	Funding to expand State Aging and Disability Resource Centers	10	10	10	10	10	0	0	0	0	0	50	50
2406	Sense of the Senate regarding long-term care	0	0	0	0	0	0	0	0	0	0	0	0
	Subtitle F—Medicaid Prescription Drug Coverage												
2501(a)(1)	Increase minimum rebate percentage for brand drugs	-240	-440	-440	-470	-500	-530	-560	-590	-630	-670	-2,090	-5,070
2501(a)(2)	Recapture of total savings	-230	-610	-680	-720	-770	-820	-870	-920	-980	-1,040	-3,010	-7,640
2501(b)	Increase rebate percentage for generic drugs	-20	-30	-30	-30	-40	-40	-40	-40	-50	-50	-150	-370
2501(c)	Extension of prescription drug discounts to enrollees of Medicaid managed care organizations	-580	-720	-720	-770	-820	-870	-930	-990	-1,040	-1,100	-3,610	-8,540
2501(d)	Rebates on new drug formulations	-110	-210	-210	-220	-230	-250	-260	-280	-290	-310	-980	-2,370
2501(e)	Maximum rebate amount	0	0	0	0	0	0	0	0	0	0	0	0
2501(f)	Conforming Amendment	0	0	0	0	0	0	0	0	0	0	0	0
2502	Elimination of exclusion of coverage of certain drugs	0	0	0	0	25	30	30	40	45	45	25	215

Table 4— Estimated Federal Medicaid and CHIP Costs (+) or Savings (–) under the Patient Protection and Affordable Care Act, as Enacted and Amended, in millions

Sec.	Provision	Fiscal Year 2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	Total, 2010-14	2010-19
2503	Providing adequate pharmacy reimbursement	0	135	275	290	310	325	345	370	390	415	1,010	2,855
	Subtitle G—Medicaid Disproportionate Share Hospital Payments												
2551	Disproportionate share hospital payments	0	0	0	0	-500	-600	-600	-1,800	-5,000	-5,600	-500	-14,100
	Subtitle H—Dual Eligibles												
2601	5-year period for demonstration projects	0	0	0	0	0	0	0	0	0	0	0	0
2602	Providing Federal coverage and payment coordination for low-income Medicare beneficiaries	0	0	0	0	0	0	0	0	0	0	0	0
	Subtitle I—Medicaid Quality												
2701	Adult health quality measures	40	50	60	70	80	0	0	0	0	0	300	300
2702	Payment Adjustment for Health Care-Acquired Conditions	0	-1	-4	-5	-5	-5	-6	-6	-7	-7	-15	-46
2703	State option to provide health homes for enrollees with chronic conditions	0	35	90	115	145	175	150	135	135	135	385	1,115
2704	Demonstration project to evaluate integrated care around a hopitalization	0	0	0	0	0	0	0	0	0	0	0	0
2705	Medicaid Global Payment System Demonstration Project	0	0	0	0	0	0	0	0	0	0	0	0
2706	Pediatric Accountable Care Organization Demonstration Project	0	0	0	0	0	0	0	0	0	0	0	0
2707	Medicaid emergency psychiatric demonstration project	15	15	15	15	15	0	0	0	0	0	75	75
	Subtitle J—Improvements to the Medicaid and CHIP Payment and Access Commission (MACPAC)												
2801	MACPAC assessment of policies affecting all Medicaid beneficiaries	0	0	0	0	0	0	0	0	0	0	0	0
	Subtitle K—American Indians and Alaska Natives												
2901	Special rules relating to Indians	1/	1/	1/	1/	1/	1/	1/	1/	1/	1/	1/	1/
2902	Elimination of sunset for reimbursement for all Medicare Part B services furnished by certain Indian hospitals and clinics	0	20	20	20	30	30	30	30	30	30	90	240
	TITLE III—IMPROVING THE QUALITY AND EFFICIENCY OF HEALTH CARE												
	Subtitle B—Improving Medicare for Patients and Providers												
	PART III—Improving payment accuracy												
3139	Payment for biosimilar biological products - Medicaid impact	0	0	0	0	-10	-30	-50	-60	-80	-90	-10	-320
	TITLE IV—PREVENTION OF CHRONIC DISEASE AND IMPROVING PUBLIC HEALTH												
	Subtitle A—Modernizing Disease prevention and Public Health Systems												
4004(i)	Public awareness of preventive and obesity-related services	0	0	0	0	0	0	0	0	0	0	0	0
	Subtitle B—Increasing Access to clinical Preventive Services												
4101	School-based health centers	155	200	105	115	125	135	145	160	175	190	700	1,505
4106	Improving access to preventive services for eligible adults	0	0	0	6	9	9	10	11	11	12	15	68
4107	Coverage of comprehensive tobacco cessation services for pregnant women	0	0	0	0	-10	-10	-10	-10	-10	-20	-10	-70
4108	Incentives for prevention of chronic disease	0	20	20	20	20	20	0	0	0	0	80	100
	Subtitle D—Support for Prevention and Public Health Innovation												
4302(b)	Addressing health care disparities in Medicaid and CHIP	0	0	0	0	0	0	0	0	0	0	0	0
4306	Funding for Childhood Obesity Demonstration Project	5	5	5	5	5	0	0	0	0	0	25	25

Table 4— Estimated Federal Medicaid and CHIP Costs (+) or Savings (–) under the Patient Protection and Affordable Care Act, as Enacted and Amended, in millions

Sec.	Provision	Fiscal Year 2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	Total, 2010-14	2010-19
	TITLE VI—TRANSPARENCY AND PROGRAM INTEGRITY												
	Subtitle E—Medicare, Medicaid & CHIP Program Integrity Provisions												
6201	Background checks for certain employees of LTC facilities	0	30	20	30	30	30	30	30	30	30	110	260
6401	Provider screening and other enrollment requirements under Medicare, Medicaid & CHIP	0	0	0	0	0	0	0	0	0	0	0	0
6402	Enhanced Medicare and Medicaid program integrity provisions	0	0	0	0	0	0	0	0	0	0	0	0
6403	Elimination of duplication between the Healthcare Integrity and Protection Data Bank and the National Practitioner Data Bank	0	0	0	0	0	0	0	0	0	0	0	0
6407	Face to face encounter with patient required before physicians may certify eligibility for home health services or durable medical equipment under Medicare	0	0	0	0	0	0	0	0	0	0	0	0
6408	Enhanced penalties	0	0	0	0	0	0	0	0	0	0	0	0
6411	Expansion of the Recovery Audit Contractor Program	0	-80	-170	-250	-310	-330	-360	-390	-420	-450	-810	-2,760
	Subtitle F—Additional Medicaid Program Integrity Provisions												
6501	Termination of provider participation under Medicaid if terminated under Medicare or other State plan	0	0	0	0	0	0	0	0	0	0	0	0
6502	Medicaid exclusion from participation relating to certain ownership, control, and management affiliations	0	0	0	0	0	0	0	0	0	0	0	0
6503	Billing agents, clearinghouses, or other alternate payees required to register under Medicaid	0	0	0	0	0	0	0	0	0	0	0	0
6504	Requirement to report expanded set of data elements under MMIS to detect fraud and abuse	0	0	0	0	0	0	0	0	0	0	0	0
6505	Prohibition on payments to institutions or entities located outside of the United States	0	0	0	0	0	0	0	0	0	0	0	0
6506	Overpayments	260	480	-65	-70	-75	-80	-85	-90	-95	-105	530	75
6507	Mandatory State use of national correct coding initiative	-10	-25	-40	-45	-55	-75	-85	-90	-95	-100	-175	-620
6508	General effective date	0	0	0	0	0	0	0	0	0	0	0	0
	TITLE VII—IMPROVING ACCESS TO INNOVATIVE MEDICAL THERAPIES												
	Subtitle B—More Affordable Medicines for Children and Underserved Communities												
7101(d)	Expanded participation in 340B programs - Medicaid credits	2/	2/	2/	2/	2/	2/	2/	2/	2/	2/	2/	2/
	TITLE X—STRENGTHENING QUALITY, AFFORDABLE HEALTH CARE FOR ALL AMERICANS												
	Subtitle B—Provisions Relating to Title II												
	Part I—Medicaid and CHIP												
10202	Incentives for States to offer home and community-based services as a long-term care alternative to nursing homes	0	0	800	910	1,030	260	0	0	0	0	2,740	3,000
SUBTOTAL, P.L. 111-148		*-664*	*-605*	*1,279*	*1,463*	*3,675*	*4,593*	*5,875*	*4,903*	*3,040*	*3,617*	*5,149*	*27,177*

Table 4— Estimated Federal Medicaid and CHIP Costs (+) or Savings (–) under the Patient Protection and Affordable Care Act, as Enacted and Amended, in millions

Sec.	Provision	Fiscal Year 2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	Total, 2010-14	2010-19
	Health Care and Education Reconciliation Act of 2010 (P.L. 111-152)												
	TITLE I—Coverage Medicare, Medicaid, and Revenues												
	Subtitle C—Medicaid												
1202	Payment to primary care physicians	0	0	0	3,670	5,460	1,450	0	0	0	0	9,130	10,580
SUBTOTAL, P.L. 111-152		*0*	*0*	*0*	*3,670*	*5,460*	*1,450*	*0*	*0*	*0*	*0*	*9,130*	*10,580*
	Interaction - Prescription Drugs	-190	-250	-270	-280	-300	-320	-330	-360	-390	-410	-1,290	-3,100
	Interaction - Medicaid Expansion	0	0	0	0	200	-90	-270	-300	-320	-350	200	-1,130
	Interaction with Medicare Premium Provisions	0	-70	-220	-320	-400	-520	-670	-840	-1,010	-1,140	-1,010	-5,190
TOTAL, P.L. 111-148 and P.L. 111-152, with interactions		**-854**	**-925**	**789**	**4,533**	**8,635**	**5,113**	**4,605**	**3,403**	**1,320**	**1,717**	**12,179**	**28,337**

[1] Included with Title I impacts.
[2] Insufficient detail for estimation.

Table 5 — Estimated Increases (+) or Decreases (–) in National Health Expenditures under the Patient Protection and Affordable Care Act, as Enacted and Amended, in billions

Prior Law Baseline	Calendar Year 2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	Total, CY 2010-2019
Total National Health Expenditures (NHE)	$ 2,632.2	$ 2,778.7	$ 2,944.4	$ 3,125.4	$ 3,325.5	$ 3,551.5	$ 3,798.5	$ 4,067.7	$ 4,358.8	$ 4,670.6	$ 35,253.3
Medicare	515.5	550.5	591.0	634.1	679.7	732.1	790.4	857.2	930.9	1,010.9	7,292.3
Medicaid/CHIP	436.1	473.0	512.4	553.4	593.9	641.7	696.6	755.9	821.7	893.2	6,377.9
Federal	282.2	277.9	292.7	315.9	337.8	364.3	395.0	427.9	464.6	504.5	3,662.8
State & Local	153.9	195.1	219.6	237.6	256.1	277.4	301.5	328.0	357.1	388.7	2,715.1
Other Public	307.7	325.1	343.9	364.6	386.6	410.5	436.4	464.0	493.2	523.6	4,055.5
Out of Pocket	285.1	297.7	308.9	322.3	340.3	359.4	379.1	400.2	422.8	446.7	3,562.4
Employer-Sponsored Private Health Insurance	847.0	879.0	919.3	966.0	1,024.5	1,088.4	1,156.0	1,228.7	1,305.6	1,387.3	10,801.8
Other Private Health Insurance*	49.2	51.0	54.6	57.7	59.4	61.5	63.5	65.9	68.2	70.6	601.7
Other Private†	191.6	202.4	214.5	227.3	241.1	257.8	276.4	296.0	316.4	338.3	2,561.8
NHE as percent of Gross Domestic Product (GDP)‡	17.8%	17.9%	18.1%	18.3%	18.6%	19.0%	19.4%	19.8%	20.3%	20.8%	

New Law — PPACA	Calendar Year 2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	Total, CY 2010-2019
Total National Health Expenditures (NHE)	$ 2,636.4	$ 2,774.4	$ 2,932.7	$ 3,101.5	$ 3,358.8	$ 3,615.9	$ 3,875.2	$ 4,139.6	$ 4,413.1	$ 4,716.5	$ 35,564.0
Medicare	516.0	545.7	577.1	604.8	626.1	682.1	726.1	778.1	836.4	897.9	6,790.2
Medicaid/CHIP	434.2	471.4	513.3	557.7	657.3	716.6	779.4	832.7	900.8	977.9	6,841.4
Federal	281.2	277.4	294.5	321.4	398.3	435.7	478.2	503.6	543.8	588.7	4,122.7
State & Local	153.0	194.1	218.9	236.3	259.0	280.8	301.2	329.1	357.1	389.2	2,718.7
Other Public	312.3	325.2	344.0	364.9	381.7	406.2	434.6	463.4	493.5	523.6	4,049.4
Out of Pocket	285.1	297.9	308.6	321.6	313.6	323.9	334.7	352.5	381.4	405.8	3,325.1
Employer-Sponsored Private Health Insurance	848.2	881.0	921.3	968.3	1,038.8	1,112.3	1,160.7	1,212.2	1,259.7	1,336.1	10,738.7
Other Private Health Insurance*	49.3	50.9	54.1	57.0	14.9	14.9	14.5	14.2	13.9	13.6	297.4
Other Private†	191.4	202.3	214.3	227.2	234.8	251.9	272.8	293.4	314.5	335.6	2,538.1
Exchanges	—	—	—	—	91.7	107.9	152.4	193.1	212.8	225.8	983.7
NHE as percent of Gross Domestic Product (GDP)‡	17.8%	17.9%	18.0%	18.2%	18.8%	19.3%	19.8%	20.2%	20.5%	21.0%	

Table 5, continued — Estimated Increases (+) or Decreases (–) in National Health Expenditures under the Patient Protection and Affordable Care Act, as Enacted and Amended, in billions

Impact of PPACA	Calendar Year 2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	Total, CY 2010-2019
Total National Health Expenditures (NHE)	$ 4.2	-$ 4.3	-$ 11.7	-$ 24.0	$ 33.4	$ 64.4	$ 76.7	$ 71.9	$ 54.3	$ 45.8	$ 310.8
Medicare	0.4	-4.8	-13.9	-29.4	-53.6	-50.0	-64.3	-79.1	-94.5	-113.0	-502.1
Medicaid/CHIP	-1.9	-1.5	1.0	4.3	63.4	74.8	82.8	76.8	79.2	84.7	463.5
Federal	-1.1	-0.5	1.7	5.6	60.4	71.4	83.2	75.7	79.2	84.2	459.9
State & Local	-0.8	-1.0	-0.8	-1.3	2.9	3.5	-0.4	1.1	0.0	0.5	3.6
Other Public	4.6	0.1	0.2	0.3	-4.9	-4.3	-1.9	-0.6	0.3	0.0	-6.1
Out of Pocket	-0.1	0.2	-0.3	-0.7	-26.7	-35.5	-44.4	-47.6	-41.3	-40.9	-237.3
Employer-Sponsored Private Health Insurance	1.2	2.0	2.0	2.3	14.3	24.0	4.8	-16.4	-45.9	-51.2	-63.1
Other Private Health Insurance*	0.1	-0.1	-0.4	-0.7	-44.5	-46.5	-49.1	-51.7	-54.3	-57.0	-304.2
Other Private†	-0.2	-0.2	-0.2	-0.1	-6.3	-5.9	-3.7	-2.6	-2.0	-2.7	-23.7
Exchanges	—	—	—	—	91.7	107.9	152.4	193.1	212.8	225.8	983.7
NHE as percent of Gross Domestic Product (GDP)‡	0.0%	0.0%	-0.1%	-0.1%	0.2%	0.3%	0.4%	0.3%	0.3%	0.2%	

*In the prior-law baseline, other private health insurance includes private Medicare supplemental coverage and individual coverage. In the new-law estimates, other private health insurance includes only those with Medicare supplemental coverage.

†In the NHE accounts, other private spending includes philanthropic giving and income from non-patient sources, such as parking and investment income, for institutional providers.

‡Based on Gross Domestic Product (GDP) projections that accompanied the February 24, 2009 NHE projections release for 2008-2018. (http://www.cms.hhs.gov/NationalHealthExpendData/downloads/proj2008.pdf)

Source: Centers for Medicare & Medicaid Services, Office of the Actuary.

April 22, 2010

Federal Register

Monday,
June 28, 2010

Part III

Department of the Treasury

Internal Revenue Service

26 CFR Parts 54 and 602

Department of Labor

Employee Benefits Security Administration

29 CFR Part 2590

Department of Health and Human Services

45 CFR Parts 144, 146, and 147

Patient Protection and Affordable Care Act; Requirements for Group Health Plans and Health Insurance Issuers Under the Patient Protection and Affordable Care Act Relating to Preexisting Condition Exclusions, Lifetime and Annual Limits, Rescissions, and Patient Protections; Final Rule and Proposed Rule

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 54 and 602

[TD 9491]

RIN 1545–BJ61

DEPARTMENT OF LABOR

Employee Benefits Security Administration

29 CFR Part 2590

RIN 1210–AB43

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[OCIIO–9994–IFC]

45 CFR Parts 144, 146, and 147

RIN 0991–AB69

Patient Protection and Affordable Care Act: Preexisting Condition Exclusions, Lifetime and Annual Limits, Rescissions, and Patient Protections

AGENCIES: Internal Revenue Service, Department of the Treasury; Employee Benefits Security Administration, Department of Labor; Office of Consumer Information and Insurance Oversight, Department of Health and Human Services.

ACTION: Interim final rules with request for comments.

SUMMARY: This document contains interim final regulations implementing the rules for group health plans and health insurance coverage in the group and individual markets under provisions of the Patient Protection and Affordable Care Act regarding preexisting condition exclusions, lifetime and annual dollar limits on benefits, rescissions, and patient protections.

DATES: *Effective Date.* These interim final regulations are effective on August 27, 2010.

Comment Date. Comments are due on or before August 27, 2010.

Applicability Dates:

1. *Group health plans and group health insurance coverage.* These interim final regulations, except those under Public Health Service Act (PHS Act) section 2704 (26 CFR 54.9815–2704T, 29 CFR 2590.715–2704, 45 CFR 147.108), generally apply to group health plans and group health insurance issuers for plan years beginning on or after September 23, 2010. These interim final regulations under PHS Act section 2704 (26 CFR 54.9815–2704T, 29 CFR 2590.715–2704, 45 CFR 147.108) generally apply for plan years beginning on or after January 1, 2014, except that in the case of individuals who are under 19 years of age, these interim final regulations under PHS Act section 2704 apply for plan years beginning on or after September 23, 2010.

2. *Individual health insurance coverage.* These interim final regulations, except those under PHS Act section 2704 (45 CFR 147.108), generally apply to individual health insurance issuers for policy years beginning on or after September 23, 2010. These interim final regulations under PHS Act section 2704 (45 CFR 147.108) generally apply to individual health insurance issuers for policy years beginning on or after January 1, 2014, except that in the case of enrollees who are under 19 years of age, these interim final regulations under PHS Act section 2704 apply for policy years beginning on or after September 23, 2010.

ADDRESSES: Written comments may be submitted to any of the addresses specified below. Any comment that is submitted to any Department will be shared with the other Departments. Please do not submit duplicates.

All comments will be made available to the public. **Warning:** Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments are posted on the Internet exactly as received, and can be retrieved by most Internet search engines. No deletions, modifications, or redactions will be made to the comments received, as they are public records. Comments may be submitted anonymously.

Department of Labor. Comments to the Department of Labor, identified by RIN 1210–AB43, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *E-mail: E-OHPSCA715.EBSA@dol.gov.*
- *Mail or Hand Delivery:* Office of Health Plan Standards and Compliance Assistance, Employee Benefits Security Administration, Room N–5653, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210, *Attention:* RIN 1210–AB43.

Comments received by the Department of Labor will be posted without change to *http://www.regulations.gov* and *http://www.dol.gov/ebsa,* and available for public inspection at the Public Disclosure Room, N–1513, Employee Benefits Security Administration, 200 Constitution Avenue, NW., Washington, DC 20210.

Department of Health and Human Services. In commenting, please refer to file code OCIIO–9994–IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

- *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions under the "More Search Options" tab.
- *By regular mail.* You may mail written comments to the following address ONLY: Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, Attention: OCIIO–9994–IFC, P.O. Box 8016, Baltimore, MD 21244–1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

- *By express or overnight mail.* You may send written comments to the following address ONLY: Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, Attention: OCIIO–9994–IFC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.
- *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

○ For delivery in Washington, DC—Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the OCIIO drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

○ For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call (410) 786–7195 in advance to

schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the "Collection of Information Requirements" section in this document.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately three weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. EST. To schedule an appointment to view public comments, phone 1–800–743–3951.

Internal Revenue Service. Comments to the IRS, identified by REG–120399–10, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* CC:PA:LPD:PR (REG–120399–10), Room 5205, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.
- *Hand or courier delivery:* Monday through Friday between the hours of 8 a.m. and 4 p.m. to: CC:PA:LPD:PR (REG–120399–10), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington DC 20224.

All submissions to the IRS will be open to public inspection and copying in Room 1621, 1111 Constitution Avenue, NW., Washington, DC from 9 a.m. to 4 p.m.

FOR FURTHER INFORMATION CONTACT: Amy Turner or Beth Baum, Employee Benefits Security Administration, Department of Labor, at (202) 693–8335; Karen Levin, Internal Revenue Service, Department of the Treasury, at (202) 622–6080; Jim Mayhew, Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, at (410) 786–1565.

Customer Service Information: Individuals interested in obtaining information from the Department of Labor concerning employment-based health coverage laws may call the EBSA Toll-Free Hotline at 1–866–444–EBSA (3272) or visit the Department of Labor's Web site (*http://www.dol.gov/ebsa*). In addition, information from HHS on private health insurance for consumers can be found on the Centers for Medicare & Medicaid Services (CMS) Web site (*http://www.cms.hhs.gov/HealthInsReformforConsume/01_Overview.asp*) and information on health reform can be found at *http://www.healthreform.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Patient Protection and Affordable Care Act (the Affordable Care Act), Public Law 111–148, was enacted on March 23, 2010; the Health Care and Education Reconciliation Act (the Reconciliation Act), Public Law 111–152, was enacted on March 30, 2010. The Affordable Care Act and the Reconciliation Act reorganize, amend, and add to the provisions of part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets. The term "group health plan" includes both insured and self-insured group health plans.[1] The Affordable Care Act adds section 715(a)(1) to the Employee Retirement Income Security Act (ERISA) and section 9815(a)(1) to the Internal Revenue Code (the Code) to incorporate the provisions of part A of title XXVII of the PHS Act into ERISA and the Code, and make them applicable to group health plans, and health insurance issuers providing health insurance coverage in connection with group health plans. The PHS Act sections incorporated by this reference are sections 2701 through 2728. PHS Act sections 2701 through 2719A are substantially new, though they incorporate some provisions of prior law. PHS Act sections 2722 through 2728 are sections of prior law renumbered, with some, mostly minor, changes.

Subtitles A and C of title I of the Affordable Care Act amend the requirements of title XXVII of the PHS Act (changes to which are incorporated into ERISA section 715). The preemption provisions of ERISA section 731 and PHS Act section 2724[2] (implemented in 29 CFR 2590.731(a) and 45 CFR 146.143(a)) apply so that the requirements of part 7 of ERISA and title XXVII of the PHS Act, as amended by the Affordable Care Act, are not to be "construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with group or individual health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement" of the Affordable Care Act. Accordingly, State laws that impose on health insurance issuers requirements that are stricter than the requirements imposed by the Affordable Care Act will not be superseded by the Affordable Care Act.

The Departments of Health and Human Services, Labor, and the Treasury (the Departments) are issuing regulations in several phases implementing the revised PHS Act sections 2701 through 2719A and related provisions of the Affordable Care Act. The first phase in this series was a pair of publications consisting of a Request for Information relating to the medical loss ratio provisions of PHS Act section 2718 and a Request for Information relating to the rate review process of PHS Act 2794, both published in the **Federal Register** on April 14, 2010 (75 FR 19297 and 19335). The second phase was interim final regulations implementing PHS Act section 2714 (requiring coverage of adult children to age 26), published in the **Federal Register** on May 13, 2010 (75 FR 27122). The third phase was interim final regulations implementing section 1251 of the Affordable Care Act (relating to status as a grandfathered health plan), published in the **Federal Register** on June 17, 2010 (75 FR 34538). These interim final regulations are being published to implement PHS Act sections 2704 (prohibiting preexisting condition exclusions), 2711 (regarding lifetime and annual dollar limits on benefits), 2712 (regarding restrictions on rescissions), and 2719A (regarding patient protections). PHS Act section 2704 generally is effective for plan years (in the individual market, policy years) beginning on or after January 1, 2014.

[1] The term "group health plan" is used in title XXVII of the PHS Act, part 7 of ERISA, and chapter 100 of the Code, and is distinct from the term "health plan," as used in other provisions of title I of the Affordable Care Act. The term "health plan" does not include self-insured group health plans.

[2] Code section 9815 incorporates the preemption provisions of PHS Act section 2724. Prior to the Affordable Care Act, there were no express preemption provisions in chapter 100 of the Code.

However, with respect to enrollees, including applicants for enrollment, who are under 19 years of age, PHS Act section 2704 is effective for plan years beginning on or after September 23, 2010 (which is six months after the March 23, 2010 date of enactment of the Affordable Care Act); or in the case of individual health insurance coverage, for policy years beginning, or applications denied, on or after September 23, 2010.[3] The rest of these provisions generally are effective for plan years (in the individual market, policy years) beginning on or after September 23, 2010. The implementation of other provisions of PHS Act sections 2701 through 2719A will be addressed in future regulations.

II. Overview of the Regulations

A. PHS Act Section 2704, Prohibition of Preexisting Condition Exclusions (26 CFR 54.9815–2704T, 29 CFR 2590.715–2704, 45 CFR 147.108)

Section 1201 of the Affordable Care Act adds a new PHS Act section 2704, which amends the HIPAA[4] rules relating to preexisting condition exclusions to provide that a group health plan and a health insurance issuer offering group or individual health insurance coverage may not impose any preexisting condition exclusion. The HIPAA rules (in effect prior to the effective date of these amendments) apply only to group health plans and group health insurance coverage, and permit limited exclusions of coverage based on a preexisting condition under certain circumstances. The Affordable Care Act provision prohibits any preexisting condition exclusion from being imposed by group health plans or group health insurance coverage and extends this protection to individual health insurance coverage. This prohibition generally is effective with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2014, but for enrollees who are under 19 years of age, this prohibition becomes effective for plan years (in the individual market, policy years) beginning on or after September 23, 2010. Until the new Affordable Care Act rules take effect, the HIPAA rules regarding preexisting condition exclusions continue to apply.

HIPAA generally defines a preexisting condition exclusion[5] as a limitation or exclusion of benefits relating to a condition based on the fact that the condition was present before the date of enrollment for the coverage, whether or not any medical advice, diagnosis, care, or treatment was recommended or received before that date. Based on this definition, PHS Act section 2704, as added by the Affordable Care Act, prohibits not just an exclusion of coverage of specific benefits associated with a preexisting condition in the case of an enrollee, but a complete exclusion from such plan or coverage, if that exclusion is based on a preexisting condition.

The protections in the new PHS Act section 2704 generally apply for plan years (in the individual market, policy years) beginning on or after January 1, 2014. The Affordable Care Act provides, however, that these protections apply with respect to enrollees under age 19 for plan years (in the individual market, policy years) beginning on or after September 23, 2010. An enrollee under age 19 thus could not be denied benefits based on a preexisting condition. In order for an individual seeking enrollment to receive the same protection that applies in the case of such an enrollee, the individual similarly could not be denied enrollment or specific benefits based on a preexisting condition. Thus, for plan years (in the individual market, policy years) beginning on or after September 23, 2010, PHS Act section 2704 protects individuals under age 19 with a preexisting condition from being denied coverage under a plan or health insurance coverage (through denial of enrollment or denial of specific benefits) based on the preexisting condition.

These interim final regulations do not change the HIPAA rule that an exclusion of benefits for a condition under a plan or policy is not a preexisting condition exclusion if the exclusion applies regardless of when the condition arose relative to the effective date of coverage. This point is illustrated with examples in the HIPAA regulations on preexisting condition exclusions, which remain in effect.[6] (Other requirements of Federal or State law, however, may prohibit certain benefit exclusions.)

Application to grandfathered health plans. Under the statute and these interim final regulations, a grandfathered health plan that is a group health plan or group health insurance coverage must comply with the PHS Act section 2704 prohibition against preexisting condition exclusions; however, a grandfathered health plan that is individual health insurance coverage is not required to comply with PHS Act section 2704. See 26 CFR 54.9815–1251T, 29 CFR 2590.715–1251, and 45 CFR 147.140 regarding status as a grandfathered health plan.

B. PHS Act Section 2711, Lifetime and Annual Limits (26 CFR 54.9815–2711T, 29 CFR 2590.715–2711, 45 CFR 147.126)

Section 2711 of the PHS Act, as added by the Affordable Care Act, and these interim final regulations generally prohibit group health plans and health insurance issuers offering group or individual health insurance coverage from imposing lifetime or annual limits on the dollar value of health benefits.

The restriction on annual limits applies differently to certain account-based plans, especially where other rules apply to limit the benefits available. For example, under section 9005 of the Affordable Care Act, salary reduction contributions for health flexible spending arrangements (health FSAs) are specifically limited to $2,500 (indexed for inflation) per year, beginning with taxable years in 2013. These interim final regulations provide that the PHS Act section 2711 annual limit rules do not apply to health FSAs. The restrictions on annual limits also do not apply to Medical Savings Accounts (MSAs) under section 220 of the Code and Health Savings Accounts (HSAs) under section 223 of the Code. Both MSAs and HSAs generally are not treated as group health plans because the amounts available under the plans are available for both medical and non-medical expenses.[7] Moreover, annual contributions to MSAs and HSAs are subject to specific statutory provisions that require that the contributions be limited.

Health Reimbursement Arrangements (HRAs) are another type of account-based health plan and typically consist of a promise by an employer to reimburse medical expenses for the year up to a certain amount, with unused amounts available to reimburse medical expenses in future years. *See* Notice 2002–45, 2002–28 IRB 93; Rev. Rul. 2002–41, 2002–28 IRB 75. When HRAs are integrated with other coverage as part of a group health plan and the other coverage alone would comply with the

[3] Section 1255 of the Affordable Care Act. *See also* section 10103(e)–(f) of the Affordable Care Act.

[4] HIPAA is the Health Insurance Portability and Accountability Act of 1996 (Pub. L. 104–191).

[5] Before the amendments made by the Affordable Care Act, PHS Act section 2701(b)(1); after the amendments made by the Affordable Care Act, PHS Act section 2704(b)(1). *See also* ERISA section 701(b)(1) and Code section 9801(b)(1).

[6] *See* Examples 6, 7, and 8 in 26 CFR 54.9801–3(a)(1)(ii), 29 CFR 701–3(a)(1)(ii), 45 CFR 146.111(a)(1)(ii).

[7] Distributions from MSAs and HSAs that are not used for qualified medical expenses are included in income and subject to an additional tax, under sections 220(f)(1), (4) and 223(f)(1), (4) of the Code.

requirements of PHS Act section 2711, the fact that benefits under the HRA by itself are limited does not violate PHS Act section 2711 because the combined benefit satisfies the requirements. Also, in the case of a stand-alone HRA that is limited to retirees, the exemption from the requirements of ERISA and the Code relating to the Affordable Care Act for plans with fewer than two current employees means that the retiree-only HRA is generally not subject to the rules in PHS Act section 2711 relating to annual limits. The Departments request comments regarding the application of PHS Act section 2711 to stand-alone HRAs that are not retiree-only plans.

The statute prohibits annual limits on the dollar value of benefits generally, but allows "restricted annual limits" with respect to essential health benefits (as defined in section 1302(b) of the Affordable Care Act) for plan years (in the individual market, policy years) beginning before January 1, 2014. Grandfathered individual market policies are exempted from this provision. In addition, the statute provides that, with respect to benefits that are not essential health benefits, a plan or issuer may impose annual or lifetime per-individual dollar limits on specific covered benefits. These interim final regulations define "essential health benefits" by cross-reference to section 1302(b) of the Affordable Care Act [8] and applicable regulations. Regulations under section 1302(b) of the Affordable Care Act have not yet been issued.

For plan years (in the individual market, policy years) beginning before the issuance of regulations defining "essential health benefits", for purposes of enforcement, the Departments will take into account good faith efforts to comply with a reasonable interpretation of the term "essential health benefits". For this purpose, a plan or issuer must apply the definition of essential health benefits consistently. For example, a plan could not both apply a lifetime limit to a particular benefit—thus taking the position that it was not an essential health benefit—and at the same time treat that particular benefit as an essential health benefit for purposes of applying the restricted annual limit.

[8] Section 1302(b) of the Affordable Care Act defines essential health benefits to "include at least the following general categories and the items and services covered within the categories: ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral and vision care."

These interim final regulations clarify that the prohibition under PHS Act section 2711 does not prevent a plan or issuer from excluding all benefits for a condition, but if any benefits are provided for a condition, then the requirements of the rule apply. Therefore, an exclusion of all benefits for a condition is not considered to be an annual or lifetime dollar limit.

The statute and these interim final regulations provide that for plan years (in the individual market, policy years) beginning before January 1, 2014, group health plans and health insurance issuers offering group or individual health insurance coverage may establish a restricted annual limit on the dollar value of essential health benefits. The statute provides that in defining the term restricted annual limit, the Departments should ensure that access to needed services is made available with a minimal impact on premiums. For a detailed discussion of the basis for determining restricted annual limits, see section IV.B.3 later in this preamble.

In order to mitigate the potential for premium increases for all plans and policies, while at the same time ensuring access to essential health benefits, these interim final regulations adopt a three-year phased approach for restricted annual limits. Under these interim final regulations, annual limits on the dollar value of benefits that are essential health benefits may not be less than the following amounts for plan years (in the individual market, policy years) beginning before January 1, 2014:

- For plan or policy years beginning on or after September 23, 2010 but before September 23, 2011, $750,000;
- For plan or policy years beginning on or after September 23, 2011 but before September 23, 2012, $1.25 million; and
- For plan or policy years beginning on or after September 23, 2012 but before January 1, 2014, $2 million.

As these are minimums for plan years (in the individual market, policy years) beginning before 2014, plans or issuers may use higher annual limits or impose no limits. Plans and policies with plan or policy years that begin between September 23 and December 31 have more than one plan or policy year under which the $2 million minimum annual limit is available; however, a plan or policy generally may not impose an annual limit for a plan year (in the individual market, policy year) beginning after December 31, 2013.

The minimum annual limits for plan or policy years beginning before 2014 apply on an individual-by-individual basis. Thus, any overall annual dollar limit on benefits applied to families may not operate to deny a covered individual the minimum annual benefits for the plan year (in the individual market, policy year). These interim final regulations clarify that, in applying annual limits for plan years (in the individual market, policy years) beginning before January 1, 2014, the plan or health insurance coverage may take into account only essential health benefits.

The restricted annual limits provided in these interim final regulations are designed to ensure, in the vast majority of cases, that individuals would have access to needed services with a minimal impact on premiums. So that individuals with certain coverage, including coverage under a limited benefit plan or so-called "mini-med" plans, would not be denied access to needed services or experience more than a minimal impact on premiums, these interim final regulations provide for the Secretary of Health and Human Services to establish a program under which the requirements relating to restricted annual limits may be waived if compliance with these interim final regulations would result in a significant decrease in access to benefits or a significant increase in premiums. Guidance from the Secretary of Health and Human Services regarding the scope and process for applying for a waiver is expected to be issued in the near future.

Under these interim final regulations, individuals who reached a lifetime limit under a plan or health insurance coverage prior to the applicability date of these interim final regulations and are otherwise still eligible under the plan or health insurance coverage must be provided with a notice that the lifetime limit no longer applies. If such individuals are no longer enrolled in the plan or health insurance coverage, these interim final regulations also provide an enrollment (in the individual market, reinstatement) opportunity for such individuals. In the individual market, this reinstatement opportunity does not apply to individuals who reached their lifetime limits on individual health insurance coverage if the contract is not renewed or otherwise is no longer in effect. It would apply, however, to a family member who reached the lifetime limit in a family policy in the individual market while other family members remain in the coverage. These notices and the enrollment opportunity must be provided beginning not later than the first day of the first plan year (in the individual market, policy year) beginning on or after September 23, 2010. Anyone eligible for an enrollment

opportunity must be treated as a special enrollee.[9] That is, they must be given the right to enroll in all of the benefit packages available to similarly situated individuals upon initial enrollment.

Application to grandfathered health plans. The statute and these interim final regulations relating to the prohibition on lifetime limits apply to all group health plans and health insurance issuers offering group or individual health insurance coverage, whether or not the plan qualifies as a grandfathered health plan, for plan years (in the individual market, policy years) beginning on or after September 23, 2010. The statute and these interim final regulations relating to the prohibition on annual limits, including the special rules regarding restricted annual limits for plan years beginning before January 1, 2014, apply to group health plans and group health insurance coverage that qualify as a grandfathered health plan, but do not apply to grandfathered health plans that are individual health insurance coverage. The interim final regulations issued under section 1251 of the Affordable Care Act provide that:

- A plan or health insurance coverage that, on March 23, 2010, did not impose an overall annual or lifetime limit on the dollar value of all benefits ceases to be a grandfathered health plan if the plan or health insurance coverage imposes an overall annual limit on the dollar value of benefits.
- A plan or health insurance coverage, that, on March 23, 2010, imposed an overall lifetime limit on the dollar value of all benefits but no overall annual limit on the dollar value of all benefits ceases to be a grandfathered health plan if the plan or health insurance coverage adopts an overall annual limit at a dollar value that is lower than the dollar value of the lifetime limit on March 23, 2010.
- A plan or health insurance coverage that, on March 23, 2010, imposed an overall annual limit on the dollar value of all benefits ceases to be a grandfathered health plan if the plan or health insurance coverage decreases the dollar value of the annual limit (regardless of whether the plan or health insurance coverage also imposed an overall lifetime limit on March 23, 2010 on the dollar value of all benefits).

C. PHS Act Section 2712, Prohibition on Rescissions (26 CFR 54.9815–2712T, 29 CFR 2590.715–2712, 45 CFR 147.128)

PHS Act section 2712 provides rules regarding rescissions of health coverage for group health plans and health insurance issuers offering group or individual health insurance coverage. Under the statute and these interim final regulations, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, must not rescind coverage except in the case of fraud or an intentional misrepresentation of a material fact. This standard sets a Federal floor and is more protective of individuals with respect to the standard for rescission than the standard that might have previously existed under State insurance law or Federal common law. That is, under prior law, rescission may have been permissible if an individual made a misrepresentation of material fact, even if the misrepresentation was not intentional or made knowingly. Under the new standard for rescissions set forth in PHS Act section 2712 and these interim final regulations, plans and issuers cannot rescind coverage unless an individual was involved in fraud or made an intentional misrepresentation of material fact. This standard applies to all rescissions, whether in the group or individual insurance market, and whether insured or self-insured coverage. These rules also apply regardless of any contestability period that may otherwise apply.

This provision in PHS Act section 2712 builds on already-existing protections in PHS Act sections 2703(b) and 2742(b) regarding cancellations of coverage. These provisions generally provide that a health insurance issuer in the group and individual markets cannot cancel, or fail to renew, coverage for an individual or a group for any reason other than those enumerated in the statute (that is, nonpayment of premiums; fraud or intentional misrepresentation of material fact; withdrawal of a product or withdrawal of an issuer from the market; movement of an individual or an employer outside the service area; or, for bona fide association coverage, cessation of association membership). Moreover, this new provision also builds on existing HIPAA nondiscrimination protections for group health coverage in ERISA section 702, Code section 9802, and PHS Act section 2705 (previously included in PHS Act section 2702 prior to the Affordable Care Act's amendments and reorganization to PHS Act title XXVII). The HIPAA nondiscrimination provisions generally provide that group health plans and group health insurance issuers may not set eligibility rules based on factors such as health status and evidence of insurability—including acts of domestic violence or disability. They also provide limits on the ability of plans and issuers to vary premiums and contributions based on health status. For policy years beginning on or after January 1, 2014, additional protections will apply in the individual market, including guaranteed issue of all products, nondiscrimination based on health status, and no preexisting condition exclusions. These protections will reduce the likelihood of rescissions.

These interim final regulations also clarify that other requirements of Federal or State law may apply in connection with a rescission or cancellation of coverage beyond the standards established in PHS Act section 2712, if they are more protective of individuals. For example, if a State law applicable to health insurance issuers were to provide that rescissions are permitted only in cases of fraud, or only within a contestability period, which is more protective of individuals, such a law would not conflict with, or be preempted by, the Federal standard and would apply.

These interim final regulations include several clarifications regarding the standards for rescission in PHS Act section 2712. First, these interim final regulations clarify that the rules of PHS Act section 2712 apply whether the rescission applies to a single individual, an individual within a family, or an entire group of individuals. Thus, for example, if an issuer attempted to rescind coverage of an entire employment-based group because of the actions of an individual within the group, the standards of these interim final regulations would apply. Second, these interim final regulations clarify that the rules of PHS Act section 2712 apply to representations made by the individual or a person seeking coverage on behalf of the individual. Thus, if a plan sponsor seeks coverage from an issuer for an entire employment-based group and makes representations, for example, regarding the prior claims experience of the group, the standards of these interim final regulations would also apply. Finally, PHS Act section 2712 refers to acts or practices that constitute fraud. These interim final regulations clarify that, to the extent that an omission constitutes fraud, that omission would permit the plan or issuer to rescind coverage under this section. An example in these interim final regulations illustrates the application of the rule to misstatements of fact that are inadvertent.

For purposes of these interim final regulations, a rescission is a cancellation or discontinuance of

[9] *See* 26 CFR 54.9801–6(d), 29 CFR 2590.701–6(d), and 45 CFR 146.117(d).

coverage that has retroactive effect. For example, a cancellation that treats a policy as void from the time of the individual's or group's enrollment is a rescission. As another example, a cancellation that voids benefits paid up to a year before the cancellation is also a rescission for this purpose. A cancellation or discontinuance of coverage with only a prospective effect is not a rescission, and neither is a cancellation or discontinuance of coverage that is effective retroactively to the extent it is attributable to a failure to timely pay required premiums or contributions towards the cost of coverage. Cancellations of coverage are addressed under other Federal and State laws, including section PHS Act section 2703(b) and 2742(b), which limit the grounds for cancellation or non-renewal of coverage, as discussed above. Moreover, PHS Act section 2719, as added by the Affordable Care Act and incorporated in ERISA section 715 and Code section 9815, addresses appeals of coverage determinations and includes provisions for keeping coverage in effect pending an appeal. The Departments expect to issue guidance on PHS Act section 2719 in the very near future.

In addition to setting a new Federal floor standard for rescissions, PHS Act section 2712 adds a new advance notice requirement when coverage is rescinded where still permissible. Specifically, the second sentence in section 2712 provides that coverage may not be cancelled unless prior notice is provided. These interim final regulations provide that a group health plan, or a health insurance issuer offering group health insurance coverage, must provide at least 30 calendar days advance notice to an individual before coverage may be rescinded.[10] The notice must be provided regardless of whether the rescission is of group or individual coverage; or whether, in the case of group coverage, the coverage is insured or self-insured, or the rescission applies to an entire group or only to an individual within the group. This 30-day period will provide individuals and plan sponsors with an opportunity to explore their rights to contest the rescission, or look for alternative coverage, as appropriate. The Departments expect to issue future guidance on any notice requirements under PHS Act section 2712 for cancellations of coverage other than in the case of rescission.

[10] Even though prior notice must be provided in the case of a rescission, applicable law may permit the rescission to void coverage retroactively.

In this new Federal statutory protection against rescissions, the Affordable Care Act provides new rights to individuals who, for example, may have done their best to complete what can sometimes be long, complex enrollment questionnaires but may have made some errors, for which the consequences were overly broad and unfair. These interim final regulations provide initial guidance with respect to the statutory restrictions on rescission. If the Departments become aware of attempts in the marketplace to subvert these rules, the Departments may issue additional regulations or administrative guidance to ensure that individuals do not lose health coverage unjustly or without due process.

Application to grandfathered health plans. The rules regarding rescissions and advance notice apply to all grandfathered health plans.

D. PHS Act Section 2719A, Patient Protections (26 CFR 54.9815–2719AT, 29 CFR 2590.715–2719A, 45 CFR 147.138)

Section 2719A of the PHS Act imposes, with respect to a group health plan, or group or individual health insurance coverage, a set of three requirements relating to the choice of a health care professional and requirements relating to benefits for emergency services. The three requirements relating to the choice of health care professional apply only with respect to a plan or health insurance coverage with a network of providers.[11] Thus, a plan or issuer that has not negotiated with any provider for the delivery of health care but merely reimburses individuals covered under the plan for their receipt of health care is not subject to the requirements relating to the choice of a health care professional. However, such plans or health insurance coverage are subject to requirements relating to benefits for emergency services. These interim final regulations reorder the statutory requirements so that all three of the requirements relating to the choice of a health care professional are together and add a notice requirement for those three requirements. None of these requirements apply to grandfathered health plans.

[11] The statute and these interim final regulations refer to providers both in terms of their participation (participating provider) and in terms of a network (in-network provider). In both situations, the intent is to refer to a provider that has a contractual relationship or other arrangement with a plan or issuer.

1. Choice of Health Care Professional

The statute and these interim final regulations provide that if a group health plan, or a health insurance issuer offering group or individual health insurance coverage, requires or provides for designation by a participant, beneficiary, or enrollee of a participating primary care provider, then the plan or issuer must permit each participant, beneficiary, or enrollee to designate any participating primary care provider who is available to accept the participant, beneficiary, or enrollee. Under these interim final regulations, the plan or issuer must provide a notice informing each participant (or in the individual market, the primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a primary care provider.

The statute and these interim final regulations impose a requirement for the designation of a pediatrician similar to the requirement for the designation of a primary care physician. Specifically, if a plan or issuer requires or provides for the designation of a participating primary care provider for a child by a participant, beneficiary, or enrollee, the plan or issuer must permit the designation of a physician (allopathic or osteopathic) who specializes in pediatrics as the child's primary care provider if the provider participates in the network of the plan or issuer and is available to accept the child. In such a case, the plan or issuer must comply with the notice requirements with respect to designation of a primary care provider. The general terms of the plan or health insurance coverage regarding pediatric care otherwise are unaffected, including any exclusions with respect to coverage of pediatric care.

The statute and these interim final regulations also provide rules for a group health plan, or a health insurance issuer offering group or individual health insurance coverage, that provides coverage for obstetrical or gynecological care and requires the designation of an in-network primary care provider. In such a case, the plan or issuer may not require authorization or referral by the plan, issuer, or any person (including a primary care provider) for a female participant, beneficiary, or enrollee who seeks obstetrical or gynecological care provided by an in-network health care professional who specializes in obstetrics or gynecology. The plan or issuer must inform each participant (in the individual market, primary subscriber) that the plan or issuer may not require authorization or referral for obstetrical or gynecological care by a participating health care professional

who specializes in obstetrics or gynecology. Nothing in these interim final regulations precludes the plan or issuer from requiring an in-network obstetrical or gynecological provider to otherwise adhere to policies and procedures regarding referrals, prior authorization for treatments, and the provision of services pursuant to a treatment plan approved by the plan or issuer. The plan or issuer must treat the provision of obstetrical and gynecological care, and the ordering of related obstetrical and gynecological items and services, by the professional who specializes in obstetrics or gynecology as the authorization of the primary care provider. For this purpose, a health care professional who specializes in obstetrics or gynecology is any individual who is authorized under applicable State law to provide obstetrical or gynecological care, and is not limited to a physician.

The general terms of the plan or coverage regarding exclusions of coverage with respect to obstetrical or gynecological care are otherwise unaffected. These interim final regulations do not preclude the plan or issuer from requiring that the obstetrical or gynecological provider notify the primary care provider or the plan or issuer of treatment decisions.

When applicable, it is important that individuals enrolled in a plan or health insurance coverage know of their rights to (1) choose a primary care provider or a pediatrician when a plan or issuer requires designation of a primary care physician; or (2) obtain obstetrical or gynecological care without prior authorization. Accordingly, these interim final regulations require such plans and issuers to provide a notice to participants (in the individual market, primary subscribers) of these rights when applicable. Model language is provided in these interim final regulations. The notice must be provided whenever the plan or issuer provides a participant with a summary plan description or other similar description of benefits under the plan or health insurance coverage, or in the individual market, provides a primary subscriber with a policy, certificate, or contract of health insurance.

2. Emergency Services

If a plan or health insurance coverage provides any benefits with respect to emergency services in an emergency department of a hospital, the plan or issuer must cover emergency services in a way that is consistent with these interim final regulations. These interim final regulations require that a plan or health insurance coverage providing emergency services must do so without the individual or the health care provider having to obtain prior authorization (even if the emergency services are provided out of network) and without regard to whether the health care provider furnishing the emergency services is an in-network provider with respect to the services. The emergency services must be provided without regard to any other term or condition of the plan or health insurance coverage other than the exclusion or coordination of benefits, an affiliation or waiting period permitted under part 7 of ERISA, part A of title XXVII of the PHS Act, or chapter 100 of the Code, or applicable cost-sharing requirements. For a plan or health insurance coverage with a network of providers that provides benefits for emergency services, the plan or issuer may not impose any administrative requirement or limitation on benefits for out-of-network emergency services that is more restrictive than the requirements or limitations that apply to in-network emergency services.

Additionally, for a plan or health insurance coverage with a network, these interim final regulations provide rules for cost-sharing requirements for emergency services that are expressed as a copayment amount or coinsurance rate, and other cost-sharing requirements. Cost-sharing requirements expressed as a copayment amount or coinsurance rate imposed for out-of-network emergency services cannot exceed the cost-sharing requirements that would be imposed if the services were provided in-network. Out-of-network providers may, however, also balance bill patients for the difference between the providers' charges and the amount collected from the plan or issuer and from the patient in the form of a copayment or coinsurance amount. Section 1302(c)(3)(B) of the Affordable Care Act excludes such balance billing amounts from the definition of cost sharing, and the requirement in section 2719A(b)(1)(C)(ii)(II) that cost sharing for out-of-network services be limited to that imposed in network only applies to cost sharing expressed as a copayment or coinsurance rate.

Because the statute does not require plans or issuers to cover balance billing amounts, and does not prohibit balance billing, even where the protections in the statute apply, patients may be subject to balance billing. It would defeat the purpose of the protections in the statute if a plan or issuer paid an unreasonably low amount to a provider, even while limiting the coinsurance or copayment associated with that amount to in-network amounts. To avoid the circumvention of the protections of PHS Act section 2719A, it is necessary that a reasonable amount be paid before a patient becomes responsible for a balance billing amount. Thus, these interim final regulations require that a reasonable amount be paid for services by some objective standard. In establishing the reasonable amount that must be paid, the Departments had to account for wide variation in how plans and issuers determine both in-network and out-of-network rates. For example, for a plan using a capitation arrangement to determine in-network payments to providers, there is no in-network rate per service. Accordingly, these interim final regulations consider three amounts: the in-network rate, the out-of-network rate, and the Medicare rate. Specifically, a plan or issuer satisfies the copayment and coinsurance limitations in the statute if it provides benefits for out-of-network emergency services in an amount equal to the greatest of three possible amounts—

(1) The amount negotiated with in-network providers for the emergency service furnished;

(2) The amount for the emergency service calculated using the same method the plan generally uses to determine payments for out-of-network services (such as the usual, customary, and reasonable charges) but substituting the in-network cost-sharing provisions for the out-of-network cost-sharing provisions; or

(3) The amount that would be paid under Medicare for the emergency service.[12] Each of these three amounts is calculated excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee.

For plans and health insurance coverage under which there is no per-service amount negotiated with in-network providers (such as under a capitation or other similar payment arrangement), the first amount above is disregarded, meaning that the greatest amount is going to be either the out-of-network amount or the Medicare amount. Additionally, with respect to determining the first amount, if a plan or issuer has more than one negotiated amount with in-network providers for a particular emergency service, the amount is the median of these amounts, treating the amount negotiated with each provider as a separate amount in determining the median. Thus, for example, if for a given emergency

[12] As of the date of publication of these interim final regulations, these rates are available to the public at *http://www.cms.hhs.gov/MedicareAdvtgSpecRateStats/downloads/oon-payments.pdf.*

service a plan negotiated a rate of $100 with three providers, a rate of $125 with one provider, and a rate of $150 with one provider; the amounts taken into account to determine the median would be $100, $100, $100, $125, and $150; and the median would be $100. Following the commonly accepted definition of median, if there are an even number of amounts, the median is the average of the middle two. (Cost sharing imposed with respect to the participant, beneficiary, or enrollee would be deducted from this amount before determining the greatest of the three amounts above.)

The second amount above is determined without reduction for out-of-network cost sharing that generally applies under the plan or health insurance coverage with respect to out-of-network services. Thus, for example, if a plan generally pays 70 percent of the usual, customary, and reasonable amount for out-of-network services, the second amount above for an emergency service is the total (that is, 100 percent) of the usual, customary, and reasonable amount for the service, not reduced by the 30 percent coinsurance that would generally apply to out-of-network services (but reduced by the in-network copayment or coinsurance that the individual would be responsible for if the emergency service had been provided in-network).

Although a plan or health insurance coverage is generally not constrained by the requirements of PHS Act section 2719A for cost-sharing requirements other than copayments or coinsurance, these interim final regulations include an anti-abuse rule with respect to such other cost-sharing requirements so that the purpose of limiting copayments and coinsurance for emergency services to the in-network rate cannot be thwarted by manipulation of these other cost-sharing requirements. Accordingly, any other cost-sharing requirement, such as a deductible or out-of-pocket maximum, may be imposed with respect to out-of-network emergency services only if the cost-sharing requirement generally applies to out-of-network benefits. Specifically, a deductible may be imposed with respect to out-of-network emergency services only as part of a deductible that generally applies to out-of-network benefits. Similarly, if an out-of-pocket maximum generally applies to out-of-network benefits, that out-of-pocket maximum must apply to out-of-network emergency services. A plan or health insurance coverage could fashion these other cost-sharing requirements so that a participant, beneficiary, or enrollee is required to pay less for emergency services than for general out-of-network services; the anti-abuse rule merely prohibits a plan or health insurance coverage from fashioning such rules so that a participant, beneficiary, or enrollee is required to pay more for emergency services than for general out-of-network services.

In applying the rules relating to emergency services, the statute and these interim final regulations define the terms emergency medical condition, emergency services, and stabilize. These terms are defined generally in accordance with their meaning under the Emergency Medical Treatment and Labor Act (EMTALA), section 1867 of the Social Security Act. There are, however, some minor variances from the EMTALA definitions. For example, both EMTALA and PHS Act section 2719A define "emergency medical condition" in terms of the same consequences that could reasonably be expected to occur in the absence of immediate medical attention. Under EMTALA regulations, the likelihood of these consequences is determined by qualified hospital medical personnel, while under PHS Act section 2719A the standard is whether a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in such consequences.

Application to grandfathered health plans. The statute and these interim final regulations relating to certain patient protections do not apply to grandfathered health plans. However, other Federal or State laws related to these patient protections may apply regardless of grandfather status.

III. Interim Final Regulations and Request for Comments

Section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act authorize the Secretaries of the Treasury, Labor, and HHS (collectively, the Secretaries) to promulgate any interim final rules that they determine are appropriate to carry out the provisions of chapter 100 of the Code, part 7 of subtitle B of title I of ERISA, and part A of title XXVII of the PHS Act, which include PHS Act sections 2701 through 2728 and the incorporation of those sections into ERISA section 715 and Code section 9815.

In addition, under Section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) a general notice of proposed rulemaking is not required when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. The provisions of the APA that ordinarily require a notice of proposed rulemaking do not apply here because of the specific authority granted by section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act. However, even if the APA were applicable, the Secretaries have determined that it would be impracticable and contrary to the public interest to delay putting the provisions in these interim final regulations in place until a full public notice and comment process was completed. As noted above, numerous provisions of the Affordable Care Act are applicable for plan years (in the individual market, policy years) beginning on or after September 23, 2010, six months after date of enactment. Had the Departments published a notice of proposed rulemaking, provided for a 60-day comment period, and only then prepared final regulations, which would be subject to a 60-day delay in effective date, it is unlikely that it would have been possible to have final regulations in effect before late September, when these requirements could be in effect for some plans or policies. Moreover, the requirements in these interim final regulations require significant lead time in order to implement. For example, in the case of the requirement under PHS Act section 2711 prohibiting overall lifetime dollar limits, these interim final regulations require that an enrollment opportunity be provided for an individual whose coverage ended by reason of reaching a lifetime limit no later than the first day this requirement takes effect. Preparations presumably would have to be made to put such an enrollment process in place. In the case of requirements for emergency care under PHS Act section 2719A, plans and issuers need to know how to process charges by out-of-network providers by as early as the first plan or policy year beginning on or after September 23, 2010. With respect to all the changes that would be required to be made under these interim final regulations, whether adding coverage of children with a preexisting condition under PHS Act section 2704, or determining the scope of rescissions prohibited under PHS Act section 2712, group health plans and health insurance issuers have to be able to take these changes into account in establishing their premiums, and in making other changes to the designs of plan or policy benefits, and these premiums and plan or policy changes would have to receive necessary approvals in advance of the plan or policy year in question.

Accordingly, in order to allow plans and health insurance coverage to be

designed and implemented on a timely basis, regulations must be published and available to the public well in advance of the effective date of the requirements of the Affordable Care Act. It is not possible to have a full notice and comment process and to publish final regulations in the brief time between enactment of the Affordable Care Act and the date regulations are needed.

The Secretaries further find that issuance of proposed regulations would not be sufficient because the provisions of the Affordable Care Act protect significant rights of plan participants and beneficiaries and individuals covered by individual health insurance policies and it is essential that participants, beneficiaries, insureds, plan sponsors, and issuers have certainty about their rights and responsibilities. Proposed regulations are not binding and cannot provide the necessary certainty. By contrast, the interim final regulations provide the public with an opportunity for comment, but without delaying the effective date of the regulations.

For the foregoing reasons, the Departments have determined that it is impracticable and contrary to the public interest to engage in full notice and comment rulemaking before putting these interim final regulations into effect, and that it is in the public interest to promulgate interim final regulations.

IV. Economic Impact and Paperwork Burden

A. Summary—Department of Labor and Department of Health and Human Services

As stated earlier in this preamble, these interim final regulations implement PHS Act sections 2704 (prohibiting preexisting condition exclusions), 2711 (prohibiting lifetime and annual dollar limits on benefits), 2712 (rules regarding rescissions), and 2719A (patient protections).[13] These interim final regulations also provide guidance on the requirement to provide enrollment opportunities to individuals who reached a lifetime limit. PHS Act section 2704 regarding preexisting condition exclusions generally is effective for plan years (in the individual market, policy years) beginning on or after January 1, 2014. However, with respect to enrollees, including applicants for enrollment, who are under 19 years of age, this section is effective for plan years beginning on or after September 23, 2010; or in the case of individual health insurance coverage, for policy years beginning on or after September 23, 2010.[14] The rest of these provisions generally are effective for plan years (in the individual market, policy years) beginning on or after September 23, 2010, which is six months after the March 23, 2010 date of enactment of the Affordable Care Act.

The Departments have crafted these interim final regulations to secure the protections intended by Congress in the most economically efficient manner possible. In accordance with OMB Circular A–4, they have quantified the benefits and costs where possible and provided a qualitative discussion of some of the benefits and the costs that may stem from these interim final regulations.

B. Executive Order 12866—Department of Labor and Department of Health and Human Services

Under Executive Order 12866 (58 FR 51735), "significant" regulatory actions are subject to review by the Office of Management and Budget (OMB). Section 3(f) of the Executive Order defines a "significant regulatory action" as an action that is likely to result in a rule (1) having an annual effect on the economy of $100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as "economically significant"); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. OMB has determined that this rule is significant within the meaning of section 3(f)(1) of the Executive Order, because it is likely to have an effect on the economy of $100 million in any one year. Accordingly, OMB has reviewed these rules pursuant to the Executive Order. The Departments provide an assessment of the potential costs and benefits of each regulatory provision below, summarized in the following table.

Table 1.1 Accounting Table

TABLE 1.1—*Accounting Table*

Benefits				
Qualitative: These patient protections are expected to expand coverage for children with preexisting conditions and individuals who face rescissions, lifetime limits, and annual limits as a result of high health care costs. Expanded coverage is likely to increase access to health care, improve health outcomes, improve worker productivity, and reduce family financial strain and "job lock". Many of these benefits have a distributional component, and promote equity, in the sense that they will be enjoyed by those who are especially vulnerable as a result of health problems and financial status. Choice of physician will likely lead to better, sustained patient-provider relationships, resulting in decreased malpractice claims and improved medication adherence and health promotion. Removing referrals and prior authorizations for primary care, obstetrical and gynecological care, and emergency services is likely to reduce administrative and time burdens on both patients and physicians, while improving health outcomes by allowing quicker access to medical services when necessary.				
Costs	Estimate	Year dollar	Discount rate	Period covered[15]
Annualized Monetized ($millions/year)	4.9	2010	7%	2011–2013
	4.9	2010	3%	2011–2013

[13] The Affordable Care Act adds Section 715 to the Employee Retirement Income Security Act (ERISA) and section 9815 to the Internal Revenue Code (the Code) to make the provisions of part A of title XXVII of the PHS Act applicable to group health plans, and health insurance issuers providing health insurance coverage in connection with group health plans, under ERISA and the Code as if those provisions of the PHS Act were included in ERISA and the Code.

[14] Section 1255 of the Affordable Care Act. *See also* section 10103(e)–(f) of the Affordable Care Act.

TABLE 1.1—*Accounting Table*—Continued

Monetized costs are due to a requirement to notify participants that exceeded their lifetime limit and were disenrolled from their plan or coverage of their right to re-enroll in the plan; a requirement that a group health plan or a health insurance issuer offering group or individual health insurance coverage must notify an affected individual 30 days before coverage may be rescinded; and a notice of a participant's right to choose any available participating primary care provider or pediatrician as their primary care provider, and of increased protections for those participants seeking emergency services.
Qualitative: To the extent these patient protections increase access to health care services, increased health care utilization and costs will result due to increased uptake. Expanding coverage to children with preexisting conditions and individuals subject to rescissions will likely increase overall health care costs, given that these groups tend to have high cost conditions and require more costly care than average.
Transfers
Qualitative: These patient protections create a small transfer from those paying premiums in the group market to those obtaining the increased patient protections. To the extent there is risk pooling in the individual market, a similar transfer will occur.

1. Need for Regulatory Action

a. Preexisting Condition Exclusions

As discussed earlier in this preamble, Section 2704 of the PHS Act as added by the Affordable Care Act, prohibits group health plans and health insurance issuers offering group or individual health insurance from imposing any preexisting condition exclusion. This new protection applies to children who are under age 19 for plan years (in the individual market, policy years) beginning on or after September 23, 2010. For individuals age 19 and over, this provision applies for plan years (in the individual market, policy years) beginning on or after January 1, 2014.

Preexisting conditions affect millions of Americans and include a broad range of conditions from heart disease—which affects one in three adults [16]—or cancer—which affects 11 million Americans [17]—to relatively minor conditions like hay fever, asthma, or previous sports injuries.[18]

Denials of benefits or coverage based on a preexisting condition make adequate health insurance unavailable to millions of Americans. Before the enactment of the Affordable Care Act, in 45 States, health insurance issuers in the individual market could deny coverage, charge higher premiums, and/or deny benefits for a preexisting condition.[19]

These interim final regulations are necessary to amend the Departments' existing regulations to implement this statutory provision, which was enacted by Congress to ensure that quality health coverage is available to more Americans without the imposition of a preexisting condition exclusion.

b. Lifetime and Annual Limits

As discussed earlier in this preamble, Section 2711 of the PHS Act was added to the Affordable Care Act to prohibit group health plans and health insurance issuers offering group or individual health insurance coverage from imposing lifetime limits on the dollar value of health benefits. Annual limits also are prohibited, but the statute includes a phase-in of this provision before January 1, 2014, that allows plans and issuers to impose "restricted annual limits" at the levels discussed earlier in this preamble.

These new protections ensure that patients are not confronted with devastating health costs because they have exhausted their health coverage when faced with a serious medical condition. For example, in one recent national survey, ten percent of all cancer patients reported that they reached a benefit limit in their insurance policy and were forced to seek alternative insurance coverage or pay the remainder of their treatment out-of-pocket.[20]

These interim final regulations are necessary to amend the Departments' existing regulations to implement the statutory provisions with respect to annual and lifetime limits that Congress enacted to help ensure that more Americans with chronic, long-term, and/or expensive illnesses have access to quality health coverage. The provisions of the regulations regarding restricted annual limits function as a type of transition rule, providing for staged implementation and helping ensure against adverse impacts on premiums or the offering of health coverage in the marketplace. For more detail about these provisions, see the discussion of PHS Act Section 2711, Lifetime and Annual Limits, in section II.B earlier in this preamble.

c. Rescission

As discussed earlier in this preamble, Section 2712 of the PHS Act was added by the Affordable Care Act to prohibit group health plans and health insurance issuers offering group or individual health insurance coverage from rescinding coverage except in the case of fraud or intentional misrepresentation of material fact.

Prior to the Affordable Care Act, thousands of Americans lost health coverage each year due to rescission. According to a House Energy and Commerce Committee staff memorandum,[21] rather than reviewing medical histories when applications are submitted, if the policyholders become sick and file expensive claims, insurance companies then initiate investigations to scrutinize the details of the policyholder's application materials and medical records, and if discrepancies, omissions, or misrepresentations are found, the insurer rescinds the policies, returns the premiums, and refuses payment for medical services. The Committee found some questionable practices in this area including insurance companies rescinding coverage even when discrepancies are unintentional or caused by others, for conditions that are unknown to policyholders, and for discrepancies unrelated to the medical

[15] The Departments' analysis extends to 2013. The analysis does not attempt to estimate effects in 2014 and beyond because the extensive changes provided for by the Affordable Care Act in sources of coverage, rating rules, and the structure of insurance markets make it nearly impossible to isolate the effects of the provisions of these interim final regulations.

[16] American Heart Association. *Heart Disease and Stroke Statistics 2009 Update-at-a-Glance. http://www.americanheart.org/downloadable/heart/1240250946756LS—1982%20Heart%20and%20Stroke%20Update.042009.pdf.*

[17] National Cancer Institute. *Cancer Query System: Cancer Prevalence Database. http://srab.cancer.gov/prevalence/canques.html.*

[18] Pollitz K, Sorian R. *How Accessible is Individual Health Insurance for Consumers in Less than Perfect Health?* Kaiser Family Foundation, June 2001.

[19] Kaiser State Health Facts. *http://statehealthfacts.org/comparetable.jsp?ind=353&cat=7.*

[20] USA Today/Kaiser Family Foundation/Harvard School of Public Health. National Survey of Households Affected by Cancer. November 2006.

[21] Terminations of Individual Health Insurance Policies by Insurance Companies, Hearing before the House Comm. on Energy and Commerce, Subcommittee on Oversight and Investigations, June 16, 2009) (supplemental memorandum) *http://energycommerce.house.gov/Press_111/20090616/rescission_supplemental.pdf.*

conditions for which patients sought medical care.

When a coverage rescission occurs, an individual's health coverage is retroactively cancelled, which means that the insurance company is no longer responsible for medical care claims that they had previously accepted and paid. Rescissions can result in significant financial hardship for affected individuals, because, in most cases, the individuals have accumulated significant medical expenses. The NAIC Regulatory Framework Task Force collected data on 52 companies covering the period 2004–2008, and found that rescissions averaged 1.46 per thousand policies in force.[22] This estimate implies there are approximately 10,700 rescissions per year.

These interim final regulations implement the statutory provision enacted by Congress to protect the most vulnerable Americans, those that incur substantial medical expenses due to a serious medical condition, from financial devastation by ensuring that such individuals do not unjustly lose health coverage by rescission.

d. Patient Protections

As discussed earlier in this preamble, Section 2719A of the PHS Act was added by the Affordable Care Act to require group health plans and health insurance issuers offering group or individual health insurance coverage to ensure choice of health care professionals and greater access to benefits for emergency services. As discussed in more detail below, provider choice is a strong predictor of patient trust in a provider, and patient-provider trust can increase health promotion and therapeutic effects.[23] Studies also have found that patients tend to experience better quality health care if they have long-term relationships with their health care provider.[24]

The emergency care provisions of PHS Act section 2719A require (1) non-grandfathered group health plans and health insurance issuers that cover emergency services to cover such services without prior authorization and without regard to whether the health care provider providing the services is a participating network provider, and (2) copayments and coinsurance for out-of-network emergency care not to exceed the cost-sharing requirements that would have been imposed if the services were provided in-network. These provisions will ensure that patients get emergency care when they need it, especially in situations where prior authorization cannot be obtained due to exigent circumstances or an in-network provider is not available to provide the services. It also will protect patients from the substantial financial burden that can be imposed when differing copayment or coinsurance arrangements apply to in-network and out-of-network emergency care.

This regulation is necessary to implement the statutory provision enacted by Congress to provide these essential patient protections.

2. PHS Act Section 2704, Prohibition of Preexisting Condition Exclusions (26 CFR 54.9815–2704T, 29 CFR 2590.715–2704, 45 CFR 147.108)

a. Summary

As discussed earlier in this preamble, section 1201 of the Affordable Care Act adds a new PHS Act section 2704, which amends the HIPAA rules relating to preexisting condition exclusions to provide that a group health plan and a health insurance issuer offering group or individual health insurance coverage may not impose any preexisting condition exclusion. The HIPAA rules (in effect prior to the effective date of these amendments) apply only to group health plans and group health insurance coverage, and permit limited exclusions of coverage based on a preexisting condition under certain circumstances. The Affordable Care Act and these interim final regulations prohibit any preexisting condition exclusions imposed by group health plans or group health insurance coverage and extends this protection to individual health insurance coverage. This prohibition generally is effective with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2014, but for enrollees who are under 19 years of age, this prohibition becomes effective for plan years (in the individual market, policy years) beginning on or after September 23, 2010.

Under the statute and these interim final regulations, a grandfathered health plan that is a group health plan or group health insurance coverage must comply with the prohibition against preexisting condition exclusions; however, a grandfathered health plan that is individual health insurance coverage is not required to comply with PHS Act section 2704.

In this section, the Departments estimate the likely effects of these interim final regulations. Beginning with the population of individuals age 0–18, the number of individuals potentially affected is estimated in several steps. First, the number of children who have preexisting conditions that might cause them to be excluded from coverage is estimated. Second, a range of take-up rates is used to estimate the number of children who might be newly covered after these interim final regulations are implemented. In addition, the potential cost implications are discussed.

b. Estimated Number of Affected Individuals

In the individual market, those applying for insurance will no longer face exclusions or denials of coverage based on a preexisting condition exclusion if they are under the age of 19. In addition, children covered by non-grandfathered individual coverage with a rider or an exclusion period that excludes coverage for a preexisting condition will gain coverage for that condition. In the group market, participants and dependents who are under 19 years old and have experienced a lapse in coverage will no longer face up to a twelve-month exclusion for preexisting conditions.

The Departments' estimates in this section are based on the 2004–2006 Medical Expenditure Panel Survey Household Component (MEPS–HC) which was projected to 2010 and calibrated to be consistent with the National Health Accounts projections. The analysis tabulated counts and costs for persons under age 19 by age, health status, and insurance status.

There are two main categories of children who are most likely to be directly affected by these interim final regulations: First, children who have a preexisting condition and who are uninsured; second, children who are covered by individual insurance with a rider excluding coverage for a preexisting condition or a preexisting condition exclusion period. For the latter category, obtaining coverage for the preexisting condition may require terminating the child's existing policy and beginning a new one, because individual health insurance coverage that is a grandfathered health plan is not required to comply with PHS Act section 2704 or these interim final regulations.

[22] NAIC Rescission Data Call, December 17, 2009, p. 1.

[23] Piette, John, *et al.*, "The Role of Patient-Physician Trust in Moderating Medication Nonadherence Due to Cost Pressures." *Archives of Internal Medicine* 165, August (2005) and Roberts, Kathleen J., "Physician-Patient Relationships, Patient Satisfaction, and Antiretroviral Medication Adherence Among HIV-Infected Adults Attending a Public Health Clinic." *AIDS Patient Care and STDs* 16.1 (2002).

[24] Blewett, Lynn, *et al.*, "When a Usual Source of Care and Usual Provider Matter: Adult Prevention and Screening Services." *Journal of General Internal Medicine* 23.9 (2008).

It is difficult to estimate precisely how many uninsured children have a preexisting condition that would cause them to be denied coverage for that condition if they were to apply. Information on whether individuals have a preexisting condition for the purpose of obtaining health insurance is not collected in any major population-based survey. In its annual survey on market practices, America's Health Insurance Plans (AHIP) estimated that 429,464 applications for children were medically underwritten, and 20,747, or 4.8 percent, were denied.[25] The survey does not measure the number of applicants who did not make it through an underwriting process, nor does it measure the applicants' prior insurance status, and therefore, while useful, it does not provide direct estimates of the number or proportion of uninsured children who would be denied coverage based on a preexisting condition. Thus, the Departments use proxies for preexisting conditions available in nationally representative surveys to estimate the universe of potentially eligible individuals.

The Departments estimate that in 2010 there are approximately 78.0 million children under the age of 19 in the United States, of whom an estimated 19.4 million report "fair" or "poor" health or take three or more prescription medications. The Departments assume that these children have a preexisting condition. Whether or not the statute and these interim final regulations are likely to affect these children depends on their own and their parents' insurance status. Of the 19.4 million children that potentially have a preexisting condition, 10.2 million already have employer-sponsored insurance (ESI), 760,000 have individual coverage, and 7.9 million have public or other coverage, leaving 540,000 uninsured children with preexisting conditions.[26] The Departments assume that this group of 540,000 uninsured children with a preexisting condition would be denied coverage for that condition or altogether if they were to apply.

The likelihood that an uninsured child with a preexisting condition will gain coverage due to these interim final regulations will likely vary by the insurance status of the child's parent. As shown in Table 2.1, approximately one-half of the 540,000 uninsured children who the Departments estimate have a preexisting condition live with a parent who is also uninsured and is not offered ESI. An additional 190,000 have a parent who is covered by ESI, and 60,000 children have a parent who was offered ESI but did not accept the offer (and the insurance status of the parent is unknown).

TABLE 2.1—ESTIMATED NUMBER OF UNINSURED CHILDREN WITH PRE-EXISTING CONDITIONS, BY PARENT'S INSURANCE STATUS, 2010

Parent's insurance status	Number of children
Parent has employer-sponsored insurance (ESI)	190,000
Parent offered ESI	60,000
Parent has individual market insurance	10,000
Parent does not have private insurance*	270,000
No parent	20,000
Total **	540,000

*Primarily parents who are uninsured, but also including a small number who have public coverage.

**Total is not the sum of the components due to rounding.

Source: Departments' analysis of MEPS–HC data, 2004–2006, trended forward to 2010.

The group most likely to be affected by these interim final regulations is uninsured children whose parents have purchased non-group coverage, of whom there are an estimated 10,000. These parents have demonstrated a strong preference for coverage by being willing to pay for a non-group premium for themselves, but their child is uninsured. Although the Departments cannot know with any certainty, it is quite plausible that the child is uninsured because the insurer refused to sell coverage to the child due to a preexisting condition. If an individual market insurance policy does not change substantially and retains its grandfather status, the insurer is not required to add a child with a preexisting condition. However, if the parent terminates the existing policy and purchases a new policy (which is quite plausible given the high prevalence of churning in the individual insurance market), then the new policy will be required to cover the child, and a substantial proportion of these children could gain access to coverage due to these interim final regulations.[27]

At the other extreme, roughly 190,000 uninsured children with a preexisting condition have a parent with ESI. It is possible that these children are uninsured because their parents' ESI does not offer dependent coverage. It is also possible that the parent could not afford the employee portion of a family plan premium. These interim final regulations are not likely to have much effect on coverage for children in these circumstances. A very small subset of uninsured children whose parents have ESI could have had to be in a preexisting exclusion period before coverage is provided for services to treat that condition. Under the statute and these interim final regulations, there would no longer be such a period, making coverage desirable. Such children may be affected by this provision.

Approximately 60,000 uninsured children with a preexisting condition have parents who were offered ESI but did not accept that offer. It also seems unlikely that these interim final regulations will have much effect on that group, because almost all of those parents could have chosen to cover themselves, and potentially their child, through ESI in the absence of these interim final regulations.

In between these extremes are the approximately 270,000 uninsured children whose parents are themselves uninsured. Many of these parents have low to moderate income, and many may not be able to afford insurance.[28] However, some of these parents might purchase a policy for their child with a preexisting condition if it were available to them.

While it is relatively easy to hypothesize about the relationship between parental insurance status and the likelihood that a child will be newly covered, it is much more difficult to estimate with any precision the take-up rates for each parental coverage category. Acknowledging substantial uncertainty, based on the discussion above, the Departments' mid-range estimate is that 50 percent of uninsured children whose parents have individual coverage will be newly insured, 15 percent of uninsured children whose parents are uninsured will be newly insured, and that very few children whose parents have ESI, are offered ESI, or who do not live with a parent will become covered as a result of these

[25] AHIP Center for Health Policy Research. *Individual Health Insurance 2009. http://www.ahipresearch.org/pdfs/2009IndividualMarketSurveyFinalReport.pdf.*

[26] These estimates are from the Departments' analysis of the 2004–2006 Medical Expenditure Panel Survey, trended forward to 2010.

[27] Adele M. Kirk. The Individual Insurance Market: A Building Block for Health Care Reform? *Health Care Financing Organization Research Synthesis. May 2008.*

[28] Approximately two-thirds of the uninsured are in families with income below 200 percent of the Federal Poverty Level. Current Population Survey, March 2008.

interim final regulations.[29] For the high-end estimate, the Departments assume that the 50 percent and 15 percent assumptions increase to 75 percent and 20 percent, respectively. For the low-end assumption, they assume that they decrease to 25 percent and 10 percent.

As shown in Table 2.2, the Departments' mid-range estimate is that 51,000 uninsured children with preexisting conditions could gain coverage as a result of these interim final regulations. At the low end of the range, this could be 31,000 and at the high end of the range, it could be 72,000. Given that most ESI already covers children with preexisting conditions, almost all of these children newly gaining coverage are expected to gain individual coverage.[30]

TABLE 2.2—ESTIMATED NUMBER OF UNINSURED CHILDREN GAINING COVERAGE

	Gain employer-sponsored insurance	Gain individual market insurance	Total
High Take-Up	10,000	62,000	72,000
Medium Take-Up	6,000	45,000	51,000
Low Take-Up	2,000	29,000	31,000

Source: Departments' analysis of 2004–2006 MEPS–HC, trended forward to 2010.

The other group of children who will be affected by these interim final regulations is children who already have non-group insurance coverage, but who are covered with a "condition waiver" that excludes coverage or imposes an exclusion period for coverage of a preexisting condition. After the implementation of these interim final regulations, children whose parents purchase individual coverage will not be subject to condition waivers or preexisting condition exclusion periods. The Departments estimate that there are 90,000 children covered by individual insurance with a condition waiver (or with a period during which coverage for a preexisting condition is excluded).[31] The individual market issuers who insure these estimated 90,000 children with a condition waiver may decide to remain grandfathered health plans and thus these children will not be directly affected by these interim final regulations. However, the parents of those children could choose to switch from an individual policy that is a grandfathered health plan to a new policy that is not grandfathered, although the premium that they pay for such coverage could increase. Similarly, for those children currently covered but in a preexisting condition exclusion period, curtailing the exclusion period would require the termination of the current plan and purchase of a policy on or after September 23, 2010.

c. Benefits

The benefits of PHS Act Section 2704 and these interim final regulations are expected to amply justify the costs. These interim final regulations will expand and improve coverage for those under the age of 19 with preexisting conditions. This will likely increase access to health care, improve health outcomes, and reduce family financial strain and "job lock," as described below.

Numerous studies confirm that when children become insured, they are better able to access health care. Uninsured children are six times more likely than insured children to lack a usual site of care.[32] By contrast, one year after enrollment in health insurance, nearly every child in one study had a regular physician and the percentage of children who saw a dentist increased by approximately 25 percent.[33] Insured children also experience fewer unmet needs and delays in care. In one study, 37 percent of the children 15 to 19 years of age faced some unmet need or delayed physician care in the prior 6 months, whereas at 12 months after insurance enrollment, only 3.7 percent reported such delays or care deficiencies.[34]

With regular access to health care, children's health and well-being are likely to improve. When children are sick and without health insurance, they may, out of financial necessity, have to forgo treatment; insurance improves the likelihood that children get timely and appropriate health care services.[35] Insured children are less likely to experience avoidable hospital stays than uninsured children[36] and, when hospitalized, insured children are at less risk of dying.[37] When children are insured, it not only improves their health status, but also confers corollary benefits. Children without health insurance may not be allowed to participate in as many physical activities as peers because parents are

[29] The Departments researched the literature in an attempt to provide support for the take-up rate assumptions made here. There is a substantial literature on take-up rates among employees who are offered ESI, on take-up rates of public coverage among people eligible for Medicaid and Children's Health Insurance Program, and some work on the purchasing behavior of people who are choosing between being uninsured and buying individual insurance (Aizer, 2006; Kronson, 2009; KFF, 2007; Bernard and Selden, 2006; Sommers and Krimmel, 2008). This work shows that take-up rates are very high for workers who are offered ESI, but that approximately 25 percent of people without ESI purchase individual coverage. This literature can also be used to estimate the price-elasticity of demand, as has been used by the Congressional Budget Office in its estimates of the effects of the Affordable Care Act (*http://www.cbo.gov/ftpdocs/87xx/doc8712/10-31-HealthInsurModel.pdf*). However, none of this work is very helpful in estimating the level of take-up the Departments should expect as parents are given the opportunity to purchase coverage for their children with preexisting conditions. In the absence of strong empirical guidance, the Departments consulted with experts, used their best judgment, and provide a wide range for our assumptions.

[30] For those parents who turned down an offer of ESI and whose insurance status is not known, the Departments assume that half of the children who takeup coverage join ESI, and half join a private insurance plan in the individual insurance market.

[31] The 2009 AHIP survey for individual coverage estimated that approximately 2.7 percent of children with individual coverage are covered with a condition waiver. This 3 percent estimate was applied to the MEPS-based estimate that there are approximately 3.3 million children covered by individual insurance. A separate analysis of MEPS by the Departments similarly found about 90,000 children with a preexisting condition (defined as being in fair or poor health or taking three or more prescription medications) had a low actuarial value of coverage for their condition.

[32] "Children's Health, Why Health Insurance Matters." *Kaiser Commission on Medicaid and the Uninsured*, available at: *http://www.kff.org/uninsured/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=14132*.

[33] Ibid.

[34] Keane, Christopher *et al.* "The Impact of Children's Health Insurance Program by Age." *Pediatrics* 104:5 (1999), available at: *http://pediatrics.aappublications.org/cgi/reprint/104/5/1051*.

[35] Uninsured children are at least 70 percent more likely than insured children to not receive medical care for common childhood conditions like sore throats, ear infections, and asthma. Ibid.

[36] Ibid.

[37] Bernstein, Jill *et al.* "How Does Insurance Coverage Improve Health Outcomes?" *Mathematica Policy Research* (2010), available: *http://www.mathematica-mpr.com/publications/PDFs/Health/Reformhealthcare_IB1.pdf*.

concerned about the financial impacts of unintentional injury. One study determined that 12 percent of uninsured children had various activity restrictions (*e.g.*, related to sports or biking). However, almost all of these restrictions were removed once they gained insurance.[38] And health insurance and access to care improve school attendance. An evaluation of an initiative designed to connect children to Healthy Kids, an insurance program piloted in Santa Clara County, California for children in low-income families, found that the proportion of children missing three or more school days in the previous month decreased from 11 percent among non-enrollees to 5 percent after enrollment in the insurance program.[39]

In addition to their benefits relating to access to care, health, and well-being of children, these interim final regulations are likely to lower families' out of pocket health care spending. Some families would face the possibility of paying high out-of-pocket expenses for health care for children under 19 who could not obtain insurance because of a preexisting condition. Further, expanded insurance coverage should reduce the number of medical bankruptcies.[40] In cases where medical expenses are substantial, families may no longer need to spend down their assets in order to qualify for Medicaid and other public assistance programs. Approximately 34 States offer Medicaid eligibility to adults and children who spend-down to State-established medically needy income limits.[41] Eight percent of Medicaid beneficiaries qualify via spend-down yet this group accounts for a disproportionately high percentage of Medicaid spending nationally (14 percent), due to the fact that coverage kicks in when individuals' medical costs are high.[42] Despite the fact that medically needy populations become eligible on account of onerous medical bills, this group is especially vulnerable to losing coverage because States are not *required* to cover this group. For example, in 2003, when Oklahoma eliminated its medically needy program due to a budget shortfall, an estimated 800 children lost coverage.[43] Such coverage interruptions likely contribute to higher rates of uncompensated care—the primary source for which is Federal funding.[44] Reduced reliance on these programs under these interim final regulations will benefit State and Federal governments and, by extension, taxpayers.

In addition, these interim final regulations may reduce instances of "job lock"—situations in which workers are unable to change jobs due to concerns regarding health insurance coverage for their children.[45] For example, under the Affordable Care Act and these interim final regulations, someone currently insured through the group market with less than 18 months of continuous coverage may be more willing to leave her job and become a self-employed entrepreneur if she has a child under age 19 with a preexisting condition, because her child now will be able to obtain immediate coverage for the preexisting condition in the individual market. Similarly, even a worker with more than 18 months of continuous coverage who is already protected by HIPAA may be more likely to consider switching firms and changing policies because he would not have to worry that his child's preexisting condition would be excluded for up to 12 months.[46] While the total reduction in job-lock may be small, the impact on those families with children with preexisting conditions may be significant. The effect of these interim final regulations on job-lock is discussed further in the summary section below.

Executive Order 12866 explicitly requires agencies to take account of "distributive impacts" and "equity." Requiring health insurers to provide coverage to children with preexisting conditions will, as described below, result in a small increase in premium for relatively healthy adults and children, and a large increase in health and financial security for children with preexisting conditions and their parents. This transfer is a meaningful increase in equity, and is a benefit of these interim final regulations.

d. Costs and Transfers

Children with preexisting conditions have high health care costs—approximately three times the average for those without such conditions.[47] Although children with preexisting conditions have higher health care costs than healthier children, among children with preexisting conditions, those who are uninsured have expenditures that are somewhat lower than the average for all children with preexisting conditions. Therefore, it is expected that when uninsured children obtain coverage, there will be additional demand for and utilization of services. There will also be a transfer from out-of-pocket spending to spending covered by insurance, which will partially be mitigated by a reduction in cost-shifting of uncompensated care to the insured population as coverage expands.

As shown above in Table 2.2, the Departments estimate that approximately 2,000 to 10,000 children whose parents have ESI or an offer of ESI will be newly covered in the group market. Because few children are likely to be newly covered in the group market, the estimated costs and transfers are extremely small, on the order of hundredths of a percent.

The Departments expect that these interim final regulations will have a larger effect on the number of children covered in the individual market, resulting in new coverage for between 29,000 and 62,000 children. Medical expenses for these newly covered children are likely to be greater than for the average child covered by individual insurance. The Departments' analysis

[38] "Children's Health, Why Health Insurance Matters." *Kaiser Commission on Medicaid and the Uninsured*, available at: *http://www.kff.org/uninsured/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=14132*.

[39] Howell, Embry and Trenholm, Christopher "Santa Clara County Children's Health Initiative Improves Children's Health." *Mathematica Policy Research and The Urban Institute* (2007), available at: *http://www.mathematica-mpr.com/publications/PDFs/CHIimproves.pdf*.

[40] Himmelstein, D., Warren, E., Thorne, D., and Woolhandler, S. Illness and Injury as Contributors to Bankruptcy, *Health Affairs* W5–63, February 2 (2005); Himmelstein, D., Thorne, D., Warren, E., Woolhandler, S. Medical Bankruptcy in the United States, 2007: The Results of a National Study, *The American Journal of Medicine* June 4 (2009).

[41] *http://www.statehealthfacts.org/comparereport.jsp?rep=60&cat=4*.

[42] Page 4: *http://www.kff.org/medicaid/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=14325*.

[43] Page 4: *http://www.nashp.org/sites/default/files/shpmonitor_medicallyneedy.pdf*.

[44] Page 4: *http://www.kff.org/uninsured/upload/The-Cost-of-Care-for-the-Uninsured-What-Do-We-Spend-Who-Pays-and-What-Would-Full-Coverage-Add-to-Medical-Spending.pdf*.

[45] A CEA report suggests that the overall cost of job-lock could be $3.7 billion annually, which is about 10 percent of affected workers wages. While these interim final regulations may only have an impact on a small percentage of all individuals affected by job-lock it could still have a large dollar impact for those affected. Council of Economic Advisors Report, The Economic Case for Health Reform (June 2009), at *http://www.whitehouse.gov/assets/documents/CEA_Health_Care_Report.pdf*.

[46] A 2006 study found no evidence that the introduction of HIPAA, which reduced preexisting condition exclusions, had any impact on job lock, but HIPAA still allows a 12-month preexisting condition exclusion meaning that for conditions that need immediate care someone could still effectively be uninsured for up to a year. In contrast, the provisions of the statute and these interim final regulations would not allow any preexisting condition exclusion. *See e.g.*, Paul Fronstin, *Health Insurance Portability and Job Lock: Findings from the 1998 Health Confidence Survey*, Employee Benefit Research Institute Notes, Volume 19, Number 8, pages 4–6 (Aug. 1998) and Anna Sanz-de-Galdeano, *Job-Lock and Public Policy: Clinton's Second Mandate*, Industrial and Labor Relations Review, Volume 59, Number 3, pages 430–37 (Apr. 2006).

[47] From the Departments' analysis of MEPS data.

also assumes that children with preexisting conditions gaining insurance under these interim final regulations will have greater health needs than the average uninsured child with a preexisting condition. This assumption concerning adverse selection is common to most analyses of purchasing behavior in the individual insurance market.

In the majority of States that do not require community rating, much of the additional cost of care for newly-covered children with preexisting condition is likely to be borne by the parents who purchase coverage for their children. Based on discussions with industry experts, it appears that even in the absence of community rating, it is rare for an insurer to charge more than twice the standard rate for someone in poor health. The Departments' analysis assumes that in non-community rated States, the parents of newly insured children will pay a premium that is equal to twice the standard rate, and the remainder of the additional costs will be spread to other policy holders in the individual market.[48] However, with the enactment of the Affordable care Act and the issuance of these interim final regulations, rating practices in the insurance industry could certainly change, lending uncertainty to this estimate. In the approximately twenty States that require adjusted community rating or rating bands in the individual market, the Departments' analysis assumes that all of the additional costs of newly covered children will be spread across policies in the individual market that are not grandfathered health plans.[49] Making these assumptions, the estimated increase in premiums is 1 percent or less in community rated States, and approximately one-half of one percent in States without community rating.

Finally, for the estimated 90,000 children with existing individual coverage that excludes coverage for the preexisting condition or requires an exclusion period before coverage for that condition begins, the Departments assume that many of these children will receive coverage for their condition(s). Because their existing individual policies could be grandfathered, the parents of these children may need to purchase new policies in order to gain coverage for their children's condition without a waiver. Children in a preexisting condition exclusion period in particular will need to terminate their current policy and purchase a new one in order to take advantage of the elimination of any preexisting condition exclusion period. Of note, the Departments estimate that turnover in the individual market is between 40 percent and 70 percent per year.[50] Therefore, in a few years, most children who would have been covered with a condition waiver in the absence of these interim final regulations are expected to be in new policies that are not grandfathered health plans in any case.

The Departments analyzed expenditures for the approximately 90,000 children who reported fair or poor health, or who were taking three or more prescription medications, and for whom insurance covered only a small portion of spending for one or more medical conditions. Total spending for these 90,000 children was not much different than spending for the children who did not appear to have a preexisting condition waiver, although less of the spending was covered by private insurance, and more of it was paid for out-of-pocket or by other sources.[51]

Similar to the expectations for newly covered children in the individual market, in States that require rating bands or some form of community rating, much of the additional cost for eliminating condition waivers will be spread across the insured population, while in States without rating restrictions, much of the additional costs will be borne by the parents who purchase the coverage. However, the estimate that insured benefits per child will increase by a relatively modest amount suggests that even in States with community rating, the cost and transfer effects will be relatively small, at most a few tenths of a percent over the next few years.

In evaluating the impact of this provision, it is important to remember that the full net effects of this provision cannot be estimated because of its interactions with other provisions in the Affordable Care Act that go into effect at the same time. For example, under the current guaranteed renewability protections in the individual market, if a child with a preexisting condition is now able to obtain coverage on a parental plan, he or she can potentially stay on that plan until age 26. As another example, the Affordable Care Act will require non-grandfathered health plans to provide recommended preventive services at no cost-sharing. This will amplify the benefits of coverage for newly insured children with preexisting conditions. Therefore, the Departments cannot provide a more precise estimation of either the benefits or the costs and transfers of this provision.

3. PHS Act Section 2711, No Lifetime or Annual Limits (26 CFR 54.9815–2711T, 29 CFR 2590.715–2711, 45 CFR 147.126)

a. Summary

As discussed earlier in this preamble, section 2711 of the PHS Act, as added by the Affordable Care Act, and these interim final regulations generally prohibits group health plans and health insurance issuers offering group or individual health insurance coverage from imposing lifetime or annual limits on the dollar value of health benefits. The statute also provides a special rule allowing "restricted annual limits" with respect to essential health benefits (as defined in section 1302(b) of the Affordable Care Act) for plan years (in the individual market, policy years) beginning before January 1, 2014. In addition, the statute specifies that a plan or issuer may impose annual or lifetime per-individual limits on specific covered benefits that are not essential health benefits to the extent that such limits are permitted under Federal or State law.

For purposes of establishing a restricted annual limit on the dollar value of essential health benefits, the statute provides that in defining the term restricted annual limit, the Departments "ensure that access to needed services is made available with a minimal impact on premiums."[52] Based on this Congressional directive, the interim final regulations allow annual limits on the dollar value of benefits that are essential health benefits of no less than $750,000 for plan years

[48] The Departments assume that in non-community rated States, parents purchasing individual coverage for a child with a preexisting condition will be charged a rate equal to 200 percent of the standard rate for a child, because it is rare for insurers to charge more than this amount, but it seems unlikely they will charge less. To the extent that the estimated expenditures for newly covered children are above the premium that the Departments assume will be charged, the analysis assumes that the difference will be spread over all policies in the individual market.

[49] *http://www.statehealthfacts.kff.org/comparetable.jsp?ind=354&cat=7.*

[50] Adele M. Kirk. The Individual Insurance Market: A Building Block for Health Care Reform? *Health Care Financing Organization Research Synthesis.* May 2008.

[51] The Departments' analysis used MEPS data to identify approximately 90,000 children with individual coverage for whom insurance coverage for one or more conditions was extremely low—averaging 10 percent of covered expenditures, compared to approximately 80 percent for other children. The analysis assumes that these children were subject to a preexisting condition waiver, and then assumes that when these waivers are eliminated, the expenditures that are not covered by insurance in the MEPS data will now be shifted to insurance.

[52] PHS Act section 2711(a)(2) as added by Section 1001(5) of the Affordable Care Act and amended by section 10101(a) of such Act.

(in the individual market, policy years) beginning on or after September 23, 2010, but before September 23, 2011; $1.25 million for plan years (in the individual market, policy years) beginning on or after September 23, 2011, but before September 23, 2012; and $2 million for plan years (in the individual market, policy years) beginning on or after September 23, 2012, but before January 1, 2014. For plan years (in the individual market, policy years) beginning January 1, 2014, no annual limits may be placed on essential health benefits.

The statute and these interim final regulations relating to the prohibition on *lifetime* limits generally apply to all group health plans and health insurance issuers offering group or individual health insurance coverage, whether or not the plan qualifies as a grandfathered health plan, for plan years (in the individual market, policy years) beginning on or after September 23, 2010. The statute and these interim final regulations relating to the prohibition on *annual* limits, including the special rules for plan years beginning before January 1, 2014, generally apply to group health plans and group health insurance coverage that qualify as a grandfathered health plan, but do not apply to grandfathered health plans that are individual health insurance coverage.

b. Estimated Number of Affected Entities

In 2009, the latest data available indicates that both the incidence and amount of lifetime limits vary by market and plan type (*e.g.*, HMO, PPO, POS). Table 3.1 displays the prevalence of lifetime limits for large employer, small employer and individual markets by plan type. Sixty-three percent of large employers had lifetime limits; 52 percent of small employers had lifetime limits and 89 percent of individual market plans had lifetime limits. HMO plans are the least likely to have a lifetime limit with only 37 percent of large employer HMO plans having a limit, 16 percent of small employer HMO plans having a limit and 23 percent of individual HMO plans having a limit. The generosity of the limit also varies, with 45 percent of all large employer plans imposing a lifetime limit of $2,000,000 or more; 39 percent of small employers' plans imposing a limit of $2,000,000 or more and 86 percent of individual market plans imposing a limit of $2,000,000 or more. Note that small employers are more likely than large employers to offer HMOs that tend not to have lifetime limits, but when small businesses offer plans with lifetime limits, the maximum limit tends to be lower than those in large firms.[53]

TABLE 3.1—PREVALENCE OF LIFETIME LIMITS

Market	Prevalence of limit (percent)	Number of enrollees
Large group		
Under $1,000,000	1	1,000,000
$1,000,000–$2,000,000	18	18,700,000
$2,000,000 or higher	45	46,600,000
No Limit	37	38,300,000
Small group		
Under $1,000,000	1	500,000
$1,000,000–$2,000,000	12	6,300,000
$2,000,000 or higher	39	20,500,000
No Limit	48	25,200,000
Individual		
Under $1,000,000	2	200,000
$1,000,000–$2,000,000	1	100,000
$2,000,000 or higher	86	8,400,000
No Limit	11	1,100,000

Source: Large and Small Employer Health Plan Enrollment: and Lifetime Maximum Exhibit 5.2 and Exhibit 13.12, respectively, Employer Health Benefits: 2009 Annual Survey. Washington, DC: Henry J. Kaiser Family Foundation and Health Research & Educational Trust (September 2009). Individual Health Plan Enrollment and Lifetime Maximum: Table 10 and Table 17, respectively, AHIP Center for Policy Research Individual Health Insurance 2009: A Comprehensive Survey of Premiums, Availability, and Benefits.

There are scant data on annual limits on which to base this impact analysis. Table 3.2 displays the prevalence of annual limits by market, plan type and amount of the limit. Only 8 percent of large employers, 14 percent of small employers and 19 percent of individual market policies impose an annual limit and thus would be directly impacted by these interim final regulations.[54] In the first year of implementation (beginning September 23, 2010), it is estimated that less than 0.08 percent (less than one tenth of one percent) of large employer plans, approximately 2.6 percent of

[53] *Employer Health Benefits: 2009 Annual Survey.* Washington, DC: Henry J. Kaiser Family Foundation and Health Research & Educational Trust (September 2009).

[54] There is limited survey data on annual total benefit limits. The data utilized in these analyses are derived from data collected by Mercer's Health and Benefits Research Unit for their 2005, 2008 and 2009 National Survey of Employer-Sponsored Health Plans. For employer plans, the Mercer data provides prevalence information for PPOs and HMOs, and median annual limit levels for PPOs, split by small and large employer plans. In order to generate a plausible baseline of annual benefit maximums, broken by level of maximum, the reported percentages of employer plans that had annual maximums were spread into four intervals broken at $500k, $1 million, and $2 million. For PPOs and HMOs, the data were spread using the dispersion observed in lifetime benefit maximums (using data from the KFF/HRET employer surveys), and the distribution was constrained to be consistent with the Mercer reported median values for annual maximums. For annual benefit limits in individual coverage the relationship observed between AHIP's reported lifetime benefit maximum levels and the KFF/HRET employer lifetime benefit maximums was used to generate corresponding distributions from the synthesized employer annual limits.

small employer plans, and 2.3 percent of individual plans would have to raise their annual limit to $750,000.[55] This first-year increase in annual limits would potentially affect an estimated 1,670,000 persons across the three markets. The second year of the phase-in, beginning September 23, 2011, would affect additional plans and policies, requiring a cumulative 0.7 percent of large employer plans, 3.9 percent of small employer plans, and 5.3 percent of individual policies to increase their annual limit to $1,250,000. The second-year increase in annual limits would affect an estimated 3,278,250 persons across the three markets. The third and final year of the phase-in period (beginning on September 23, 2012) would affect additional plans and policies requiring a cumulative 2.4 percent of large employer plans, 8.1 percent of small employer plans and 14.3 percent of individual policies to increase their annual limit to $2 million. The third-year increase in annual limits would affect an estimated 8,104,500 persons across the three markets. Note that the estimated number of plans and people affected are upper-bound estimates since they do not take into account grandfathered health plans and plans that receive a waiver from the annual limits policy.

TABLE 3.2—PERCENT OF PLANS EMPLOYING ANNUAL LIMITS IN EACH MARKET

Annual limit (percent)	Large employer (percent)	Small employer (percent)	Individual (percent)
Under $250,000	*	0.4	0.4
$250,000–499,999	*	1.3	1.2
$500,000–999,999	*	1.7	1.6
$1,000,000–1,999,999	2.3	5.5	12.0
$2,000,000 plus	5.8	5.5	3.8
Total	8.2	14.4	19.0

* Less than 0.1%.

Source: The data are derived from data collected by Mercer's Health and Benefits Research Unit for their 2005, 2008 and 2009 National Survey of Employer-Sponsored Health Plans. For employer plans, the Mercer data provides prevalence information for PPOs and HMOs, and median annual limit levels for PPOs, split by small and large employer plans. In order to generate a plausible baseline of annual benefit maximums, broken by level of maximum, the reported percentages of employer plans that had annual maximums were spread into four intervals broken at $500k, $1 million, and $2 million. For PPOs and HMOs, the data were spread using the dispersion observed in lifetime benefit maximums (using data from the KFF/HRET employer surveys), and the distribution was constrained to be consistent with the Mercer reported median values for annual maximums. For annual benefit limits in individual coverage the relationship observed between AHIP's reported lifetime benefit maximum levels and the KFF/HRET employer lifetime benefit maximums was used to generate corresponding distributions from the synthesized employer annual limits.

TABLE 3.3—NUMBER OF PERSONS SUBJECTED TO ANNUAL LIMITS IN EACH MARKET

Annual limit	Large employer	Small employer	Individual	Total
Under $250,000	15,000	225,000	38,000	278,000
$250,000–499,999	45,000	675,000	115,000	835,000
$500,000–999,999	60,000	900,000	153,000	1,113,000
$1,000,000–1,999,999	2,389,000	2,869,000	1,177,000	6,435,000
$2,000,000 plus	6,041,000	2,869,000	377,000	9,287,000
Total	8,550,000	7,538,000	1,860,000	17,948,000

Source: The data are derived from data collected by Mercer's Health and Benefits Research Unit for their 2005, 2008 and 2009 National Survey of Employer-Sponsored Health Plans. For employer plans, the Mercer data provides prevalence information for PPOs and HMOs, and median annual limit levels for PPOs, split by small and large employer plans. In order to generate a plausible baseline of annual benefit maximums, broken by level of maximum, the reported percentages of employer plans that had annual maximums were spread into four intervals broken at $500k, $1 million, and $2 million. For PPOs and HMOs, the data were spread using the dispersion observed in lifetime benefit maximums (using data from the KFF/HRET employer surveys), and the distribution was constrained to be consistent with the Mercer reported median values for annual maximums. For annual benefit limits in individual coverage the relationship observed between AHIP's reported lifetime benefit maximum levels and the KFF/HRET employer lifetime benefit maximums was used to generate corresponding distributions from the synthesized employer annual limits.

Fear and anxiety about reaching annual or lifetime limits on coverage is a major concern among Americans who have health insurance. At the same time, the data suggest that relatively few individuals actually reach their policies' annual and lifetime limits. Thus, while such limits are relatively common in health insurance, the numbers of people expected to exceed either an annual or lifetime limit is quite low. The estimates provided in Table 3.4 provide a high and low range of the number of people who would hit such limits. Such a range is necessary because of the tremendous uncertainty around high-cost individuals. First, data are sparse, given that high-cost individuals lie at the tail of statistical cost distributions. The Departments attempted to extrapolate characteristics of the high-cost population who would be affected by these interim final regulations using several data sources. Second, data on per-capita cost is available on a year-by-year basis, and not on a lifetime basis. Assumptions were necessary to convert annual costs into lifetime costs, including considerations of how current spending could be related to future spending.[56]

[55] These figures and the ones that follow in this paragraph are estimated from Tables 2.2 and 2.3 by assuming a uniform distribution within each cell.

[56] To estimate the conditional premium impact of moving a given plan with a given annual benefit maximum to a higher benefit maximum, the percentage change in estimated benefit rates (percent of medical spending that the plan pays for as benefits) based on simulated benefit payments for such coverage was used. The underlying assumed medical spending profile was drawn from

Considering these caveats, Table 3.4 illustrates that raising the restriction of annual limits to $2 million by 2013 would extend additional coverage to 2,700 to 3,500 people per year.[57] The elimination of lifetime limits would extend coverage to an estimated 18,650 to 20,400 people who would be expected to exceed a lifetime limit during a calendar year.

TABLE 3.4—PERCENT AND NUMBER OF PERSONS EXPECTED TO EXCEED A LIFETIME OR ANNUAL LIMIT

	Projected to ever exceed limit	
	Percentage	Number
Current Lifetime Limit:		
Under $1,000,000	0.03–0.06	550–1,050
$1,000,000 to $1,999,999	0.02	4,500–5,000
$2,000,000 plus	0.02	13,600–14,350
Current Annual Limit:		
Under $250,000	0.19–0.23	550–650
$250,000 to $499,999	0.08–0.10	650–850
$500,000 to $999,000	0.03–0.06	350–700
$1,000,000 to $1,999,999	0.02	1,150–1,300
$2,000,000 or more	0.01–0.02	750–1,750

Source: *Estimates of the expected percentage of the insured population who would exceed a limit are based on an analysis of the MEPS–HC expenditure data supplemental with adjusted insurer claims from the Society of Actuaries large claims database; http://www.soa.org/files/pdf/Large_Claims_Report.pdf. Numbers of people rounded to the nearest 50.*

c. *Benefits*

Annual and lifetime limits exist in the individual, small group and large group health insurance markets. These limits function as caps on how much an insurance company will spend on medical care for a given insured individual over the course of a year, or the individual's lifetime. Once a person reaches this limit or cap, the person is essentially uninsured: He or she must pay the remaining cost of medical care out-of-pocket. These limits particularly affect people with high-cost conditions,[58] which are typically very serious. For example, one recent survey found that 10 percent of cancer patients reached the limit of what insurance would pay for treatment.[59] The same survey also found that 25 percent of cancer patients or their family members used up all or most of their savings, 13 percent were contacted by a collection agency, and 11 percent said they were unable to pay for basic necessities like food and housing as a result of the financial cost of dealing with cancer. By prohibiting lifetime limits and restricting annual limits, these interim final regulations will help families and individuals experiencing financial burdens due to exceeding the benefit limits of their insurance policy. By ensuring and continuing coverage, these interim final regulations also reduce uncompensated care, which would otherwise increase premiums of the insured population through cost-shifting, as discussed in more detail in section IV.B.6 later in this preamble.

These interim final regulations will also improve access to care. Reaching a limit could interrupt or cause the termination of needed treatment, leading to worsening of medical conditions. Moreover, those with medical debt are more likely to skip a needed test or treatment, and less likely to fill a prescription or visit a doctor or clinic for a medical issue.[60] The removal and restriction of benefit limits helps ensure continuity of care and the elimination of the extra costs that arise when an untreated or undertreated condition leads to the need for even more costly treatment, that could have been prevented if no loss of coverage had occurred. Lack of insurance coverage leads to additional mortality and lost workplace productivity, effects that would be amplified for a sicker population such as those who would reach a benefit limit.[61] By ensuring continuation of coverage, these interim final regulations benefit the health and the economic well-being of participants, beneficiaries, and enrollees.

These interim final regulations also benefit those without an alternative source of health coverage in the group health insurance market. Under HIPAA rules, when an individual exceeds a limit and loses coverage, that individual has a special enrollment right. If his or her plan offered multiple benefit packages or a spouse has access to ESI, the individual could enroll in the coverage, although it might lead to a change in providers and less generous coverage. Those without an alternative option would lose coverage, and the history of high medical claims and presence of preexisting conditions could make health insurance in the individual market impossible. Under these interim final regulations, people will no longer be treated differently depending on whether they have an alternative source of coverage.

Executive Order 12866 explicitly requires agencies to take account of "distributive impacts" and "equity," and these considerations help to motivate the relevant statutory provisions and these interim final regulations. Prohibiting lifetime limits and restricting annual limits assures that insurance will perform the function for which it was designed—namely, protecting health and financial well being for those most in need of care.

MEPS–HC person level spending data, calibrated to National Health Account levels, with the shape of the distribution modified based on high-cost claims data from the Society of Actuaries. The conditional premium increases were then applied to the fractions of plans in each of the three market segments by level of current annual limits to calculate the aggregate increase in premiums for the possible option.

[57] Numbers in this paragraph calculated from Table 2.4 may differ due to rounding.

[58] An April 2008 study by Milliman "2008 U.S. Organ and Tissue transplant cost estimates", found that the average one year billed charges related to a heart transplant averaged $787,000 while a liver transplant averaged $523,400. The lifetime costs for the treatment chronic disease such as of HIV infection have been well documented with one estimate of $618,000 (*Med Care* 2006;44: 990–997).

[59] *See* "National Survey of Households Affected by Cancer." (2006) accessed at *http://www.kff.org/kaiserpolls/upload/7591.pdf.*

[60] Seifert, Robert W., and Mark Rukavina. "Bankruptcy Is The Tip Of A Medical-Debt Iceberg." *Health Affairs* Web Exclusive (2006).

[61] *See* Institute of Medicine.(2003). *Hidden Costs, Value Lost: Uninsurance in America.* Washington, DC: National Academy Press; and Institute of Medicine (2002) *Care Without Coverage: Too Little, Too Late.* Washington, DC: National Academy Press.

This represents a meaningful improvement in equity, which is a benefit associated with these interim final regulations.

d. *Costs and Transfers*

Extending health insurance coverage for individuals who would otherwise hit a lifetime or annual limit will increase the demand for and utilization of health care services, thereby generating additional costs to the system. The three year phase-in of the elimination of annual limits and the immediate elimination of lifetime limits will increase the actuarial value of the insurance coverage for affected plans and policies if no other changes are made to the plan or policy. Issuers and plans in the group market may choose to make changes to the plan or policy to maintain the pre-regulation actuarial value of the plan or policy, such as changing their provider networks or copayments in some manner. To the extent that higher premiums (or other plan or policy changes) are passed on to all employees, there will be an explicit transfer from workers who would not incur high medical costs to those who do incur high medical costs. If, instead, the employers do not pass on the higher costs of insurance coverage to their workers, this could result in lower profits or higher prices for the employer's goods or services. Given the relatively small proportion of people who exceed the benefit limits in the current group markets, the Departments anticipate such transfers to be minimal when spread across the insured population (at a premium increase of one-half of a percent or less for lifetime limits and one-tenth of a percent or less for annual limits), compared with the substantial benefit rendered to individual high-cost enrollees. However, as this discussion demonstrates, there is substantial uncertainty in data and in the choices plans will decide to make in response to these interim final regulations, preventing more precise estimations of effects.

In the individual market, where policies are individually underwritten with no rating bands in the majority of States, the Departments expect the added premium cost or other benefit changes to be largely borne by the individual policyholder. As discussed in the impact analysis for Section 2704, if costs exceed 200 percent of the standard rate, some of the additional costs could be spread across the insurance market. In the 20 States with modified community rating, issuers could spread the increased costs across the entire individual market, leading to a transfer from those who would not incur high medical costs to those who do incur such costs. However, as with the group market, such a transfer is expected to be modest, given the small numbers of people who would exceed their benefit limit. The Departments estimate that the transfer would be three-quarters of a percent or less for lifetime limits and one-tenth of a percent or less for annual limits, under a situation of pure community rating where all the costs get spread across the insured population. This impact does not apply to grandfathered individual market plans. Also, given the wide variation in State insurance markets, a more precise estimation is not possible, and the premium impact would be even less in the majority of States that allow underwriting in the individual insurance market.

It is worth noting that the transfers discussed above will be significantly mitigated by the associated expansion of coverage that these interim final regulations create. The Departments expect, as a result of the gradual elimination of annual limits and the immediate elimination of lifetime limits, fewer people will be left without protection against high medical costs. This will lead fewer individuals to spend down resources and enroll in Medicaid or receive other State and locally funded medical support. It can be anticipated that such an effect will be amplified due to the high-cost nature of people who exceed benefit limits. As a result, there will be a reduction in Medicaid, State and local funded health care coverage programs, as well as uncompensated care, all of which would otherwise raise taxes and/or premiums for the larger population. Unfortunately, data around these high-cost individuals is limited, preventing the Departments from quantifying these benefits at the present time.

Additional uncertainty prevents more precise estimation of the benefits and impacts of this provision. As discussed in the impact analysis for Section 2704, there are interactive effects of the various provisions in these interim final regulations which cannot be estimated. For example, prohibiting rescissions and lifetime limits could mean that someone who would have had a policy rescinded now maintains coverage, and also maintains coverage beyond a previous lifetime limit. Moreover, it is important to note that the estimates presented here, by necessity, utilize "average" experiences and "average" plans. Different plans have different characteristics of enrollees, for example in terms of age or health status, meaning that provisions such as eliminating lifetime or restricting annual limits could affect them differently. This also means that average impacts of the various provisions in these interim final regulations or others cannot simply be added to obtain a total impact, since a plan may be affected by one provision but not another. Moreover, plans and issuers will consider these impacts when making decisions about whether or not to make other changes to their coverage that could affect their grandfather status—a consideration that is pertinent in the case of restricted annual limits, which do not apply to the grandfathered individual market. This further compounds any precise calculation of benefits and costs.

e. *Enrollment Opportunity*

These interim final regulations provide an enrollment (or, in the case of the individual market, reinstatement) opportunity for individuals who reached their lifetime limits in a group health plan or health insurance coverage and remain otherwise eligible for the coverage. In the individual market, the reinstatement opportunity does not apply to individuals who reached their lifetime limits in individual health insurance coverage if the contract is not renewed or otherwise is no longer in effect. It would apply, however, to a family member who reached the lifetime limit in an individual health insurance family policy while other family members remain in coverage. Such enrollment opportunity would generate a total hour burden of 3,800 hours and a cost burden of $21,000, as detailed in the Paperwork Reduction Act section.

f. *Alternatives*

PHS Act section 2711(a)(2) requires the Departments to "ensure that access to needed services is made available with a minimal impact on premiums." Accordingly, the Departments undertook an analysis of different restricted annual limit thresholds to study the issue, taking into consideration several factors: (1) The current use of annual limits in the group and individual market; (2) the average premium impact of imposing different annual limits on the individual, small group, and large group markets; (3) the number of individuals who will continue to have annual medical expenses that exceed an annual limit; and (4) the possibility that a plan or issuer would switch to an annual limit when lifetime limits are prohibited. In order to mitigate the potential for premium increases for all plans and policies, while at the same time ensuring access to essential health benefits, the Departments decided to

adopt a three-year phased approach for restricted annual limits.

As discussed above, it is important to note that it is difficult to predict exactly how plans and issuers will respond under the new regulations. Annual or lifetime limits on benefits help control risk and costs, and the elimination of a lifetime limit or a possible increase in an annual limit may lead plans and issuers to alter benefit design (such as increasing cost-sharing), and/or raise premiums. The Departments cannot determine which option or combination of options plans and issuers will choose. Therefore, it is very difficult to measure the impact on premiums due to the elimination of lifetime limits and a maximum annual limit. This uncertainty is compounded by the data uncertainties discussed earlier in section IV.B.2.b of this preamble.

Given the above data limitations, the Departments modeled the impact on premiums of increasing the annual limits for plans that currently have annual limits, assuming that the only reaction to a required increase in annual limits would be an increase in premiums. Because some plans may choose to avoid or offset the potential premium increase by increasing cost sharing, tightening the network of providers, adopting cost savings tools, or making other plan changes, the modeled premium impacts represent the high-end of the possible increases in premiums.

The Departments modeled a range of options and ways to implement a restricted annual limit. Two of the options considered were setting the annual restricted limit on essential benefits at $1 million or at $2 million. The higher the limit is set, the fewer the people that would exceed the limit and experience a gap in insurance coverage. However, plans with current low limits could see increases in costs and potentially premiums because the proportion of claims covered by the plans would increase. One final issue to consider is that for plan years (in the individual market, policy years) beginning after January 1, 2014, all group plans and non-grandfathered individual policies will be required to remove annual limits. A low annual limit until 2014 would offer less protection to those with medical expenses exceeding the limit, and could result in an increase in premiums in 2014 (although a variety of other changes that will be implemented in 2014 could be expected to result in lower premium increases in most States). Therefore, a stepped approach allowing the restricted annual limit to be phased in over time seemed to be the fairest approach and most likely to result in a minimal impact on premiums, so it was selected.

Table 3.5 demonstrates premium impacts at different annual limit thresholds, and Table 3.4 above demonstrates the numbers of people expected to exceed different annual limit thresholds. The Departments chose to set the restricted annual limit relatively low in the first year, and to then increase the limit up to $2 million over the three-year period. This phased approach was intended to ease any increases in premiums in any one year, particularly for plans with low initial annual limits, and to help group plans and non-grandfathered individual policies transition to no annual limits starting in 2014. With this approach, a threshold of $750,000 was associated with a 5.1 percent premium impact for plans with very low annual limits of $250,000, but it is anticipated that these plans comprise only less than one-half of one percent of the market. On the other hand, raising the restricted annual limits to $2,000,000 under these interim final regulations could be expected to help an estimated 2,700 to 3,500 people[62] who would no longer exceed their annual limit, ensuring financial protection to those who have high medical claims.

It is important to note that these interim final regulations also provide that the Secretary of HHS may establish a waiver program under which issuers or plans may assert that adhering to the restricted annual limit provisions of these interim final regulations would result in a significant decrease in access to benefits or a significant premium increase. The Departments provided for this waiver in order to prevent the loss of coverage for enrollees in low-benefit plans (for example, "mini-med" plans) that have low annual limits. While the impact of this policy is not quantified, it, too, is intended to mitigate any unintended consequences given the paucity of data on the incidence and prevalence of annual limits in the markets today.[63]

TABLE 3.5—ESTIMATED PREMIUM IMPACTS FOR A PLAN MOVING TO A NEW ANNUAL LIMIT

Current limit	People subject to current limit	New limit				
		$500k %	$750k %	$1 million %	$1.5 million %	$2 million %
$250k	278,000	3.7	5.1	6.1	6.2–6.4	[63] 6.2–6.6
$500k	835,000		1.4	2.3	2.4–2.6	2.4–2.8
$750k	1,113,000			1.0	1.0–1.2	1.0–1.5
$1 million	6,435,000				0.1–0.3	0.1–0.5
$1.5 million	9,287,000					0.04–0.2

Source: Premium estimates are calculated based MEPS–HC supplemented with the Society of Actuaries Large Claim Database—To estimate the conditional premium impact of moving a given plan with a given annual benefit maximum to a higher benefit maximum, the percentage change in estimated benefit rates (percent of medical spending that the plan pays for as benefits) based on simulated benefit payments for such coverages was used. The underlying assumed medical spending profile was drawn from MEPS–HC person level spending data, calibrated to National Health Account levels, with the shape of the distribution modified based on high-cost claims data from the Society of Actuaries. The conditional premium increases were then applied to the fractions of plans in each of the three market segments by level of current annual limits to calculate the aggregate increase in premiums for the possible option. For the low impact estimates, the distributions were then adjusted only for the expected marginal loading impact of using commercial reinsurance for many of the smaller carriers. For the high impact estimates, the distributions were also adjusted to reflect possible underestimation of the tails of the expenditure distribution once coverage of unlimited benefit levels was required. The adjustments were set at levels that generated aggregate impacts that were conservative relative to estimates from PricewaterhouseCoopers' March 2009 study of lifetime limits for the National Hemophilia Foundation.

[62] Numbers calculated from Table 3.4 may differ due to rounding.

[63] If a second decimal place were included, the lower end of the range in this column would be greater than the lower end of the range in the $1.5 million column.

4. PHS Act Section 2712, Rescissions (26 CFR 54.9815–2712T, 29 CFR 2590.715–2712, 45 CFR 147.128)

a. Summary

As discussed earlier in this preamble, PHS Act Section 2712 provides rules regarding rescissions for group health plans and health insurance issuers that offer group or individual health insurance coverage. A plan or issuer must not rescind coverage under the plan, policy, certificate, or contract of insurance from the individual covered under the plan or coverage unless the individual (or a person seeking coverage on behalf of the individual) performs an act, practice, or omission that constitutes fraud, or unless the individual makes an intentional misrepresentation of material fact, as prohibited by the terms of the plan or coverage. These interim final regulations provide that a group health plan, or a health insurance issuer offering group health insurance coverage, must provide at least 30 calendar days advance notice to an individual before coverage may be rescinded.[64] The notice must be provided regardless of whether the rescission is of group or individual coverage; or whether, in the case of group coverage, the coverage is insured or self-insured, or the rescission applies to an entire group or only to an individual within the group.

PHS Act Section 2712 and these interim final regulations create a statutory Federal standard and enforcement power in the group and individual markets where it did not exist. Prior to this provision taking effect, varying court-made Federal common law existed for ERISA plans. State rules pertaining to rescission have been found to be preempted by ERISA by five circuit courts (5th, 6th, 7th, 9th and 11th as of 2008). Each styled a remedy looking to State law, the majority of Federal courts or the Restatement of Contracts. According to a House Energy and Commerce Committee staff memorandum,[65] rather than reviewing medical histories when applications are submitted, some insurers engage in "post-claims underwriting." Under this practice, if the policyholders become sick and file expensive claims, the insurance companies initiate investigations to scrutinize the details of the policyholder's application materials and medical records, and if discrepancies, omissions, or misrepresentations are found, the insurer rescinds the policies, returns the premiums, and refuses payment for medical services. The Committee found some questionable practices in this area including insurance companies rescinding coverage even when discrepancies are unintentional or caused by others, for conditions that are unknown to policyholders, and for discrepancies unrelated to the medical conditions for which patients sought medical care. According to the Committee, the current regulatory framework governing the individual insurance market in this area is a haphazard collection of inconsistent State and Federal laws. Protections for consumers and enforcement actions by regulators vary depending on where individuals live. Because of these varying standards, many patients lack adequate protections against rescission, prompting the need for and benefits from this rule.

When a coverage rescission occurs, an individual's health insurance coverage is retroactively cancelled, which means that the insurance company is no longer responsible for medical care claims that they had previously accepted and paid. Rescissions can result in significant financial hardship for affected individuals, because, in most cases, the individuals have accumulated significant medical expenses.

b. Estimated Number of Affected Entities

The Departments assume that these interim final regulations will have their largest impact on the individual insurance market, because group health coverage rarely is rescinded.[66] By creating a new Federal standard governing when policies can be rescinded, the Departments expect these interim final regulations to potentially affect the approximately 17 million non-elderly individual health insurance policy holders and their dependents in the individual health insurance market.[67] In addition, approximately 490 health insurance issuers offering coverage in the individual health insurance market who currently could rescind health insurance coverage are expected to be affected.[68] That said, the actual incidence of individuals who are subject to rescissions each year is likely to be small. The NAIC Regulatory Framework Task Force collected data on 52 companies covering the period 2004–2008, and found that rescissions averaged 1.46 per thousand policies in force.[69] This estimate implies there are approximately 10,700 rescissions per year.

c. Benefits

There are many benefits that flow from these interim final regulations, which the Departments believe justify the costs. As noted, Executive Order 12866 requires consideration of "distributive impacts" and "equity." To the extent that rescissions are arbitrary and revoke the insurance that enrollees paid for and expected to cover the cost of expensive illnesses and conditions, preventing rescissions would prevent inequity and greatly increase health and economic well-being. Consumers would have greater confidence that purchasing insurance would be worthwhile, and policies would represent better value for money. As discussed further in section IV.B.6.b of this preamble, it is also well-documented that lack of insurance leads to lost workplace productivity and additional mortality and morbidity. Thus, these rules would contribute to reducing the burden from lost productivity that arises from people being uncovered. These effects would be especially large relative to the number of individuals affected given that the affected population tends to be much sicker on average.

Specifically, this provision also could protect against interruptions or terminations in care resulting from rescissions. As a result of the statute and these interim final regulations, people with high-cost illnesses at risk of rescission would have continued access to care throughout their illness, possibly avoiding more expensive and debilitating complications down the road. Gaps in health insurance, even if brief, can have significant health and financial consequences.[70] A survey from the Commonwealth Fund found that about three of five adults with any time uninsured said they had not received needed health care in the past year because of costs—more than two times the rate of adults who were insured all year. Further, 44 percent of respondents who had experienced any coverage break during the prior year said they had failed to go to a doctor or clinic

[64] Even though prior notice must be provided in the case of a rescission, applicable law may permit the rescission to void coverage retroactively.

[65] *Terminations of Individual Health Insurance Policies by Insurance Companies, Hearing before the House Comm. On Energy and Commerce, Subcommittee On Oversight and Investigations*, June 16, 2009 (supplemental memorandum), at: *http://energycommerce.house.gov/Press_111/20090616/rescission_supplemental.pdf.*

[66] This statement is based on the Departments' conversations with industry experts.

[67] 2009 Current Population Survey.

[68] Estimates are from 2007 NAIC financial statements data and the California Department of Managed Healthcare (*http://wpso.dmhc.ca.gov/hpsearch/viewall.aspx*).

[69] NAIC Rescission Data Call, December 17, 2009, p.1.

[70] This point is discussed further in the section IV.B.6.b. later in this preamble.

when they had a medical problem because of costs, compared with 15 percent of adults who did not experience such breaks.[71]

These interim final regulations will also have substantial financial benefits for individuals who otherwise would have had their policies rescinded. While there has been minimal documentation of financial losses associated with rescissions, reports suggest severe financial hardships may result. In one case, a woman faced more than $129,000 in medical bills and was forced to stop chemotherapy for several months after being dropped by an insurer.[72] The maintenance of coverage through illness not only prevents financial hardship for the particular enrollee, but can also translate into lower premiums for the broader insured population by reducing cost-shifting from the costs of uncompensated care.

d. Costs and Transfers

The prohibition of rescissions except in cases of fraud or intentional misrepresentation of material fact could lead insurers to spend more resources checking applications before issuing policies than they did before the Affordable Care Act, which would increase administrative costs. However, these costs could be partially offset by decreased costs associated with reduced post-claims underwriting under the interim final rule. Due to lack of data on the administrative costs of underwriting and post-claims underwriting, as well as lack of data on the full prevalence of rescissions, it is difficult for the Departments to quantify these costs. The new requirement for an advance notice prior to rescission of a policy imposes an hour burden of 350 hours and a cost burden of $29,000. These costs are discussed in more detail in the Paperwork Reduction Act section later in this preamble.

To the extent that continuing coverage for these generally high-cost populations leads to additional demand for and utilization of health care services, there will be additional costs generated in the health care system. However, given the relatively low rate of rescissions (approximately 0.15 percent of individual policies in force) and the relatively sick nature of people who have policies rescinded (who would have difficulty going without treatment), the Departments estimate that these additional costs would be small.

Under this provision of these interim final regulations, a transfer likely will occur within the individual health insurance market from policyholders whose policies would not have been rescinded before the Affordable Care Act to some of those whose policies would have been rescinded before the Affordable Care Act, depending on the market and the rules which apply to it. This transfer could result from higher overall premiums insurers will charge to recoup their increased costs to cover the health care costs of very sick individuals whose policies previously could be rescinded (the precise change in premiums depends on the competitive conditions in specific insurance markets). However, rescissions are extremely rare in group markets where such costs would be most likely to be transferred through premium increases. As described earlier, they are also rare in the individual market, affecting 0.15 percent of policies. In this market, the potential costs would likely be born by the individuals themselves unless they live in a State with regulations limiting rate increases based on health, as discussed further below.

While the Departments are unable to estimate the impact of prohibiting rescissions except in cases of fraud or intentional misrepresentation with certainty, they expect it to be small. Even the high rates of rescission acknowledged by some smaller insurers would still be expected to translate into only a small average impact across the individual health insurance market. And since this small impact across the market would be primarily attributable to insurers paying benefits to persons with substantial medical expenditures, the transfer would be useful.

The Departments assume for their analysis that the individuals covered by the rescinded policies are much sicker than average. Specifically, these individuals are assumed to have total spending in the top 10 percent of spending, which represents about 70 percent of total spending for the population as a whole, as estimated from the 2007 MEPS–HC person level medical expenditure distributions. If the overall NAIC rescission rate of 0.15 percent comes from this subset randomly, then they would account for one percent of claims. Depending on the percentage of rescissions that no longer occur as a result of these interim final regulations, and other changes to the insurance market as detailed below, these claims would now have to be covered, representing a transfer of costs from the affected entities to the larger insured population.

Substantial uncertainty exists around the estimated transfer discussed above. First, since post-claims underwriting is limited by these interim final regulations, plans may expand their pre-claims underwriting practices, potentially leading to increased denials, preexisting condition riders, or rate-ups.[73] This in turn would decrease the number of rescissions, but without expanding coverage or increasing claims paid. Second, there is uncertainty concerning what proportion of the rescissions would be considered to result from fraud or intentional misrepresentation of material fact, and also uncertainty regarding the interaction of this provision with other provisions, such as the elimination of lifetime limits discussed in the impact analysis for PHS Act section 2711, or the prohibition of preexisting condition exclusions for children—since new children will now be able to enroll in policies which also cannot be rescinded. As a result of this uncertainty, the Departments are unable to precisely estimate an overall or average premium impact from this provision, but given the relatively low prevalence of rescissions in the current market, the impact is estimated to be at most a few tenths of a percent.

5. PHS Act Section 2719A, Patient Protections (26 CFR 54.9815–2719AT, 29 CFR 2590.715–2719A, 45 CFR 147.138)

As discussed earlier in this preamble, Section 2719A of the PHS Act and these interim final regulations impose, with respect to a group health plan, or group or individual health insurance coverage, a set of three requirements relating to the choice of a health care professional and requirements relating to benefits for emergency services. The three requirements relating to the choice of health care professional apply only with respect to a plan or health insurance coverage with a network of providers. Thus, a plan or issuer that has not negotiated with any provider for the delivery of health care but merely reimburses individuals covered under the plan for their receipt of health care is not subject to the requirements relating to the choice of a health care professional. However, all plans or health insurance coverage are subject to requirements relating to benefits for

[71] Collins *et al.* "Gaps in Health Insurance: An All American Problem" *Commonwealth Fund* (2006), available at: *http://www.commonwealthfund.org/usr_doc/Collins_gapshltins_920.pdf.*

[72] Girion, Lisa "Health Net Ordered to Pay $9 million after Canceling Cancer Patient's Policy," *Los Angeles Times* (2008), available at: *http://www.latimes.com/business/la-fi-insure23feb23,1,5039339.story.*

[73] These interim final regulations eliminate preexisting condition riders for children, but such riders will continue to be allowed for adults until January 1, 2014.

emergency services. The cost, benefits, and transfers associated with each of these requirements are discussed separately below.

PHS Act section 2719A and these interim final regulations are generally effective for plan years (or, in the case of the individual market, policy years) beginning on or after September 23, 2010.

a. Choice of Health Care Professional

i. Designation of Primary Care Provider

Summary. The statute and these interim final regulations provide that if a group health plan, or a health insurance issuer offering group or individual health insurance coverage, requires or provides for designation by a participant, beneficiary, or enrollee of a participating primary care provider, then the plan or issuer must permit each participant, beneficiary, and enrollee to designate any participating primary care provider who is available to accept the participant, beneficiary, or enrollee.

Estimated Number of Affected Entities. Choice or assignment to a primary care provider is typically required by health maintenance organizations (HMOs) and Point of Service plans (POS). Recent data suggest that there are 577 HMOs in the United States,[74] accounting for more than 32.3 million enrollees,[75] of whom about 40 percent have their primary care provider serve as a gatekeeper.[76] Similar data does not exist for POS plans, although as a reference, about 10 percent of workers with ESI are enrolled in POS plans.[77]

PHS Act section 2719A and these interim final regulations only apply to non-grandfathered health plans. However, due to the lack of data on HMO and POS enrollees by type of market, and the inability to predict new plans that may enter those markets, the Departments are unable to predict the number enrollees and plans that would be affected by these provisions. Moreover, there are no data on the number of plans that auto-assign patients to primary care physicians and do not already allow patients to make the final provider choice, as this would be the population to benefit maximally from the interim final rule. From conversations with industry experts the Departments expect, however, that this number would be very small, and therefore the benefits and costs of this provision would be small as well, as discussed further below.

Benefits. Provider choice allows patients to take into account factors they may value when choosing their provider, such as provider credentials, office hours and location, advice from professionals, and information on the experience of other patients.[78] Freedom of choice is an important value, particularly in this domain, even if it cannot easily be turned into monetary equivalents. Provider choice is a strong predictor of patient trust in their provider, which could lead to decreased likelihood of malpractice claims.[79] As well, studies show that better patient-provider trust results in improved medication adherence.[80] Research literature suggests that better patient-provider relationships also increase health promotion and therapeutic effects.[81] Moreover, one study found that adults who identified having a primary care provider, rather than a specialist, as their regular source of care had 33 percent lower annual adjusted health care expenditures and lower adjusted mortality.[82]

Studies have also found that patients who have long-term relationships with their health care providers tend to experience better quality health care. Adults that have a usual provider and place are more likely to receive preventive care and screening services than those who do not. For example, adults were 2.8 times more likely to receive a flu shot and women between the ages of 20–64 were 3.9 times more likely to receive a clinical breast exam if they had a usual provider and place of service.[83]

Regular contact with primary care providers also can decrease emergency department visits and hospitalizations. One study found that adolescents with the same regular source of care were more likely to receive preventive care and less likely to seek care in an emergency room.[84] Another study found that patients without a relationship with a regular physician were 60 percent more likely to go to the emergency department with a non-urgent condition.[85] Patients that have a usual source of care tend to also have fewer hospital admissions.[86]

Costs and Transfers. Although difficult to estimate given the data limitations described above, the costs for this provision are likely to be minimal. As previously noted, when enrollees like their providers, they are more likely to maintain appointments and comply with treatment, both of which could induce demand for services, but these services could then in turn reduce costs associated with treating more advanced conditions. However, the number of affected entities from this provision is very small, leading to small additional costs.

There will likely be negligible transfers due to this provision given no changes in coverage or cost-sharing.

ii. Designation of Pediatrician as Primary Care Provider

Summary. If a plan or issuer requires or provides for the designation of a participating primary care provider for a child by a participant, beneficiary, or enrollee, the plan or issuer must permit the designation of a physician (allopathic or osteopathic) who specializes in pediatrics as the child's primary care provider if the provider participates in the network of the plan or issuer and is available to accept the child. The general terms of the plan or health insurance coverage regarding pediatric care otherwise are unaffected,

[74] Kaiser Family Foundation, "Number of HMOs, July 2008," *available at http://www.statehealthfacts.kff.org/comparetable.jsp?ind=347&cat=7&sub=85&yr=71&typ=1&sort=a* Note that the number of HMOs also includes Medicaid and Medicare only HMOs that are not covered by these interim final regulations.

[75] Departments' estimates are based on the 2009 CPS and the 2008 Medical Expenditure Panel Survey.

[76] *See* Fang, Hai, *et al.*, "Has the use of physician gatekeepers declined among HMOs? Evidence from the United States." *International Journal of Health Care Finance and Economics* 9:183–19 5 (2009).

[77] *See* Kaiser Employer Health Benefits Annual Survey, 2009, Exhibit 5.2 ("Distribution of Health Plan Enrollment for Covered Workers, by Firm Size, Region, and Industry, 2009"), *available at http://ehbs.kff.org/pdf/2009/7936.pdf.*

[78] *See* Fanjiang, Gary, *et al.*, "Providing Patients Web-based Data to Inform Physician Choice: If You Build It, Will They Come?." *Journal of General Internal Medicine* 22.10 (2007).

[79] Balkrishnan, Rajesh, and Chu-Weininger, Ming Ying L., "Consumer Satisfaction with Primary Care Provider Choice and Associated Trust." *BMC Health Services Research* 22.10 (2007).

[80] Piette, John, *et al.*, "The Role of Patient-Physician Trust in Moderating Medication Nonadherence Due to Cost Pressures." *Archives of Internal Medicine* 165, August (2005) and Roberts, Kathleen J., "Physician-Patient Relationships, Patient Satisfaction, and Antiretroviral Medication Adherence Among HIV-Infected Adults Attending a Public Health Clinic." *AIDS Patient Care and STDs* 16.1 (2002).

[81] *Ibid. See also* DiMatteo, Robin M., *et al.*, "Physicians' Characteristics Influence Patients' Adherence to Medical Treatment: Results From the Medical Outcomes Study." *Health Psychology* 12.2 (1993), and Bazemore, Andrew, and Phillips, Robert, "Primary Care and Why it Matters for U.S. Health Reform." *Health Affairs* 29.5 (2010).

[82] Franks, P., and K. Fiscella, "Primary Care Physicians and Specialists as Personal Physicians. Health Care Expenditures and Mortality Experience." *Journal of Family Practice* 47 (1998).

[83] Blewett, Lynn, *et al.*, "When a Usual Source of Care and Usual Provider Matter: Adult Prevention and Screening Services." *Journal of General Internal Medicine* 23.9 (2008).

[84] Macinko, James, *et al.*, "Contribution of Primary Care to Health Systems and Health." *Milbank Quarterly* 83.3 (2005).

[85] Burstin, "Nonurgent Emergency Department Visits: The Effect of Having a Regular Doctor."

[86] Bazemore, "Primary Care and Why it Matters for U.S. Health Reform."

including any exclusions with respect to coverage of pediatric care.

Estimated Number of Affected Entities. Due to lack of data on enrollment in managed care organizations by age, as well as lack of data on HMO and POS enrollees by type of market, and the inability to predict new plans that may enter those markets, the Departments are unable to predict the number enrollees and plans that would be affected by these provisions. As a reference, there are an estimated 11.8 million individuals under age 19 with ESI who are in an HMO plan.[87]

Benefits. By expanding participating primary care provider options for children to include physicians who specialize in pediatrics, this provision could benefit individuals who are making decisions about care for their children. As discussed in the previous section, research indicates that when doctors and patients have a strong, trusting relationship, patients often have improved medication adherence, health promotion, and other beneficial health outcomes. Considering this research, this provision could lead to better, sustained patient-provider relationships and health outcomes.

In addition, allowing enrollees to select a physician specializing in pediatrics as their children's primary care provider could remove any referral-related delays for individuals in plans that require referrals to pediatricians and do not allow physicians specializing in pediatrics to serve as primary care providers.[88] The American Academy of Pediatrics (AAP) strongly supports the idea that the choice of primary care clinicians for children should include pediatricians.[89] Relatedly, at least two States have laws providing children immediate access to pediatricians.[90]

Regular pediatric care, including care by physicians specializing in pediatrics, can improve child health outcomes and avert preventable health care costs. For example, one study of Medicaid enrolled children found that when children were up to date for age on their schedule of well-child visits, they were less likely to have an avoidable hospitalization at a later time.[91] Likewise, if providers are able to proactively identify and monitor obesity in child patients, they may reduce the incidence of adult health conditions that can be expensive to treat; various studies have documented links between childhood obesity and diabetes, hypertension, and adult obesity.[92] One recent study modeled that a one-percentage-point reduction in obesity among twelve-year-olds would save $260.4 million in total medical expenditures.[93]

Giving enrollees in covered plans (that require the designation of a primary care provider) the ability to select a participating physician who specializes in pediatrics as the child's primary care provider benefits individuals who would not otherwise have been given these choices. Again, the extent of these benefits will depend on the number of enrollees with children that are covered by plans that do not allow the selection of a pediatrician as the primary care provider, which industry experts suggest would be small.

Costs and Transfers. Although difficult to estimate given the data limitations described above, the costs for this provision are likely to be small. Giving enrollees a greater choice of primary care providers by allowing them to select participating physicians who specialize in pediatrics as their child's primary care provider could lead to health care costs by increasing the take-up of primary care services, assuming they would not have utilized appropriate services as frequently if they had not been given this choice.

Any transfers associated with these interim final regulations are expected to be minimal. To the extent that pediatricians acting as primary care providers would receive higher payment rates for services provided than would other primary care physicians, there may be some transfer of wealth from policy holders of non grandfathered group plans to those enrollees that choose the former providers. However, the Departments do not believe that this is likely given the similarity in income for primary care providers that care for children.[94]

iii. Patient Access to Obstetrical and Gynecological Care

Summary. The statute and these interim final regulations also provide rules for a group health plan, or a health insurance issuer offering group or individual health insurance coverage, that provides coverage for obstetrical or gynecological care and requires the designation of an in-network primary care provider. Specifically, the plan or issuer may not require authorization or referral by the plan, issuer, or any person (including a primary care provider) for a female participant, beneficiary, or enrollee who seeks obstetrical or gynecological care provided by an in-network health care professional who specializes in obstetrics or gynecology. These plans and issuers must also treat the provision of obstetrical and gynecological care, and the ordering of related obstetrical and gynecological items and services, by the professional who specializes in obstetrics or gynecology as the authorization of the primary care provider. For this purpose, a health care professional specializing in obstetrics or gynecology is any individual who is authorized under applicable State law to provide obstetrical or gynecological care, and is not limited to a physician.

Estimated Number of Affected Entities. Requiring referrals or authorizations to health care professional who specializes in obstetrics or gynecology (OB/GYNs) is typically required by health maintenance organizations (HMOs) and Point of Service plans (POS). As a reference, according to the 2004 Kaiser Women's Health Survey, 46 percent of women reported seeing an OB/GYN in the past year and 47 percent of women of reproductive age counted OB/GYNs among their routine health care providers.[95] In 2006, there were 69.4 million visits to an OB/GYN according to the National Ambulatory Medical Care Survey conducted by the Centers for Disease Control and Prevention.[96] Although more recent data is not available, a 1999 survey showed that 60 percent of all OB/GYNs in plans

[87] U.S. Department of Labor/EBSA calculations using the March 2009 Current Population Survey Annual Social and Economic Supplement and the 2008 Medical Expenditure Panel Survey.

[88] There is no data available to estimate the number of plans that fall into this category.

[89] *See* AAP Policy, "Guiding Principles for Managed Care Arrangements for the Health Care of Newborns, Infants, Children, Adolescents, and Young Adults," *available at http://aappolicy.aappublications.org/cgi/reprint/pediatrics;105/1/132.pdf.*

[90] For example, Michigan and North Carolina mandate direct access to pediatricians as a part of patients' rights requirements. *See* Kaiser Family Foundation, "Patients' Rights: Direct Access to Providers, 2008," *available at http://www.statehealthfacts.kff.org/comparetable.jsp?ind=364&cat=7.*

[91] Bye, "Effectiveness of Compliance with Pediatric Preventative Care Guidelines Among Medicaid Beneficiaries."

[92] "Working Group Report on Future Research Directions in Childhood Obesity Prevention and Treatment." National Heart Lung and Blood Institute, National Institute of Health, U.S. Department of Health and Human Services (2007), *available at http://www.nhlbi.nih.gov/meetings/workshops/child-obesity/index.htm.*

[93] *Ibid.*

[94] *http://www.merritthawkins.com/pdf/2008-mha-survey-primary-care.pdf.*

[95] *See* Salganicoff, Alina, *et al.*, "Women and Health Care: A National Profile." Kaiser Family Foundation (2005).

[96] *See* Cherry, Donald K., *et al.*, "National Ambulatory Medical Care Survey: 2006 Summary." National Health Statistics Reports (August 2008), Centers for Disease Control and Prevention, *available at http://www.cdc.gov/nchs/data/nhsr/nhsr003.pdf.*

requiring the designation of a primary care provider reported that their gynecologic patients were either limited or barred from seeing their OB/GYNs without first getting permission from another physician, and 28 percent reported that their pregnant patients needed permission before seeing an OB/GYN.[97] Nearly 75 percent of surveyed OB/GYNs reported that their patients needed to return to their primary care physicians for permission before they could provide necessary follow-up care.

Notably, beginning in 1994, due to both consumer demand and efforts to regulate managed care, many States passed direct access laws for OB/GYNs, allowing patients to seek care at an OB/GYN office without a referral from a primary care physician. As of 2008, 36 States plus the District of Columbia have laws that provide direct access to OB/GYNs. However, 14 States have not mandated direct access: Alaska, Arizona, Hawaii, Indiana, Iowa, Nebraska, New Jersey, New Mexico, North Dakota, Oklahoma, South Dakota, Tennessee, Vermont, and Wyoming.[98] This provision gives females direct access to OB/GYNs in covered plans in these States, who may otherwise not have had this direct access. As well, because State law is preempted by ERISA, women in self-insured plans did not previously receive this legal protection. In addition, these women will not need to get an authorization from their primary care provider for the care and ordering of obstetrical and gynecological items and services by their participating OB/GYN.

These interim final regulations apply to non-grandfathered health plans. However, due to the lack of data on HMO and POS enrollees by type of market, and the inability to predict new plans that may enter those markets, the Departments are unable to predict the number enrollees and plans that would be affected by this provision. As a reference, there are an estimated 14.8 million females between ages 21 to 65 with ESI who are in HMO plans.[99]

Benefits. This provision gives women in covered plans easier access to their OB/GYNs, where they can receive preventive services such as pelvic and breast exams, without the added time, expense, and inconvenience of needing permission first from their primary care providers. Moreover, this provision may also save time and reduce administrative burden since participating OB/GYNs do not need to get an authorization from a primary care provider to provide care and order obstetrical and gynecological items and services. To the extent that primary care providers spend less time seeing women who need a referral to an OB/GYN, access to primary care providers will be improved. To the extent that the items and services are critical and would have been delayed while getting an authorization from the primary care provider, this provision could improve the treatment and health outcomes of female patients.

Access to such care can have substantial benefits in women's lives. About 42,000 American women die each year from breast cancer, and it is estimated that about 4,000 additional lives would be saved each year just by increasing the percentage of women who receive recommended breast cancer screenings to 90 percent.[100] As well, regular screening with pap smears is the major reason for the 30-year decline in cervical cancer mortality.[101]

To the extent that direct access to OB/GYN services results in increased utilization of recommended and appropriate care, this provision may result in benefits associated with improved health status for the women affected. Potential cost savings also exist since women in affected plans will not need to visit their primary care provider in order to get a referral for routine obstetrical and gynecological care, items, and services, thereby reducing unnecessary time and administrative burden, and decreasing the number of office visits paid by her and by her health plan.

Costs and Transfers. One potential area of additional costs associated with this provision would be induced demand, as women who no longer need a referral to see an OB/GYN may be more likely to receive preventive screenings and other care. Data is limited to provide an estimate of this induced demand, but the Departments believe it to be small.

To the extent these interim final regulations result in a shift in services to higher cost providers, it would result in a transfer of wealth from enrollees in non grandfathered group plans to those individuals using the services affected. However, such an effect is expected to be small.

b. Coverage of Emergency Services

i. Summary

PHS Act section 2719A and these interim final regulations provide that a group health plan and a health insurance issuer covering emergency services must do so without the individual or the health care provider having to obtain prior authorization (even if the emergency services are provided out of network). For a plan or health insurance coverage with a network of providers that provide benefits for emergency services, the plan or issuer may not impose any administrative requirement or limitation on benefits for out-of-network emergency services that is more restrictive than the requirements or limitations that apply to in-network emergency services.

Finally, these interim final regulations provide that cost-sharing requirements expressed as a copayment amount or coinsurance rate imposed for out-of-network emergency services cannot exceed the cost-sharing requirements that would be imposed if the services were provided in-network. These interim final regulations also provide that a plan or health insurance issuer pay for out-of-network emergency services (prior to imposing in-network cost-sharing), the greatest of: (1) The median in-network rate; (2) the usual customary and reasonable rate (or similar rate determined using the plans or issuer's general formula for determining payments for out-of-network services); or (3) the Medicare rate.

In applying the rules relating to emergency services, the statute and these interim final regulations define the terms emergency medical condition, emergency services, and stabilize. These terms are defined generally in accordance with their meaning under Emergency Medical Treatment and Labor Act (EMTALA), section 1867 of the Social Security Act. There are, however, some variances from the EMTALA definitions.

The statute and these interim final regulations relating to emergency services do not apply to grandfathered health plans; however, other Federal or State laws related to emergency services may apply regardless of grandfather status.

ii. Estimated Number of Affected Entities

These interim final regulations will directly affect out-of-pocket

[97] *See* American College of Obstetricians and Gynecologists/Princeton Survey Research Associates, 1999.

[98] Kaiser Family Foundation, "Mandates Direct Access to OB/GYNs?," *available at http://www.statehealthfacts.kff.org/comparemaptable.jsp?ind=493&cat=10&sub=114.*

[99] U.S. Department of Labor/EBSA calculations using the March 2009 Current Population Survey Annual Social and Economic Supplement and the 2008 Medical Expenditure Panel Survey.

[100] *See* National Commission on Prevention Priorities, "Preventive Care: A National Profile on Use, Disparities, and Health Benefits." Partnership for Prevention, August 2007.

[101] *See* "Preventive Care: A National Profile on Use, Disparities, and Health Benefits" at 26.

expenditures for individuals enrolled in non-grandfathered private health insurance plans (group or individual) whose copayment or coinsurance arrangements for emergency services differ between in network and out of network providers. These interim final regulations may also require some health plans to make higher payments to out of network providers than are made under their current contractual arrangements. There are no available data, however, that allow for national estimates of the number of plans (or number of enrollees in plans) that have different payment arrangements for out of network than in-network providers, or differences between in- and out-of-network copayment and coinsurance arrangements, in order to more precisely estimate the number of enrollees affected.

The Departments conducted an informal survey of benefits plans for large insurers in order to assess the landscape with regard to copayment and coinsurance for emergency department services, but found that a variety of arrangements currently exist in the marketplace. Many of the large insurers maintained identical copayment and/or coinsurance arrangements between in and out of network providers. Others have differing arrangements based on copayments, coinsurance rates, or a combination of the two. While useful for examining the types of arrangement that exist in the market place, these data do not contain enrollment information and therefore cannot be used to make impact estimates.

Although these data do not permit quantitative estimates of plans or persons affected, other data can be illustrative of overall magnitudes for emergency services. For a point of reference, in 2005, 115.3 million visits were made to hospital emergency departments. Of these, 39.9 percent were made by individuals with private insurance. This represents approximately 46.0 million visits, at approximately 1.7 visits per insured person that utilized emergency department services, or 27.4 million people.[102] While data on rates of out-of-network emergency room encounters is sparse, the Blue Cross Blue Shield (BCBS) Association reports that nationally about 8 percent of its emergency room visits are sought out-of-network.[103] Given the breadth of the Blue Cross networks, it is reasonable to assume that 8 percent to 16 percent of emergency room visits are out-of-network each year, since a plan with a smaller provider network will be more likely to have out-of-network use by enrollees. If each individual was equally likely to utilize out of network services, a maximum of 2.1 to 4.2 million individuals would be potentially affected by differing out-of-pocket requirements. Based on the informal survey, some proportion, possibly a large portion, of these individuals are covered by plans that have identical in and out-of-network requirements. Therefore, the number of individuals affected by this regulatory provision would be smaller.

iii. Benefits

Insurers maintain differing copayment and coinsurance arrangements between in- and out-of-network providers as a cost containment mechanism. Implementing reduced cost sharing for the use of in-network providers provides financial incentive for enrollees to use these providers, with whom plans often have lower-cost contractual arrangements. In emergency situations, however, the choice of an in-network provider may not be available—for example, when a patient is some distance from his or her local provider networks or when an ambulance transports a patient to the nearest hospital which may not have contractual arrangements with the person's insurer. In these situations, the differing copayment or coinsurance arrangements could place a substantial financial burden on the patient. These interim final regulations eliminate this disparity in out-of-pocket burden for enrollees, leading to potentially substantial financial benefit.

These interim final regulations also provide for potentially higher payments to out-of-network providers, if usual customary rates or Medicare rates are higher than median in-network rates. This could have a direct economic benefit to providers and patients, as the remaining differential between provider charge and plan payment will be smaller, leading to a smaller balance-bill for patients.

To the extent that expectations about such financial burden with out-of-network emergency department usage would cause individuals to delay or avoid seeking necessary medical treatment when they cannot access a network provider, this provision may result in more timely use of necessary medical care. It may therefore result in health and economic benefits associated with improved health status; and fewer complications and hospitalizations due to delayed and possibly reduced mortality. The Departments expect that this effect would be small, however, because insured individuals are less likely to delay care in emergency situations.

iv. Costs and Transfers

The economic costs associated with the emergency department provisions are likely to be minimal. These costs would occur to the extent that any lower cost-sharing would induce new utilization of out of network emergency services. Given the nature of these services as emergency services, this effect is likely to be small for insured individuals. In addition, the demand for emergency services in truly emergency situations can result in health care cost savings and population health improvements due to the timely treatment of conditions that could otherwise rapidly worsen.

The emergency services provisions are likely to result in some transfers from the general membership of non-grandfathered group policies that have differing copayment and coinsurance arrangements to those policy holders that use the out-of-network emergency services. The transfers could occur through two avenues. First, if there is reduced cost sharing for out-of-network emergency services, then plans must pay more when enrollees use those services. Out-of-pocket costs for the enrollees using out-of-network services will decrease, while plan costs will get spread across the insured market. Second, if the provision results in plans paying higher rates than they currently do for out-of-network providers, then those costs will get spread across the insured market while the individual enrollees using out-of-network care would potentially get a smaller balance bill. For all of the data issues described above, the precise amount of the transfer which would occur through an increase in premiums for these group plans is impossible to quantify with any precision, but it is likely to be less than one-tenth of one percent of premium, and only applies to non-grandfathered health plans.

c. Application to Grandfathered Health Plans

As discussed earlier in this preamble, the statute and these interim final regulations relating to certain patient protections do not apply to

[102] Vital and Health Statistics, Advanced Data No. 386, June 29, 2007.

[103] BCBS, however, reports its rates vary considerably by State, with 11 States having double digit rates ranging from 10 percent to a high of 41 percent. Moreover, because BCBS has reciprocity between many State Blue Cross Blue Shield plans, its statistics for out of network emergency services utilization should be considered a conservative estimate of the proportion of ER services that insured individuals receive out-of-network.

grandfathered health plans. However, other Federal or State laws related to these patient protections may apply regardless of grandfather status.

d. Patient Protection Disclosure Requirement

When applicable, it is important that individuals enrolled in a plan or health insurance coverage know of their rights to (1) choose a primary care provider or a pediatrician when a plan or issuer requires participants or subscribers to designate a primary care physician; or (2) obtain obstetrical or gynecological care without prior authorization. Accordingly, these interim final regulations require such plans and issuers to provide a notice to participants (in the individual market, primary subscribers) of these rights when applicable. Model language is provided in these interim final regulations. The notice must be provided whenever the plan or issuer provides a participant with a summary plan description or other similar description of benefits under the plan or health insurance coverage, or in the individual market, provides a primary subscriber with a policy, certificate, or contract of health insurance.

The Departments estimate that the cost to plans and insurance issuers to prepare and distribute the disclosure is $6.1 million in 2011. For a discussion of the Patient Protection Disclosure Requirement, see the Paperwork Reduction Act section later in this preamble.

6. Combined Effects of the Insurance Market Reforms

a. Summary

The Affordable Care Act includes a number of provisions that are effective for plan years (or in the case of individual health insurance coverage, for policy years) beginning on or after September 23, 2010. These interim final regulations include four of those provisions whose purpose is to improve consumer protections. Two additional provisions—the extension of dependent coverage to adult children and the rules defining a grandfathered health plan—were the subject of previously published interim final regulations. The implementation of other provisions—including those relating to coverage of preventive services (PHS Act section 2713) and appeals (PHS Act section 2719)—will be addressed in future regulations.

This set of regulations is distinct from the others in that its primary beneficiaries are people who generally already have some type of illness, injury or disability. The provision prohibiting preexisting condition exclusions for children could help 31,000 to 72,000 uninsured children gain insurance, and up to 90,000 children who have insurance with benefit carve-outs or preexisting condition exclusion periods. The policy on restricted annual limits could help up to 2,700 to 3,500 people who hit these limits each year; the prohibition on lifetime limits could help 18,650 to 20,400 each year who would be expected to have costs that exceed a limit. Based on an NAIC survey, the Departments estimate there are approximately 10,700 rescissions of policies in the individual market each year, and these interim final regulations are expected to reduce this number substantially.[104] And one of the patient protections, access to emergency care from out-of-network providers, could limit the out-of-pocket spending for up to 2.1 to 4.2 million individuals with some acute health care need. While the estimates on the number of people affected by these policies may be relatively small, a much larger number of Americans are at risk of hitting one of these barriers to insurance coverage and will gain indirect benefits of the legislation. This section describes the potential combined benefits, costs, and transfers of these provisions.

b. Benefits

These interim final regulations could generate significant economic and social welfare benefits to consumers. This would take the form of reductions in mortality and morbidity, a reduction in medical expenditure risk, an increase in worker productivity, and a decrease the cross-subsidy in premiums to offset uncompensated care, sometimes referred to as the "hidden tax." Each of these effects is described below. It should be noted that the benefits described are substantially greater in each of these areas once all the protections of the full Affordable Care Act are effective.

A first type of benefit is reductions in mortality and morbidity. While the empirical literature leaves many questions unresolved, a growing body of evidence convincingly demonstrates that health can be improved by spending more on at-risk individuals and by expanding health insurance coverage. For example, Almond *et al.*[105] find that newborns classified just below a medical threshold for "very low birthweight" have lower mortality rates than newborns classified as just above the threshold, despite an association between low birth weight and higher mortality in general, because they tend to receive additional medical care. In a study of severe automobile accidents, Doyle[106] found that uninsured individuals receive less care and have a substantially higher mortality rate. Currie and Gruber[107] found that increased eligibility for Medicaid coverage expanded utilization of care for otherwise uninsured children, leading to a sizeable and significant reduction in child mortality. A study of Medicare by Card et al.[108] found that individuals just old enough to qualify for coverage have lower mortality rates—despite similar illness severity—than do those just too young for eligibility. Finally, a report by the Institute of Medicine (IOM)[109] found mortality risks for uninsured individuals that were 25 percent higher than those of observably similar insured individuals. In addition to the prospect that expanded insurance coverage will result in reductions in mortality, it will almost certainly substantially reduce morbidity, as demonstrated in extensive reviews of the literature by Hadley and the IOM.[110]

These interim final regulations will expand access to currently uninsured individuals. These newly insured populations will likely achieve both mortality and meaningful morbidity reductions from the regulations, especially those populations who face rescissions, restricted annual or lifetime limits, or preexisting conditions exclusions, since they are on average in worse health and thus likely to benefit even more from insurance coverage than uninsured individuals in general.

[104] NAIC Rescission Data Call, December 17, 2009, p.1.

[105] Almond, Douglas, Joseph J. Doyle, Jr., Amanda E. Kowalski, and Heidi Williams. "Estimating Marginal Returns to Medical Care: Evidence from At-Risk Newborns." The Quarterly Journal of Economics, May 2010, 125(2): 591–634. *http://www.mit.edu/~jjdoyle/vlbw.pdf.*

[106] Doyle, Joseph J. "Health Insurance, Treatment and Outcomes: Using Auto Accidents as Health Shocks." The Review of Economics and Statistics, May 2005. 87(2):256–270. *http://www.mitpressjournals.org/doi/abs/10.1162/0034653053970348.*

[107] Currie, Janet and J. Gruber. "Health Insurance Eligibility, Utilization of Medical Care, and Child Health." The Quarterly Journal of Economics, May 1996. 111(2):431–466. *http://www.jstor.org/stable/2946684?cookieSet=1.*

[108] Card, David, C. Dobkin, and N. Maestas. "Does Medicare Save Lives?" The Quarterly Journal of Economics, May 2009. 124(2):597–636. *http://www.mitpressjournals.org/doi/abs/10.1162/qjec.2009.124.2.597.*

[109] Institute of Medicine. Care Without Coverage: Too Little, Too Late. Washington, DC: National Academy Press, 2002. *http://books.nap.edu/openbook.php?record_id=10367&page=R1.*

[110] Institute of Medicine, op. cit. Hadley J. Sicker and Poorer: The consequences of being uninsured. Medical Care Research and Review, Vol. 60, No. 2 suppl, 3S–75S (2003).

Because considerable uncertainty surrounds any specific estimate of the effect of expanded coverage on mortality and morbidity, this benefit is not quantified in this analysis.[111] However, the Departments conclude that reductions in mortality and morbidity are likely to be a significant benefit of these interim final regulations and will become substantially greater in 2014 and subsequent years, when millions of additional individuals will obtain health insurance coverage.

A second type of benefit from the cumulative effects of these interim final regulations is a reduction in medical risk. A central goal of health insurance is to protect individuals against catastrophic financial hardship that would come with a debilitating medical condition. By pooling expenses across healthy and sick individuals, insurance can substantially improve the economic well-being of the sick while imposing modest costs on the healthy. This insurance is valuable, and economic theory suggests that the gains to the sick from a properly implemented insurance system far exceed the costs to healthy individuals. A recent paper shows that the benefits from this reduction in exposure to financial risks would be sufficient to cover almost two-fifths of insurance costs.[112] Previous research also suggests that protecting patients who have very high medical costs or low financial assets is likely to have even larger benefits. Indeed, research indicates that approximately half of the more than 500,000 personal bankruptcies in the U.S. in 2007 were to some extent contributed to by very high medical expenses.[113] Exclusions from health insurance coverage based on preexisting conditions expose the uninsured to the aforementioned financial risks. Rescissions of coverage and binding annual or lifetime limits on benefits increase the chance that medical expenditures will go uncompensated, exposing individuals to the financial risks associated with illness. Regulations that prevent these practices thus reduce the uncertainty and hardship associated with these financial risks. Moreover, because they secure coverage for individuals with high probabilities of incurring extensive medical expenses, regulations that guard against rescissions and prevent insurance exclusion based on preexisting conditions for children are likely to have especially large economic benefits in terms of reducing financial risk. These interim final regulations will help insurance more effectively protect patients from the financial hardship of illness, including bankruptcy and reduced funds for non-medical purposes.

A third type of benefit from these interim final regulations is improved workplace productivity. These interim final regulations will benefit employers and workers by increasing workplace productivity and reducing absenteeism, low productivity at work due to preventable illness, and "job-lock." A June 2009 report by the Council of Economic Advisers found that increased access to health insurance coverage improves labor market outcomes by improving worker health.[114] The health benefits of eliminating coverage rescissions and lifetime coverage limits, restricting annual limits, and expanding access to primary care providers and OB/GYNs will help to reduce disability, low productivity at work due to preventable illness, and absenteeism in the work place, thereby increasing workplace productivity and labor supply. Economic theory suggests that these benefits would likely be shared by workers, employers, and consumers. In addition, these interim final regulations will increase labor market efficiency by reducing "job lock," or the reluctance to switch jobs or engage in entrepreneurship because such activities would result in the loss of health insurance or limitations on coverage. For example, without the regulations, a parent with generous coverage for a child with a medical condition might fear moving to a different employer or launching his or her own business given the concern that the new plan could exclude coverage for the child on the basis of the preexisting condition. These reforms will increase not only productivity and innovation through entrepreneurship, but also worker wages since job lock prevents workers from pursuing jobs with potentially higher salaries.[115] The Council of Economic Advisers' June 2009 report estimates that for workers between the ages of 25 and 54, the short-term gain from eliminating job lock would be an increase in wages of 0.3 percent.

Fourth, the Affordable Care Act's provisions will reduce the transfers in the health care system due to cost shifting of uncompensated care that lead to higher premiums for private insurance. The insurance market regulations will help expand the number of individuals who are insured and reduce the likelihood that individuals who have insurance do not bankrupt themselves by paying medical bills. Both effects will help reduce the amount of uncompensated care that imposes a "hidden tax" on consumers of health care since the costs of this care are shifted to those who are able to pay for services in the form of higher prices.

The Departments provide here an order of magnitude for the compensatory reduction in cost-shifting of uncompensated care that is associated with the expansion of coverage of these interim final regulations. Three assumptions were made. First, the uninsured populations affected by these interim final regulations tend to have worse health, greater needs for health care, higher health care spending, and less ability to reduce utilization when they are uninsured. These interim final regulations are therefore unlikely to induce as much demand for health care as would be assumed for the uninsured population in general when coverage expands. As such, the Departments assume that extending insurance coverage to this group is unlikely to significantly increase the overall costs of the U.S. health care system. The Departments therefore assume that the vast majority of the premium increases estimated in this regulatory impact analysis result from transfers from out-of-pocket or uncompensated care costs to covered costs, although we emphasize that there is considerable uncertainty surrounding this estimate.

Second, on the basis of the economics literature on the subject,[116] the Departments estimate that two-thirds of the previously uncovered costs would have been uncompensated care (with the remaining one-third paid for out-of-pocket), of which 75 percent would have been paid for by public sources, and 25 percent would have been paid for by private sources. If reductions in privately-financed uncompensated care are passed on in the form of lower prices charged by hospitals, and result in lower insurance premiums charged to consumers, then the Departments estimate that increased insurance

[111] Kronick, Richard. "Health insurance coverage and mortality revisited." Health Services Research. April 2009. 44(4):1211–1231. *http://www3.interscience.wiley.com/journal/122342601/abstract?CRETRY=1&SRETRY=0.*

[112] Amy Finkelstein and Robin McKnight. What Did Medicare Do? The Initial Impact of Medicare on Mortality and Out of Pocket Medical Spending. 2008. *Journal of Public Economics* 92: 1644–1669.

[113] David Himmelstein *et al,* 2009.

[114] Council of Economic Advisers. "The Economic Case for Health Reform." (2009).

[115] Gruber, J. and B. Madrian. "Health Insurance, Labor Supply, and Job Mobility: A Critical Review of the Literature." (2001).

[116] Hadley, Jack, J. Holahan, T. Coughlin, and D. Miller. "Covering the Uninsured in 2008: Current Costs, Sources of Payment, and Incremental Costs." Health Affairs. 2008. 27(5): w399–w415.

coverage for the vulnerable populations affected by these interim final regulations could result in reductions in insurance premiums of up to $1 billion in 2013.[117] There would also be corresponding decreases in public expenditure as uncompensated care is reduced.

c. Costs and Transfers

Premiums reflect both effects on health system costs as well as transfers in the payment of costs from one payer or group of individuals to another. For example, as consumer protections expand coverage and/or reduce cost-sharing, the costs for services that people previously paid for out of pocket—often creating substantial burdens as described above—will be distributed over a wider insured population. On the other hand, the cost-shifting that previously occurred onto the insured population when people could no longer pay for their out-of-pocket care will be reduced. Expansion of coverage will also generate induced demand for services, with corresponding benefits to health and productivity. These costs and transfers together will generate a change in premiums. As discussed previously, the populations affected by these interim final regulations tend to be in poorer health than the general uninsured population, leading to less induced demand when coverage expands.

The Departments estimate that the premium effect of prohibiting preexisting condition exclusions for children would be on average one percent or less in the individual market and negligible in the group market. The provisions relating to annual and lifetime limits would have approximately one-half of one percent impact on premiums in the group market and less than a one percent impact on premiums in the individual market. While the prohibition on lifetime limits applies to individual plans that are grandfathered, the restricted annual limit policy and preexisting condition exclusion policy for children do not, limiting the premium effect for the grandfathered market. Although precise estimates of the effects of restricting rescissions and expanding patient protections are even more difficult to make than for preexisting condition exclusions or annual and lifetime limits, the Departments' analysis suggest that the effects of restricting rescissions will be no more than a few tenths of one percent of premium, and that patient protections will increase premiums by less than one tenth of one percent.

The Departments emphasize that these individual premium effects cannot be simply added to get a combined impact on premiums for several reasons. The first relates to their simultaneous implementation. Quantifying the precise and unique premium impact of policies that take effect at the same time is difficult. Health insurers will consider the totality of the provisions in making decisions about coverage modifications, so that disentangling the effects of each provision is impossible. This is especially so given the complex interactions among the policies. For example, prohibiting rescissions and lifetime limits could mean that someone who would have had a policy rescinded now maintains coverage, and also maintains coverage beyond a previous lifetime limit. Under the current guaranteed renewability protections in the individual market, if a child with a preexisting condition is now able to obtain coverage on a parental plan, he or she can potentially stay on that plan until age 26.

This difficulty is compounded by the flexibility afforded in the grandfather rule. Plans and issuers will consider the cumulative impact of these provisions when making decisions about whether or not to make other changes to their coverage that could affect their grandfather status. It can be expected that the plans that are most affected by these provisions in terms of potential premium impact will likely be the most aggressive in taking steps to maintain grandfather status, although, as described in that regulatory impact analysis, other factors affect plans' decisions as well. It is unlikely that plans will make this calculation multiple times for the multiple provisions that will take effect at the same time.

Lastly, estimating these effects cumulatively compounds the errors of highly uncertain estimates. As discussed, plan and enrollee behaviors may change in response to the incentives created by these interim final regulations. Data are also limited in many areas, including: The prevalence of annual limits in insurance markets; characteristics of high-cost enrollees; prevalence and characteristics of rescissions; and take-up rates under different insurance scenarios. As discussed above, the estimates presented here, by necessity, utilize "average" experiences and "average" plans. Variability around the average increases substantially when multiple provisions are considered, since the number of provisions that affect each plan will differ (for example, a plan may already offer coverage without preexisting condition exclusions and bar rescissions, meaning they will not be affected by those provisions, but may have a lifetime limit of $1 million, meaning they will be affected by that provision). Different plans also have different characteristics of enrollees, for example in terms of age or health status, meaning that provisions such as eliminating lifetime limits could affect them differently. It is especially important to note the variation in insurance market reforms across States. Only a few States have community rating, where costs get distributed across the entire insured pool. Fractions of the cost will get distributed across the pool and to individual enrollees in other States depending on the degree of rating restrictions, if any exist. Uncertainty compounds as ranges and errors and assumptions are summed across provisions.

D. Regulatory Flexibility Act—Department of Labor and Department of Health and Human Services

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) imposes certain requirements with respect to Federal rules that are subject to the notice and comment requirements of section 553(b) of the APA (5 U.S.C. 551 *et seq.*) and that are likely to have a significant economic impact on a substantial number of small entities. Section 9833 of the Code, section 734 of ERISA, and section 2792 of the PHS Act authorize the Secretaries to promulgate any interim final rules that they determine are appropriate to carry out the provisions of chapter 100 of the Code, part 7 of subtitle B or title I of ERISA, and part A of title XXVII of the PHS Act, which include PHS Act sections 2701 through 2728 and the incorporation of those sections into ERISA section 715 and Code section 9815.

Moreover, under Section 553(b) of the APA, a general notice of proposed rulemaking is not required when an

[117] The Departments come to this estimate using the following methods. First, they estimated the proportion of the population in group and individual markets using the Medical Expenditure Panel Survey (2008). Next, information from 75 FR 34538 (June 17, 2010) was used to estimate the proportion of employer and individual plans that maintain or lose grandfather status by 2013. Projections of national health expenditures from the National Health Expenditure Accounts to 2013 were distributed among these groups, and premium impacts as discussed in this regulatory impact analysis were applied. Potential premium reductions secondary to reductions in the cost-shifting of uncompensated care were then calculated using the information from the economic literature as presented in this discussion. The Departments note that to the extent that not all of the reductions in uncompensated care costs are passed onto insured populations, these estimates may be an overestimate.

agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. These interim final regulations are exempt from APA, because the Departments made a good cause finding that a general notice of proposed rulemaking is not necessary earlier in this preamble. Therefore, the RFA does not apply and the Departments are not required to either certify that the rule would not have a significant economic impact on a substantial number of small entities or conduct a regulatory flexibility analysis.

Nevertheless, the Departments carefully considered the likely impact of the rule on small entities in connection with their assessment under Executive Order 12866. Consistent with the policy of the RFA, the Departments encourage the public to submit comments that suggest alternative rules that accomplish the stated purpose of the Affordable Care Act and minimize the impact on small entities.

E. Special Analyses—Department of the Treasury

Notwithstanding the determinations of the Department of Labor and Department of Health and Human Services, for purposes of the Department of the Treasury, it has been determined that this Treasury decision is not a significant regulatory action for purposes of Executive Order 12866. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the APA (5 U.S.C. chapter 5) does not apply to these interim final regulations. For the applicability of the RFA, refer to the Special Analyses section in the preamble to the cross-referencing notice of proposed rulemaking published elsewhere in this issue of the **Federal Register**. Pursuant to section 7805(f) of the Code, these temporary regulations have been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small businesses.

F. Paperwork Reduction Act

1. Department of Labor and Department of the Treasury

As further discussed below, these interim final regulations contain enrollment opportunity, rescission notice, and patient protection disclosure requirements that are information collection requests (ICRs) subject to the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)). Each of these requirements is discussed in detail below.

Currently, the Departments are soliciting 60 days of public comments concerning these disclosures. The Departments have submitted a copy of these interim final regulations to OMB in accordance with 44 U.S.C. 3507(d) for review of the information collections. The Departments and OMB are particularly interested in comments that:

- Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, for example, by permitting electronic submission of responses.

Comments should be sent to the Office of Information and Regulatory Affairs, Attention: Desk Officer for the Employee Benefits Security Administration either by fax to (202) 395–7285 or by e-mail to *oira_submission@omb.eop.gov*. A copy of the ICR may be obtained by contacting the PRA addressee: G. Christopher Cosby, Office of Policy and Research, U.S. Department of Labor, Employee Benefits Security Administration, 200 Constitution Avenue, NW., Room N–5718, Washington, DC 20210. Telephone: (202) 693–8410; Fax: (202) 219–4745. These are not toll-free numbers. E-mail: *ebsa.opr@dol.gov*. ICRs submitted to OMB also are available at reginfo.gov (*http://www.reginfo.gov/public/do/PRAMain*).

a. ICR Regarding Affordable Care Act Enrollment Opportunity Notice Relating to Lifetime Limits

As discussed earlier in this preamble these interim final regulations require a plan or issuer to provide an individual whose coverage ended due to reaching a lifetime limit on the dollar value of all benefits with an opportunity to enroll (including notice of an opportunity to enroll) that continues for at least 30 days, regardless of whether the plan or coverage offers an open enrollment period and regardless of when any open enrollment period might otherwise occur. This enrollment opportunity must be presented not later than the first day of the first plan year (or, in the individual market, policy year) beginning on or after September 23, 2010 (which is the applicability date of PHS Act section 2711). Coverage must begin not later than the first day of the first plan year (in the individual market, policy year) beginning on or after September 23, 2010.[118] The Affordable Care Act dependent coverage enrollment notice is an ICR subject to the PRA.

The Departments estimate that approximately 29,000 individuals qualify for this enrollment right, which as discussed more fully below, should be considered an upward bound. The estimate is based on the following methodology. The Departments estimate that of the approximately 139.6 million individuals in ERISA-covered plans,[119] 63 percent of such individuals are covered by plans with lifetime limits.[120]

While limited data are available regarding lifetime limits, the Departments estimated that the average lifetime limit across all markets is about $4.7 million,[121] which means that an individual would exceed a lifetime limit by incurring at least $4.7 million in medical expenses during one year or across many years. Although the Departments are unable to track spending across time to estimate the number of individuals that would reach the lifetime limit, the Departments estimate that about 0.033 percent of individuals incur more than $1 million in medical spending in a year.[122] If

[118] The interim final regulations require any individual enrolling in group health plan coverage pursuant to this enrollment right must be treated as a special enrollee, as provided under HIPAA portability rules. Accordingly, the individual must be offered all the benefit packages available to similarly situated individuals who did not lose coverage due to reaching a lifetime limit or cessation of dependent status. The individual also cannot be required to pay more for coverage than similarly situated individuals who did not lose coverage due to reaching a lifetime limit.

[119] The Departments' estimate is based on the 2009 March Current Population Survey (CPS).

[120] The Departments' estimate for large and small employer health plans is derived from The Kaiser Family Foundation and Health Research & Educational Trust, *Employer Health Benefits: 2009 Annual Survey* (Sept. 2009), *at http://ehbs.kff.org/pdf/2009/7936.pdf*, Exhibit 13.12.

[121] The Departments' estimate is based on America's Health Insurance Plans, *Individual Health Insurance 2009: A Comprehensive Survey of Premiums, Availability and Benefits*, (Oct. 2009) *at http://www.ahipresearch.org/pdfs/2009IndividualMarketSurveyFinalReport.pdf*, Table 17; and America's Health Insurance Plans, *Individual Health Insurance 2008: Small Group Health Insurance*, Table 22.

[122] The Departments' estimate is based on adjusted insurer claims and MEPS–HC expenditures.

these individuals incurred this amount every year, 29,000 individuals would incur expenses of at least the $4.7 million limit by the fifth year.

There are several reasons to suspect that these assumptions lead to an over-estimate. First, individuals would have to average $1 million in medical expenses per year to exceed the $4.7 million limit. Second, an individual's lifetime limit is reset if he switches employers or, for employees who work for employers with multiple health insurance coverage options, switches to a different health insurance plan.

The interim final regulations require plans or insurers to notify individuals whose coverage ended due to reaching a lifetime limit on the dollar value of all benefits that they are now eligible to reenroll in the plan or policy. The Departments assume that the notice for all plans and policies (including self-insured plans that are administered by insurers) will be prepared by the estimated 630 health insurers operating in the United States.[123] On average, the Departments expect that one-half hour of a legal professional's time, valued as $119, will be required to draft this notice, resulting in an hour burden of approximately 160 hours with an equivalent cost of $19,000.

The Departments assume that insurers track information regarding individuals that have lost coverage due to reaching a lifetime limit (including contact information in their administrative records). Based on the foregoing, the Departments estimate that, on average, five minutes of a clerical staff member's time, valued at $26 per hour will be required to incorporate the specific information into the notice and mail the estimated 29,000 notices. This results in an estimated hour burden of approximately 2,400 hours with an equivalent cost of $63,000. Therefore, the total hour burden of this notice requirement is approximately 2,600 hours with an equivalent cost of $82,000.

The associated cost burden of the rule results from material and mailing costs that are required to distribute the estimated 29,000 notices. The Departments estimate that the notice will be one-page in length, material and print costs will be five cents per page, and postage will be 44 cents per notice resulting in a per notice cost of 49 cents. This leads to a total cost burden of approximately $14,000 to distribute the notices.

Type of Review: New collection.

Agencies: Employee Benefits Security Administration, Department of Labor; Internal Revenue Service, U.S. Department of the Treasury.

Title: Notice of Special Enrollment Opportunity under the Patient Protection and Affordable Care Act Relating to Lifetime Limits.

OMB Number: 1210–0143; 1545–2179.

Affected Public: Business or other for-profit; not-for-profit institutions.

Total Respondents: 315.

Total Responses: 29,000.

Frequency of Response: One-time.

Estimated Total Annual Burden Hours: 1,300 hours (Employee Benefits Security Administration); 1,300 hours (Internal Revenue Service).

Estimated Total Annual Burden Cost: $7,000 (Employee Benefits Security Administration); $7,000 (Internal Revenue Service).

b. ICR Regarding Affordable Care Act Notice Relating to Rescission

As discussed earlier in this preamble, PHS Act Section 2712 and these interim final regulations provide rules regarding rescissions for group health plans and health insurance issuers that offer group or individual health insurance coverage. A plan or issuer must not rescind coverage under the plan, policy, certificate, or contract of insurance except in the case of fraud or intentional misrepresentation of a material fact. These interim final regulations provide that a group health plan or a health insurance issuer offering group health insurance coverage must provide at least 30 calendar days advance notice to an individual before coverage may be rescinded.

The Departments assume that rescissions are rare in the group market and that small group health plans are affected by rescissions. The Departments are not aware of a data source on the number of group plans whose policy is rescinded; therefore, the Departments assume that 100 group health plan policies are rescinded in a year. The Departments estimate that there is an average of 16 participants in small, insured plans.[124] Based on these numbers the Departments estimate that approximately 100 policies are rescinded during a year, which would result in 1,600 notices being sent to affected participants. The Departments estimate that 15 minutes of legal profession time at $119 per hour would be required by the insurers of the 100 plans to prepare the notice and one minute per notice of clerical professional time at $26 per hour would be required to distribute the notice. This results in an hour burden of approximately 50 hours with an equivalent cost of approximately $3,700. The Departments estimate that the cost burden associated with distributing the notices will be approximately $800.[125]

These paperwork burden estimates are summarized as follows:

Type of Review: New collection.

Agencies: Employee Benefits Security Administration, Department of Labor; Internal Revenue Service, U.S. Department of the Treasury.

Title: Required Notice of Rescission of Coverage under the Patient Protection and Affordable Care Act Disclosures.

OMB Number: 1210–0141; 1545–2180.

Affected Public: Business or other for-profit; not-for-profit institutions.

Total Respondents: 100.

Total Responses: 1,600.

Frequency of Response: Occasionally.

Estimated Total Annual Burden Hours: 25 hours (Employee Benefits Security Administration); 25 hours (Internal Revenue Service).

Estimated Total Annual Burden Cost: $400 (Employee Benefits Security Administration); $400 (Internal Revenue Service).

c. ICR Regarding Affordable Care Act Patient Protection Disclosure Requirement

As discussed earlier in this preamble, PHS Act section 2719A imposes, with respect to a group health plan, or group or individual health insurance coverage, a set of three requirements relating to the choice of health care professionals. When applicable, it is important that individuals enrolled in a plan or health insurance coverage know of their rights to (1) choose a primary care provider or a pediatrician when a plan or issuer requires participants or subscribers to designate a primary care physician; or (2) obtain obstetrical or gynecological care without prior authorization. Accordingly, these interim final regulations require such plans and issuers to provide a notice to

[123] While plans could prepare their own notice, the Departments assume that the notices will be prepared by service providers. The Departments have previously estimated that there are 630 health insurers (460 providing coverage in the group market, and 490 providing coverage in the individual market). These estimates are from NAIC 2007 financial statements data and the California Department of Managed Healthcare (2009), *at http://wpso.dmhc.ca.gov/hpsearch/viewall.aspx.* Because the hour and cost burden is shared between the Departments of Labor/Treasury and the Department of Health and Human Services, the burden to prepare the notices is calculated using half the number of insurers (315).

[124] U.S. Department of Labor, EBSA calculations using the March 2008 Current Population Survey Annual Social and Economic Supplement and the 2008 Medical Expenditure Panel Survey.

[125] This estimate is based on an average document size of one page, $.05 cents per page material and printing costs, and $.44 cent postage costs.

participants (in the individual market, primary subscriber) of these rights when applicable. Model language is provided in these interim final regulations. The notice must be provided whenever the plan or issuer provides a participant with a summary plan description or other similar description of benefits under the plan or health insurance coverage, or in the individual market, provides a primary subscriber with a policy, certificate, or contract of health insurance. The Affordable Care Act patient protection disclosure requirement is an ICR subject to the PRA.

In order to satisfy these interim final regulations' patient protection disclosure requirement, the Departments estimate that 339,000 ERISA-covered plans will need to notify an estimated 8.0 million policy holders of their plans' policy in regards to designating a primary care physician and for obstetrical or gynecological visits.[126] The following estimates are based on the assumption that 22 percent of group health plans will not have grandfathered health plan status in 2011. Because the interim final regulations provide model language for this purpose, the Departments estimate that five minutes of clerical time (with a labor rate of $26.14/hour) will be required to incorporate the required language into the plan document and ten minutes of a human resource professional's time (with a labor rate of $89.12/hour) will be required to review the modified language.[127] Therefore, the Departments estimate that plans will incur a one-time hour burden of 85,000 hours with an equivalent cost of $5.8 million to meet the disclosure requirement in the first year.

The Departments assume that only printing and material costs are associated with the disclosure requirement, because the interim final regulations provide model language that can be incorporated into existing plan documents, such as an SPD. The Departments estimate that the notice will require one-half of a page, five cents per page printing and material cost will be incurred, and 38 percent of the notices will be delivered electronically. This results in a cost burden of $124,000 ($0.05 per page*1/2 pages per notice * 8.0 million notices*0.62).

Plans that relinquish their grandfather status in subsequent years also will become subject to this notice requirement and incur a cost to prepare and distribute the notice in the year they relinquish their grandfather status. The Departments estimate a total hour burden of 62,000 hours in 2012 and 50,000 in 2013 for plans relinquishing their grandfather status in 2012 or 2013. There also will be an estimated total cost burden of $90,000 in 2012 and $73,000 in 2013.

The Departments note that persons are not required to respond to, and generally are not subject to any penalty for failing to comply with, an ICR unless the ICR has a valid OMB control number.

These paperwork burden estimates are summarized as follows:

Type of Review: New Collection.

Agencies: Employee Benefits Security Administration, Department of Labor; Internal Revenue Service, U.S. Department of Treasury.

Title: Disclosure Requirement for Patient Protections under the Affordable Care Act.

OMB Number: 1210–0142; 1545–2181.

Affected Public: Business or other for-profit; not-for-profit institutions.

Total Respondents: 262,000 (three year average).

Total Responses: 6,186,000 (three year average).

Frequency of Response: One time.

Estimated Total Annual Burden Hours: 33,000 (Employee Benefits Security Administration); 33,000 (Internal Revenue Service).

Estimated Total Annual Burden Cost: $48,000 (Employee Benefits Security Administration); $48,000 (Internal Revenue Service).

2. Department of Health and Human Services

As discussed above in the Department of Labor and Department of the Treasury PRA section, these interim final regulations contain an enrollment opportunity notice, rescissions notice, and patient protection disclosures requirement for issuers. These requirements are information collection requirements under the Paperwork Reduction Act. Each of these requirements is discussed in detail below.

a. ICR Regarding Affordable Care Act Enrollment Opportunity Notice Regarding Lifetime Limits

PHS Act section 2711 and these interim final regulations require health insurance issuers offering individual health insurance coverage to provide an individual whose coverage ended due to reaching a lifetime limit on the dollar value of all benefits with an opportunity to enroll (including notice of an opportunity to enroll) that continues for at least 30 days, regardless of whether the plan or coverage offers an open enrollment period and regardless of when any open enrollment period might otherwise occur. This enrollment opportunity must be presented not later than the first day of the first plan year (or, in the individual market, policy year) beginning on or after September 23, 2010 (which is the applicability date of PHS Act section 2711). Coverage must begin not later than the first day of the first plan year (or policy year in the individual market) beginning on or after September 23, 2010.[128]

The Department estimates that approximately 13,182 individuals qualify for this enrollment right, which as discussed more fully below, should be considered an upward bound. The estimate is based on the following methodology. The Department estimates that of the approximately 16.5 million individuals[129] covered by family policies in the individual market, 89 percent of such individuals have a policy with a lifetime limit.[130] The Department also estimates that out of the approximately 40.1 million individuals covered by public, non-Federal employer group health plans sponsored by State and local governments,[131] 63 percent of such

[126] The Departments' estimate of the number of ERISA-covered health plans was obtained from the 2008 Medical Expenditure Panel Survey's Insurance component. The estimate of the number of policy holders was obtained from the 2009 Current Population Survey. Information on HMO and POS plans and enrollment in such plans was obtained from the Kaiser/HRET Survey of Employer Sponsored Health Benefits, 2009. The methodology used to estimate the percentage of plans that will not be grandfathered in 2011 is addressed in the Departments' Interim Final Rules for Group Health Plans and Health Insurance Coverage Relating to Status as a Grandfathered Health Plan under the Patient Protection and Affordable Care Act that were issued on June 17, 2010 (75 FR 34538).

[127] EBSA estimates of labor rates include wages, other benefits, and overhead based on the National Occupational Employment Survey (May 2008, Bureau of Labor Statistics) and the Employment Cost Index June 2009, Bureau of Labor Statistics).

[128] The interim final regulations require any individual enrolling in group health plan coverage pursuant to this enrollment right must be treated as a special enrollee, as provided under HIPAA portability rules. Accordingly, the individual must be offered all the benefit packages available to similarly situated individuals who did not lose coverage due to reaching a lifetime limit or cessation of dependent status. The individual also cannot be required to pay more for coverage than similarly situated individuals who did not lose coverage due to reaching a lifetime limit.

[129] The Department's estimate is based on the 2009 March Current Population Survey (CPS).

[130] The Department's estimate for individual health plans is derived from America's Health Insurance Plans, *Individual Health Insurance 2009: A Comprehensive Survey of Premiums, Availability and Benefits,* (Oct. 2009) *at http://www.ahipresearch.org/pdfs/2009IndividualMarketSurveyFinalReport.pdf,* Table 10 and Table 17.

[131] The Department's estimate is based on the 2009 March Current Population Survey (CPS).

individuals are covered by plans with lifetime limits.[132]

While limited data are available regarding lifetime limits, the Department estimated that the average lifetime limit across all markets is about $4.7 million,[133] which means that an individual would exceed a lifetime limit by incurring at least $4.7 million in medical expenses during one year or across many years. Although the Department is unable to track spending across time to estimate the number of individuals that would reach the lifetime limit, the Department estimates that about 0.033 percent of individuals incur more than $1 million in medical spending in a year.[134] If these individuals incurred this amount every year, 13,000 individuals would incur expenses of at least the $4.7 million limit by the fifth year.

There are several reasons to suspect that these assumptions lead to an over-estimate. First, individuals who incur $1 million of medical expenses in a year would need to sustain this level every year for five years to exceed the $4.7 million limit. Second, an individual's lifetime limit is reset if he switches employers or, for employees who work for employers with multiple health insurance coverage options, switches to a different health insurance plan.

These interim final regulations require plans or insurers to notify individuals whose coverage ended due to reaching a lifetime limit on the dollar value of all benefits that they are now eligible to reenroll in the plan or policy. The Department assumes that the notice for all plans and policies (including self-insured plans that are administered by insurers) will be prepared by the estimated 630 health insurers operating in the United States.[135] On average, the Department expects that one-half hour of a legal professional's time, valued as $119, will be required to draft this notice, resulting in an hour burden of approximately 200 hours with an equivalent cost of $19,000.

The Department assumes that plans and insurers track information regarding individuals that have lost coverage due to reaching a lifetime limit (including contact information) in their administrative records. Based on the foregoing, the Department estimates that, on average, five minutes of a clerical staff member's time, valued at $26.14 per hour will be required to incorporate the specific information into the notice and mail the estimated 13,000 notices. This results in an estimated hour burden of approximately 1,100 hours with an equivalent cost of $29,000. Therefore, the total hour burden of this notice requirement is 1,300 hours with an equivalent cost of $48,000.

The associated cost burden of the rule results from material and mailing cost to distribute the estimated 13,000 notices. The Department estimates that the notice will be one-page in length, material and print costs will be five cents per page, and postage will be 44 cents per notice resulting in a per notice cost of 49 cents. This leads to a total estimated cost burden of approximately $6,500 to distribute the notices.

Type of Review: New collection.

Agency: Department of Health and Human Services.

Title: Patient Protection and Affordable Care Act Enrollment Opportunity Notice Relating to Lifetime Limits.

OMB Number: 0938–1094.

Affected Public: Business; State, Local, or Tribal Governments.

Respondents: 630.

Responses: 13,000.

Frequency of Response: One-time.

Estimated Total Annual Burden Hours: 1,300 hours.

Estimated Total Annual Burden Cost: $6,500.

b. ICR Regarding Affordable Care Act Notice Relating to Rescission

As discussed earlier in this preamble, PHS Act Section 2712 and these interim final regulations prohibit group health plans and health insurance issuers that offer group or individual health insurance coverage generally from rescinding coverage under the plan, policy, certificate, or contract of insurance from the individual covered under the plan or coverage unless the individual (or a person seeking coverage on behalf of the individual) performs an act, practice, or omission that constitutes fraud, or unless the individual makes an intentional misrepresentation of material fact, as prohibited by the terms of the plan or coverage. These interim final regulations provide that a group health plan or a health insurance issuer offering group health insurance coverage must provide at least 30 days advance notice to an individual before coverage may be rescinded.

This analysis assumes that rescissions only occur in the individual health insurance market, because rescissions in the group market are rare. The Department estimates that there are approximately 7.1 million individual policy holders in the individual market during a year. A report on rescissions finds that 0.15 percent of policies were rescinded during the 2004 to 2008 time period.[136] Based on these numbers, the Department estimates that approximately 10,700 policies are rescinded during a year, which would result in 10,700 notices being sent to affected policyholders. The Department estimates that 15 minutes of legal profession time at $119 per hour would be required by the estimated 490 insurers in the individual market to prepare the notice and one minute per notice of clerical professional time at $26 per hour would be required to distribute the notice. This results in an hour burden of approximately 300 hours with an equivalent cost of approximately $19,200. The Department estimates that the cost burden associated with distributing the notices will be approximately $5,200.[137]

These paperwork burden estimates are summarized as follows:

Type of Review: New collection.

Agency: Department of Health and Human Services.

Title: Required Notice of Rescission of Coverage under the Patient Protection and Affordable Care Act Disclosures.

OMB Number: 0938–1094.

Affected Public: For Profit Business.

Respondents: 490.

Responses: 10,700.

Frequency of Response: Occasionally.

[132] The Departments' estimate for large and small employer health plans is derived from The Kaiser Family Foundation and Health Research & Educational Trust, *Employer Health Benefits: 2009 Annual Survey* (Sept. 2009), at *http://ehbs.kff.org/pdf/2009/7936.pdf*, Exhibit 13.12.

[133] The Department's estimate is based on America's Health Insurance Plans, *Individual Health Insurance 2009: A Comprehensive Survey of Premiums, Availability and Benefits*, (Oct. 2009) *at http://www.ahipresearch.org/pdfs/2009IndividualMarketSurveyFinalReport.pdf*, Table 17; and America's Health Insurance Plans, *Individual Health Insurance 2008: Small Group Health Insurance*, Table 22.

[134] The Departments' estimate is based on adjusted insurer claims and MEPS–HC expenditures.

[135] While plans could prepare their own notice, the Departments assume that the notices will be prepared by service providers. The Departments have previously estimated that there are 630 health insurers (460 providing coverage in the group market, and 490 providing coverage in the individual market). These estimates are from NAIC 2007 financial statements data and the California Department of Managed Healthcare (2009), *at http://wpso.dmhc.ca.gov/hpsearch/viewall.aspx*. Because the hour and cost burden is shared among the Departments of Labor/Treasury and the Department of Health and Human Services, the burden to prepare the notices is calculated using half the number of insurers (315).

[136] NAIC Report "Rescission Data Call of the NAIC Regulatory Framework (B) Task Force" December 17, 2009. *http://www.naic.org/documents/committees_b_regulatory_framework_rescission_data_call_report.pdf.*

[137] This estimate is based on an average document size of one page, $.05 cents per page material and printing costs, and $.44 cent postage costs.

Estimated Total Annual Burden Hours: 300 hours.

Estimated Total Annual Burden Cost: $5,200.

c. ICR Relating to Affordable Care Act Patient Protections Disclosure Requirement

As discussed above in the Department of Labor and Department of Treasury PRA section, these interim final regulations contains a disclosure requirement for non-grandfathered health plans or policies requiring the designation of a primary care physician or usually requiring a referral from a primary care physician before receiving care from a specialist. These requirements are information collection requirements under the PRA.

In order to satisfy the interim final regulations' patient protection disclosure requirement, the Department estimates that 14,000 State and local governmental plans will need to notify approximately 2.6 million policy holders of their plans' policy in regards to designating a primary care physician and for obstetrical or gynecological visits. An estimated 490 insurers providing coverage in the individual market will need to notify an estimated 55,000 policy holders of their policy in regards to designating a primary care physician and for obstetrical or gynecological visits. These estimates are based on the assumption that 22 percent of group plans and 40 percent of individual policies will not have grandfathered health plan status in 2011.[138]

Because the interim final regulations provide model language for this purpose, the Department estimates that five minutes of clerical time (with a labor rate of $26.14/hour) will be required to incorporate the required language into the plan document and ten minutes of a human resource professional's time (with a labor rate of $89.12/hour) will be required to review the modified language.[139] Therefore, the Department estimates that plans and insurers will incur a one-time hour burden of 3,500 hours with an equivalent cost of $239,000 to meet the disclosure requirement.

The Department assumes that only printing and material costs are associated with the disclosure requirement, because the interim final regulations provide model language that can be incorporated into existing plan documents, such as an SPD. The Department estimates that the notice will require one-half of a page, five cents per page printing and material cost will be incurred, and 38 percent of the notices will be delivered electronically. This results in a cost burden of $42,000 ($0.05 per page * 1/2 pages per notice * 1.7 million notices * 0.62).

Plans that relinquish their grandfather status in subsequent years will also become subject to this notice requirement and incur a cost to prepare and distribute the notice in the year they relinquish their grandfather status. Policy holders of non-grandfathered policies in the individual market will also have to receive this notice. The Department estimates a total hour burden of 2,500 hours in 2012 and 2,000 in 2013 for plans relinquishing their grandfather status in such years. There will, also be an estimated total cost burden of $30,000 in 2012 and $24,000 in 2013.

The Department notes that persons are not required to respond to, and generally are not subject to any penalty for failing to comply with, an ICR unless the ICR has a valid OMB control number.

These paperwork burden estimates are summarized as follows:

Type of Review: New collection.

Agency: Department of Health and Human Services.

Title: Disclosure Requirements for Patient Protection under the Affordable Care Act.

OMB Number: 0938–1094.

Affected Public: Business; State, Local, or Tribal Governments.

Respondents: 10,600.

Responses: 2,067,000.

Frequency of Response: One-time.

Estimated Total Annual Burden Hours: 2,700 hours.

Estimated Total Annual Burden Cost: $32,000.

If you comment on any of these information collection requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, OCIIO–9994–IFC; Fax: (202) 395–6974; or E-mail: *OIRA_submission@omb.eop.gov.*

G. Congressional Review Act

These interim final regulations are subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and have been transmitted to Congress and the Comptroller General for review.

H. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) requires agencies to prepare several analytic statements before proposing any rules that may result in annual expenditures of $100 million (as adjusted for inflation) by State, local and tribal governments or the private sector. These interim final regulations are not subject to the Unfunded Mandates Reform Act because they are being issued as interim final regulations. However, consistent with the policy embodied in the Unfunded Mandates Reform Act, the regulation has been designed to be the least burdensome alternative for State, local and tribal governments, and the private sector, while achieving the objectives of the Affordable Care Act.

I. Federalism Statement—Department of Labor and Department of Health and Human Services

Executive Order 13132 outlines fundamental principles of federalism, and requires the adherence to specific criteria by Federal agencies in the process of their formulation and implementation of policies that have "substantial direct effects" on the States, the relationship between the national government and States, or on the distribution of power and responsibilities among the various levels of government. Federal agencies promulgating regulations that have these federalism implications must consult with State and local officials, and describe the extent of their consultation and the nature of the concerns of State and local officials in the preamble to the regulation.

In the Departments' view, these interim final regulations have federalism implications, because they have direct effects on the States, the relationship between the national government and States, or on the distribution of power and

[138] The Department's estimate of the number of State and local governmental health plans was obtained from the 2007 Census of Governments. The estimate of the number of policy holders in the individual market were obtained from the 2009 Current Population Survey. Information on HMO and POS plans and enrollment in such plans was obtained from the Kaiser/HRET Survey of Employer Sponsored Health Benefits, 2009. The methodology used to estimate the percentage of plans that will not be grandfathered in 2011 was discussed in Departments' Interim Final Rules for Group Health Plans and Health Insurance Coverage Relating to Status as a Grandfathered Health Plan under the Patient Protection and Affordable Care Act that were issued on June 15, 2010: 75 FR 34538 (June 17, 2010).

[139] EBSA estimates of labor rates include wages, other benefits, and overhead based on the National Occupational Employment Survey (May 2008, Bureau of Labor Statistics) and the Employment Cost Index June 2009, Bureau of Labor Statistics).

responsibilities among various levels of government. However, in the Departments' view, the federalism implications of these interim final regulations are substantially mitigated because, with respect to health insurance issuers, the Departments expect that the majority of States will enact laws or take other appropriate action resulting in their meeting or exceeding the Federal standards.

In general, through section 514, ERISA supersedes State laws to the extent that they relate to any covered employee benefit plan, and preserves State laws that regulate insurance, banking, or securities. While ERISA prohibits States from regulating a plan as an insurance or investment company or bank, the preemption provisions of section 731 of ERISA and section 2724 of the PHS Act (implemented in 29 CFR 2590.731(a) and 45 CFR 146.143(a)) apply so that the HIPAA requirements (including those of the Affordable Care Act) are not to be "construed to supersede any provision of State law which establishes, implements, or continues in effect any standard or requirement solely relating to health insurance issuers in connection with group health insurance coverage except to the extent that such standard or requirement prevents the application of a requirement" of a Federal standard. The conference report accompanying HIPAA indicates that this is intended to be the "narrowest" preemption of State laws. (*See* House Conf. Rep. No. 104–736, at 205, reprinted in 1996 U.S. Code Cong. & Admin. News 2018.) States may continue to apply State law requirements except to the extent that such requirements prevent the application of the Affordable Care Act requirements that are the subject of this rulemaking. State insurance laws that are more stringent than the Federal requirements are unlikely to "prevent the application of" the Affordable Care Act, and be preempted. Accordingly, States have significant latitude to impose requirements on health insurance issuers that are more restrictive than the Federal law.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have federalism implications or limit the policy making discretion of the States, the Departments have engaged in efforts to consult with and work cooperatively with affected State and local officials, including attending conferences of the National Association of Insurance Commissioners and consulting with State insurance officials on an individual basis. It is expected that the Departments will act in a similar fashion in enforcing the Affordable Care Act requirements. Throughout the process of developing these interim final regulations, to the extent feasible within the specific preemption provisions of HIPAA as it applies to the Affordable Care Act, the Departments have attempted to balance the States' interests in regulating health insurance issuers, and Congress' intent to provide uniform minimum protections to consumers in every State. By doing so, it is the Departments' view that they have complied with the requirements of Executive Order 13132.

Pursuant to the requirements set forth in section 8(a) of Executive Order 13132, and by the signatures affixed to these interim final regulations, the Departments certify that the Employee Benefits Security Administration and the Centers for Medicare & Medicaid Services have complied with the requirements of Executive Order 13132 for the attached regulations in a meaningful and timely manner.

V. Statutory Authority

The Department of the Treasury temporary regulations are adopted pursuant to the authority contained in sections 7805 and 9833 of the Code.

The Department of Labor interim final regulations are adopted pursuant to the authority contained in 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Public Law 104–191, 110 Stat. 1936; sec. 401(b), Public Law 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Public Law 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Public Law 111–148, 124 Stat. 119, as amended by Public Law 111–152, 124 Stat. 1029; Secretary of Labor's Order 6–2009, 74 FR 21524 (May 7, 2009).

The Department of Health and Human Services interim final regulations are adopted pursuant to the authority contained in sections 2701 through 2763, 2791, and 2792 of the PHS Act (42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended.

List of Subjects

26 CFR Part 54

Excise taxes, Health care, Health insurance, Pensions, Reporting and recordkeeping requirements.

26 CFR Part 602

Reporting and recordkeeping requirements.

29 CFR Part 2590

Continuation coverage, Disclosure, Employee benefit plans, Group health plans, Health care, Health insurance, Medical child support, Reporting and recordkeeping requirements.

45 CFR Parts 144, 146, and 147

Health care, Health insurance, Reporting and recordkeeping requirements, and State regulation of health insurance.

Steven T. Miller,

Deputy Commissioner for Services and Enforcement, Internal Revenue Service.

Approved: June 18, 2010.

Michael F. Mundaca,

Assistant Secretary of the Treasury (Tax Policy).

Signed this 18th day of June 2010.

Phyllis C. Borzi,

Assistant Secretary, Employee Benefits Security Administration, Department of Labor.

Dated: June 18, 2010.

Jay Angoff,

Director, Office of Consumer Information and Insurance Oversight.

Dated: June 18, 2010.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

Department of the Treasury

Internal Revenue Service

26 CFR Chapter 1

■ Accordingly, 26 CFR parts 54 and 602 are amended as follows:

PART 54—PENSION EXCISE TAXES

■ **Paragraph 1.** The authority citation for part 54 is amended by adding entries for §§ 54.9815–2704T, 54.9815–2711T, 54.9815–2712T, and 54.9815–2719AT in numerical order to read in part as follows:

Authority: 26 U.S.C. 7805. * * *

Section 54.9815–2704T also issued under 26 U.S.C. 9833.

Section 54.9815–2711T also issued under 26 U.S.C. 9833.

Section 54.9815–2712T also issued under 26 U.S.C. 9833. * * *

Section 54.9815–2719AT also issued under 26 U.S.C. 9833. * * *

■ **Par. 2.** Section 54.9801–2 is amended by revising the definitions of *group health plan* and *preexisting condition exclusion to* read as follows:

§ 54.9801–2 Definitions.

* * * * *

Group health plan or *plan* means a *group health plan* within the meaning of § 54.9831–1(a).

* * * * *

Preexisting condition exclusion means a limitation or exclusion of benefits (including a denial of coverage) based on the fact that the condition was

present before the effective date of coverage (or if coverage is denied, the date of the denial) under a group health plan or group or individual health insurance coverage (or other coverage provided to federally eligible individuals pursuant to 45 CFR part 148), whether or not any medical advice, diagnosis, care, or treatment was recommended or received before that day. A preexisting condition exclusion includes any limitation or exclusion of benefits (including a denial of coverage) applicable to an individual as a result of information relating to an individual's health status before the individual's effective date of coverage (or if coverage is denied, the date of the denial) under a group health plan, or group or individual health insurance coverage (or other coverage provided to Federally eligible individuals pursuant to 45 CFR part 148), such as a condition identified as a result of a pre-enrollment questionnaire or physical examination given to the individual, or review of medical records relating to the pre-enrollment period.

■ **Par. 3.** Section 54.9801–3 is amended by revising paragraph (a)(1)(i) to read as follows:

§ 54.9801–3 Limitations on preexisting condition exclusion period.

(a) * * *

(1) * * *

(i) A *preexisting condition exclusion* means a *preexisting condition exclusion* within the meaning set forth in § 54.9801–2.

* * * * *

■ **Par. 4.** Section 54.9815–2704T is added to read as follows:

§ 54.9815–2704T Prohibition of preexisting condition exclusions (temporary).

(a) *No preexisting condition exclusions*—(1) *In general.* A group health plan, or a health insurance issuer offering group health insurance coverage, may not impose any preexisting condition exclusion (as defined in § 54.9801–2).

(2) *Examples.* The rules of this paragraph (a) are illustrated by the following examples (for additional examples illustrating the definition of a preexisting condition exclusion, see § 54.9801–3(a)(1)(ii)):

Example 1. (i) *Facts.* A group health plan provides benefits solely through an insurance policy offered by Issuer P. At the expiration of the policy, the plan switches coverage to a policy offered by Issuer N. N's policy excludes benefits for oral surgery required as a result of a traumatic injury if the injury occurred before the effective date of coverage under the policy.

(ii) *Conclusion.* In this *Example 1*, the exclusion of benefits for oral surgery required as a result of a traumatic injury if the injury occurred before the effective date of coverage is a preexisting condition exclusion because it operates to exclude benefits for a condition based on the fact that the condition was present before the effective date of coverage under the policy.

Example 2. (i) *Facts.* Individual C applies for individual health insurance coverage with Issuer M. M denies C's application for coverage because a pre-enrollment physical revealed that C has type 2 diabetes.

(ii) *Conclusion. See Example 2* in 45 CFR 147.108(a)(2) for a conclusion that M's denial of C's application for coverage is a preexisting condition exclusion because a denial of an application for coverage based on the fact that a condition was present before the date of denial is an exclusion of benefits based on a preexisting condition.

(b) *Effective/applicability date*—(1) *General applicability date.* Except as provided in paragraph (b)(2) of this section, the rules of this section apply for plan years beginning on or after January 1, 2014.

(2) *Early applicability date for children.* The rules of this section apply with respect to enrollees, including applicants for enrollment, who are under 19 years of age for plan years beginning on or after September 23, 2010.

(3) *Applicability to grandfathered health plans.* See § 54.9815–1251T for determining the application of this section to grandfathered health plans (providing that a grandfathered health plan that is a group health plan or group health insurance coverage must comply with the prohibition against preexisting condition exclusions).

(4) *Example.* The rules of this paragraph (b) are illustrated by the following example:

Example. (i) *Facts.* Individual F commences employment and enrolls F and F's 16-year-old child in the group health plan maintained by F's employer, with a first day of coverage of October 15, 2010. F's child had a significant break in coverage because of a lapse of more than 63 days without creditable coverage immediately prior to enrolling in the plan. F's child was treated for asthma within the six-month period prior to the enrollment date and the plan imposes a 12-month preexisting condition exclusion for coverage of asthma. The next plan year begins on January 1, 2011.

(ii) *Conclusion.* In this *Example*, the plan year beginning January 1, 2011 is the first plan year of the group health plan beginning on or after September 23, 2010. Thus, beginning on January 1, 2011, because the child is under 19 years of age, the plan cannot impose a preexisting condition exclusion with respect to the child's asthma regardless of the fact that the preexisting condition exclusion was imposed by the plan before the applicability date of this provision.

(c) *Expiration date.* This section expires on June 21, 2013.

■ **Par. 5.** Section 54.9815–2711T is added to read as follows:

§ 54.9815–2711T No lifetime or annual limits (temporary).

(a) *Prohibition*—(1) *Lifetime limits.* Except as provided in paragraph (b) of this section, a group health plan, or a health insurance issuer offering group health insurance coverage, may not establish any lifetime limit on the dollar amount of benefits for any individual.

(2) *Annual limits*—(i) *General rule.* Except as provided in paragraphs (a)(2)(ii), (b), and (d) of this section, a group health plan, or a health insurance issuer offering group health insurance coverage, may not establish any annual limit on the dollar amount of benefits for any individual.

(ii) *Exception for health flexible spending arrangements.* A health flexible spending arrangement (as defined in section 106(c)(2)) is not subject to the requirement in paragraph (a)(2)(i) of this section.

(b) *Construction*—(1) *Permissible limits on specific covered benefits.* The rules of this section do not prevent a group health plan, or a health insurance issuer offering group health insurance coverage, from placing annual or lifetime dollar limits with respect to any individual on specific covered benefits that are not essential health benefits to the extent that such limits are otherwise permitted under applicable Federal or State law. (The scope of essential health benefits is addressed in paragraph (c) of this section.)

(2) *Condition-based exclusions.* The rules of this section do not prevent a group health plan, or a health insurance issuer offering group health insurance coverage, from excluding all benefits for a condition. However, if any benefits are provided for a condition, then the requirements of this section apply. Other requirements of Federal or State law may require coverage of certain benefits.

(c) *Definition of essential health benefits.* The term "essential health benefits" means essential health benefits under section 1302(b) of the Patient Protection and Affordable Care Act and applicable regulations.

(d) *Restricted annual limits permissible prior to 2014*—(1) *In general.* With respect to plan years beginning prior to January 1, 2014, a group health plan, or a health insurance issuer offering group health insurance coverage, may establish, for any individual, an annual limit on the dollar amount of benefits that are essential health benefits, provided the limit is no less than the amounts in the following schedule:

(i) For a plan year beginning on or after September 23, 2010, but before September 23, 2011, $750,000.

(ii) For a plan year beginning on or after September 23, 2011, but before September 23, 2012, $1,250,000.

(iii) For plan years beginning on or after September 23, 2012, but before January 1, 2014, $2,000,000.

(2) *Only essential health benefits taken into account.* In determining whether an individual has received benefits that meet or exceed the applicable amount described in paragraph (d)(1) of this section, a plan or issuer must take into account only essential health benefits.

(3) *Waiver authority of the Secretary of Health and Human Services.* For plan years beginning before January 1, 2014, the Secretary of Health and Human Services may establish a program under which the requirements of paragraph (d)(1) of this section relating to annual limits may be waived (for such period as is specified by the Secretary of Health and Human Services) for a group health plan or health insurance coverage that has an annual dollar limit on benefits below the restricted annual limits provided under paragraph (d)(1) of this section if compliance with paragraph (d)(1) of this section would result in a significant decrease in access to benefits under the plan or health insurance coverage or would significantly increase premiums for the plan or health insurance coverage.

(e) *Transitional rules for individuals whose coverage or benefits ended by reason of reaching a lifetime limit*—(1) *In general.* The relief provided in the transitional rules of this paragraph (e) applies with respect to any individual—

(i) Whose coverage or benefits under a group health plan or group health insurance coverage ended by reason of reaching a lifetime limit on the dollar value of all benefits for any individual (which, under this section, is no longer permissible); and

(ii) Who becomes eligible (or is required to become eligible) for benefits not subject to a lifetime limit on the dollar value of all benefits under the group health plan or group health insurance coverage on the first day of the first plan year beginning on or after September 23, 2010, by reason of the application of this section.

(2) *Notice and enrollment opportunity requirements*—(i) If an individual described in paragraph (e)(1) of this section is eligible for benefits (or is required to become eligible for benefits) under the group health plan—or group health insurance coverage—described in paragraph (e)(1) of this section, the plan and the issuer are required to give the individual written notice that the lifetime limit on the dollar value of all benefits no longer applies and that the individual, if covered, is once again eligible for benefits under the plan. Additionally, if the individual is not enrolled in the plan or health insurance coverage, or if an enrolled individual is eligible for but not enrolled in any benefit package under the plan or health insurance coverage, then the plan and issuer must also give such an individual an opportunity to enroll that continues for at least 30 days (including written notice of the opportunity to enroll). The notices and enrollment opportunity required under this paragraph (e)(2)(i) must be provided beginning not later than the first day of the first plan year beginning on or after September 23, 2010.

(ii) The notices required under paragraph (e)(2)(i) of this section may be provided to an employee on behalf of the employee's dependent. In addition, the notices may be included with other enrollment materials that a plan distributes to employees, provided the statement is prominent. For either notice, if a notice satisfying the requirements of this paragraph (e)(2) is provided to an individual, the obligation to provide the notice with respect to that individual is satisfied for both the plan and the issuer.

(3) *Effective date of coverage.* In the case of an individual who enrolls under paragraph (e)(2) of this section, coverage must take effect not later than the first day of the first plan year beginning on or after September 23, 2010.

(4) *Treatment of enrollees in a group health plan.* Any individual enrolling in a group health plan pursuant to paragraph (e)(2) of this section must be treated as if the individual were a special enrollee, as provided under the rules of § 54.9801–6(d). Accordingly, the individual (and, if the individual would not be a participant once enrolled in the plan, the participant through whom the individual is otherwise eligible for coverage under the plan) must be offered all the benefit packages available to similarly situated individuals who did not lose coverage by reason of reaching a lifetime limit on the dollar value of all benefits. For this purpose, any difference in benefits or cost-sharing requirements constitutes a different benefit package. The individual also cannot be required to pay more for coverage than similarly situated individuals who did not lose coverage by reason of reaching a lifetime limit on the dollar value of all benefits.

(5) *Examples.* The rules of this paragraph (e) are illustrated by the following examples:

Example 1. (i) *Facts.* Employer Y maintains a group health plan with a calendar year plan year. The plan has a single benefit package. For plan years beginning before September 23, 2010, the plan has a lifetime limit on the dollar value of all benefits. Individual B, an employee of Y, was enrolled in Y's group health plan at the beginning of the 2008 plan year. On June 10, 2008, B incurred a claim for benefits that exceeded the lifetime limit under Y's plan and ceased to be enrolled in the plan. B is still eligible for coverage under Y's group health plan. On or before January 1, 2011, Y's group health plan gives B written notice informing B that the lifetime limit on the dollar value of all benefits no longer applies, that individuals whose coverage ended by reason of reaching a lifetime limit under the plan are eligible to enroll in the plan, and that individuals can request such enrollment through February 1, 2011 with enrollment effective retroactively to January 1, 2011.

(ii) *Conclusion.* In this *Example 1,* the plan has complied with the requirements of this paragraph (e) by providing a timely written notice and enrollment opportunity to B that lasts at least 30 days.

Example 2. (i) *Facts.* Employer Z maintains a group health plan with a plan year beginning October 1 and ending September 30. Prior to October 1, 2010, the group health plan has a lifetime limit on the dollar value of all benefits. Individual D, an employee of Z, and Individual E, D's child, were enrolled in family coverage under Z's group health plan for the plan year beginning on October 1, 2008. On May 1, 2009, E incurred a claim for benefits that exceeded the lifetime limit under Z's plan. D dropped family coverage but remains an employee of Z and is still eligible for coverage under Z's group health plan.

(ii) *Conclusion.* In this *Example 2,* not later than October 1, 2010, the plan must provide D and E an opportunity to enroll (including written notice of an opportunity to enroll) that continues for at least 30 days, with enrollment effective not later than October 1, 2010.

Example 3. (i) *Facts.* Same facts as *Example 2,* except that Z's plan had two benefit packages (a low-cost and a high-cost option). Instead of dropping coverage, D switched to the low-cost benefit package option.

(ii) *Conclusion.* In this *Example 3,* not later than October 1, 2010, the plan must provide D and E an opportunity to enroll in any benefit package available to similarly situated individuals who enroll when first eligible. The plan would have to provide D and E the opportunity to enroll in any benefit package available to similarly situated individuals who enroll when first eligible, even if D had not switched to the low-cost benefit package option.

Example 4. (i) *Facts.* Employer Q maintains a group health plan with a plan year beginning October 1 and ending September 30. For the plan year beginning on October 1, 2009, Q has an annual limit on the dollar value of all benefits of $500,000.

(ii) *Conclusion.* In this *Example 4,* Q must raise the annual limit on the dollar value of essential health benefits to at least $750,000

for the plan year beginning October 1, 2010. For the plan year beginning October 1, 2011, Q must raise the annual limit to at least $1.25 million. For the plan year beginning October 1, 2012, Q must raise the annual limit to at least $2 million. Q may also impose a restricted annual limit of $2 million for the plan year beginning October 1, 2013. After the conclusion of that plan year, Q cannot impose an overall annual limit.

Example 5. (i) *Facts.* Same facts as *Example 4*, except that the annual limit for the plan year beginning on October 1, 2009 is $1 million and Q lowers the annual limit for the plan year beginning October 1, 2010 to $750,000.

(ii) *Conclusion.* In this *Example 5*, Q complies with the requirements of this paragraph (e). However, Q's choice to lower its annual limit means that under § 54.9815–1251T(g)(1)(vi)(C), the group health plan will cease to be a grandfathered health plan and will be generally subject to all of the provisions of PHS Act sections 2701 through 2719A.

(f) *Effective/applicability date.* The provisions of this section apply for plan years beginning on or after September 23, 2010. *See* § 54.9815–1251T for determining the application of this section to grandfathered health plans (providing that the prohibitions on lifetime and annual limits apply to all grandfathered health plans that are group health plans and group health insurance coverage, including the special rules regarding restricted annual limits).

(g) *Expiration date.* This section expires on June 21, 2013.

■ **Par. 6.** Section 54.9815–2712T is added to read as follows:

§ 54.9815–2712T Rules regarding rescissions (temporary).

(a) *Prohibition on rescissions*—(1) A group health plan, or a health insurance issuer offering group health insurance coverage, must not rescind coverage under the plan, or under the policy, certificate, or contract of insurance, with respect to an individual (including a group to which the individual belongs or family coverage in which the individual is included) once the individual is covered under the plan or coverage, unless the individual (or a person seeking coverage on behalf of the individual) performs an act, practice, or omission that constitutes fraud, or unless the individual makes an intentional misrepresentation of material fact, as prohibited by the terms of the plan or coverage. A group health plan, or a health insurance issuer offering group health insurance coverage, must provide at least 30 days advance written notice to each participant who would be affected before coverage may be rescinded under this paragraph (a)(1), regardless of whether the coverage is insured or self-insured, or whether the rescission applies to an entire group or only to an individual within the group. (The rules of this paragraph (a)(1) apply regardless of any contestability period that may otherwise apply.)

(2) For purposes of this section, a rescission is a cancellation or discontinuance of coverage that has retroactive effect. For example, a cancellation that treats a policy as void from the time of the individual's or group's enrollment is a rescission. As another example, a cancellation that voids benefits paid up to a year before the cancellation is also a rescission for this purpose. A cancellation or discontinuance of coverage is not a rescission if—

(i) The cancellation or discontinuance of coverage has only a prospective effect; or

(ii) The cancellation or discontinuance of coverage is effective retroactively to the extent it is attributable to a failure to timely pay required premiums or contributions towards the cost of coverage.

(3) The rules of this paragraph (a) are illustrated by the following examples:

Example 1. (i) *Facts.* Individual A seeks enrollment in an insured group health plan. The plan terms permit rescission of coverage with respect to an individual if the individual engages in fraud or makes an intentional misrepresentation of a material fact. The plan requires A to complete a questionnaire regarding A's prior medical history, which affects setting the group rate by the health insurance issuer. The questionnaire complies with the other requirements of this part. The questionnaire includes the following question: "Is there anything else relevant to your health that we should know?" A inadvertently fails to list that A visited a psychologist on two occasions, six years previously. A is later diagnosed with breast cancer and seeks benefits under the plan. On or around the same time, the issuer receives information about A's visits to the psychologist, which was not disclosed in the questionnaire.

(ii) *Conclusion.* In this *Example 1*, the plan cannot rescind A's coverage because A's failure to disclose the visits to the psychologist was inadvertent. Therefore, it was not fraudulent or an intentional misrepresentation of material fact.

Example 2. (i) *Facts.* An employer sponsors a group health plan that provides coverage for employees who work at least 30 hours per week. Individual B has coverage under the plan as a full-time employee. The employer reassigns B to a part-time position. Under the terms of the plan, B is no longer eligible for coverage. The plan mistakenly continues to provide health coverage, collecting premiums from B and paying claims submitted by B. After a routine audit, the plan discovers that B no longer works at least 30 hours per week. The plan rescinds B's coverage effective as of the date that B changed from a full-time employee to a part-time employee.

(ii) *Conclusion.* In this *Example 2*, the plan cannot rescind B's coverage because there was no fraud or an intentional misrepresentation of material fact. The plan may cancel coverage for B prospectively, subject to other applicable Federal and State laws.

(b) *Compliance with other requirements.* Other requirements of Federal or State law may apply in connection with a rescission of coverage.

(c) *Effective/applicability date.* The provisions of this section apply for plan years beginning on or after September 23, 2010. See § 54.9815–1251T for determining the application of this section to grandfathered health plans (providing that the rules regarding rescissions and advance notice apply to all grandfathered health plans).

(d) *Expiration date.* This section expires on June 21, 2013.

■ **Par. 7.** Section 54.9815–2719AT is added to read as follows:

§ 54.9815–2719AT Patient protections (temporary).

(a) *Choice of health care professional*—(1) *Designation of primary care provider*—(i) *In general.* If a group health plan, or a health insurance issuer offering group health insurance coverage, requires or provides for designation by a participant or beneficiary of a participating primary care provider, then the plan or issuer must permit each participant or beneficiary to designate any participating primary care provider who is available to accept the participant or beneficiary. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant of the terms of the plan or health insurance coverage regarding designation of a primary care provider.

(ii) *Example.* The rules of this paragraph (a)(1) are illustrated by the following example:

Example. (i) *Facts.* A group health plan requires individuals covered under the plan to designate a primary care provider. The plan permits each individual to designate any primary care provider participating in the plan's network who is available to accept the individual as the individual's primary care provider. If an individual has not designated a primary care provider, the plan designates one until one has been designated by the individual. The plan provides a notice that satisfies the requirements of paragraph (a)(4) of this section regarding the ability to designate a primary care provider.

(ii) *Conclusion.* In this *Example*, the plan has satisfied the requirements of paragraph (a) of this section.

(2) *Designation of pediatrician as primary care provider*—(i) *In general.* If a group health plan, or a health insurance issuer offering group health insurance coverage, requires or provides for the designation of a participating primary care provider for a child by a participant or beneficiary, the plan or issuer must permit the participant or beneficiary to designate a physician (allopathic or osteopathic) who specializes in pediatrics as the child's primary care provider if the provider participates in the network of the plan or issuer and is available to accept the child. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant of the terms of the plan or health insurance coverage regarding designation of a pediatrician as the child's primary care provider.

(ii) *Construction.* Nothing in paragraph (a)(2)(i) of this section is to be construed to waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of pediatric care.

(iii) *Examples.* The rules of this paragraph (a)(2) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan's HMO designates for each participant a physician who specializes in internal medicine to serve as the primary care provider for the participant and any beneficiaries. Participant A requests that Pediatrician B be designated as the primary care provider for A's child. B is a participating provider in the HMO's network.

(ii) *Conclusion.* In this *Example 1*, the HMO must permit A's designation of B as the primary care provider for A's child in order to comply with the requirements of this paragraph (a)(2).

Example 2. (i) *Facts.* Same facts as *Example 1*, except that A takes A's child to B for treatment of the child's severe shellfish allergies. B wishes to refer A's child to an allergist for treatment. The HMO, however, does not provide coverage for treatment of food allergies, nor does it have an allergist participating in its network, and it therefore refuses to authorize the referral.

(ii) *Conclusion.* In this *Example 2*, the HMO has not violated the requirements of this paragraph (a)(2) because the exclusion of treatment for food allergies is in accordance with the terms of A's coverage.

(3) *Patient access to obstetrical and gynecological care*—(i) *General rights*—(A) *Direct access.* A group health plan, or a health insurance issuer offering group health insurance coverage, described in paragraph (a)(3)(ii) of this section may not require authorization or referral by the plan, issuer, or any person (including a primary care provider) in the case of a female participant or beneficiary who seeks coverage for obstetrical or gynecological care provided by a participating health care professional who specializes in obstetrics or gynecology. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology. The plan or issuer may require such a professional to agree to otherwise adhere to the plan's or issuer's policies and procedures, including procedures regarding referrals and obtaining prior authorization and providing services pursuant to a treatment plan (if any) approved by the plan or issuer. For purposes of this paragraph (a)(3), a health care professional who specializes in obstetrics or gynecology is any individual (including a person other than a physician) who is authorized under applicable State law to provide obstetrical or gynecological care.

(B) *Obstetrical and gynecological care.* A group health plan or health insurance issuer described in paragraph (a)(3)(ii) of this section must treat the provision of obstetrical and gynecological care, and the ordering of related obstetrical and gynecological items and services, pursuant to the direct access described under paragraph (a)(3)(i)(A) of this section, by a participating health care professional who specializes in obstetrics or gynecology as the authorization of the primary care provider.

(ii) *Application of paragraph.* A group health plan, or a health insurance issuer offering group health insurance coverage, is described in this paragraph (a)(3) if the plan or issuer—

(A) Provides coverage for obstetrical or gynecological care; and

(B) Requires the designation by a participant or beneficiary of a participating primary care provider.

(iii) *Construction.* Nothing in paragraph (a)(3)(i) of this section is to be construed to—

(A) Waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of obstetrical or gynecological care; or

(B) Preclude the group health plan or health insurance issuer involved from requiring that the obstetrical or gynecological provider notify the primary care health care professional or the plan or issuer of treatment decisions.

(iv) *Examples.* The rules of this paragraph (a)(3) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. Participant A, a female, requests a gynecological exam with Physician B, an in-network physician specializing in gynecological care. The group health plan requires prior authorization from A's designated primary care provider for the gynecological exam.

(ii) *Conclusion.* In this *Example 1*, the group health plan has violated the requirements of this paragraph (a)(3) because the plan requires prior authorization from A's primary care provider prior to obtaining gynecological services.

Example 2. (i) *Facts.* Same facts as *Example 1* except that A seeks gynecological services from C, an out-of-network provider.

(ii) *Conclusion.* In this *Example 2*, the group health plan has not violated the requirements of this paragraph (a)(3) by requiring prior authorization because C is not a participating health care provider.

Example 3. (i) *Facts.* Same facts as *Example 1* except that the group health plan only requires B to inform A's designated primary care physician of treatment decisions.

(ii) *Conclusion.* In this *Example 3*, the group health plan has not violated the requirements of this paragraph (a)(3) because A has direct access to B without prior authorization. The fact that the group health plan requires notification of treatment decisions to the designated primary care physician does not violate this paragraph (a)(3).

Example 4. (i) *Facts.* A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. The group health plan requires prior authorization before providing benefits for uterine fibroid embolization.

(ii) *Conclusion.* In this *Example 4*, the plan requirement for prior authorization before providing benefits for uterine fibroid embolization does not violate the requirements of this paragraph (a)(3) because, though the prior authorization requirement applies to obstetrical services, it does not restrict access to any providers specializing in obstetrics or gynecology.

(4) *Notice of right to designate a primary care provider*—(i) *In general.* If a group health plan or health insurance issuer requires the designation by a participant or beneficiary of a primary care provider, the plan or issuer must provide a notice informing each participant of the terms of the plan or health insurance coverage regarding designation of a primary care provider and of the rights—

(A) Under paragraph (a)(1)(i) of this section, that any participating primary care provider who is available to accept

the participant or beneficiary can be designated;

(B) Under paragraph (a)(2)(i) of this section, with respect to a child, that any participating physician who specializes in pediatrics can be designated as the primary care provider; and

(C) Under paragraph (a)(3)(i) of this section, that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology.

(ii) *Timing.* The notice described in paragraph (a)(4)(i) of this section must be included whenever the plan or issuer provides a participant with a summary plan description or other similar description of benefits under the plan or health insurance coverage.

(iii) *Model language.* The following model language can be used to satisfy the notice requirement described in paragraph (a)(4)(i) of this section:

(A) For plans and issuers that require or allow for the designation of primary care providers by participants or beneficiaries, insert:

[Name of group health plan or health insurance issuer] generally [requires/allows] the designation of a primary care provider. You have the right to designate any primary care provider who participates in our network and who is available to accept you or your family members. [If the plan or health insurance coverage designates a primary care provider automatically, insert: Until you make this designation, [name of group health plan or health insurance issuer] designates one for you.] For information on how to select a primary care provider, and for a list of the participating primary care providers, contact the [plan administrator or issuer] at [insert contact information].

(B) For plans and issuers that require or allow for the designation of a primary care provider for a child, add:

For children, you may designate a pediatrician as the primary care provider.

(C) For plans and issuers that provide coverage for obstetric or gynecological care and require the designation by a participant or beneficiary of a primary care provider, add:

You do not need prior authorization from [name of group health plan or issuer] or from any other person (including a primary care provider) in order to obtain access to obstetrical or gynecological care from a health care professional in our network who specializes in obstetrics or gynecology. The health care professional, however, may be required to comply with certain procedures, including obtaining prior authorization for certain services, following a pre-approved treatment plan, or procedures for making referrals. For a list of participating health care professionals who specialize in obstetrics or gynecology, contact the [plan administrator or issuer] at [insert contact information].

(b) *Coverage of emergency services*—(1) *Scope.* If a group health plan, or a health insurance issuer offering group health insurance coverage, provides any benefits with respect to services in an emergency department of a hospital, the plan or issuer must cover emergency services (as defined in paragraph (b)(4)(ii) of this section) consistent with the rules of this paragraph (b).

(2) *General rules.* A plan or issuer subject to the requirements of this paragraph (b) must provide coverage for emergency services in the following manner—

(i) Without the need for any prior authorization determination, even if the emergency services are provided on an out-of-network basis;

(ii) Without regard to whether the health care provider furnishing the emergency services is a participating network provider with respect to the services;

(iii) If the emergency services are provided out of network, without imposing any administrative requirement or limitation on coverage that is more restrictive than the requirements or limitations that apply to emergency services received from in-network providers;

(iv) If the emergency services are provided out of network, by complying with the cost-sharing requirements of paragraph (b)(3) of this section; and

(v) Without regard to any other term or condition of the coverage, other than—

(A) The exclusion of or coordination of benefits;

(B) An affiliation or waiting period permitted under part 7 of ERISA, part A of title XXVII of the PHS Act, or chapter 100 of the Internal Revenue Code; or

(C) Applicable cost sharing.

(3) *Cost-sharing requirements*—(i) *Copayments and coinsurance.* Any cost-sharing requirement expressed as a copayment amount or coinsurance rate imposed with respect to a participant or beneficiary for out-of-network emergency services cannot exceed the cost-sharing requirement imposed with respect to a participant or beneficiary if the services were provided in-network. However, a participant or beneficiary may be required to pay, in addition to the in-network cost sharing, the excess of the amount the out-of-network provider charges over the amount the plan or issuer is required to pay under this paragraph (b)(3)(i). A group health plan or health insurance issuer complies with the requirements of this paragraph (b)(3) if it provides benefits with respect to an emergency service in an amount equal to the greatest of the three amounts specified in paragraphs (b)(3)(i)(A), (b)(3)(i)(B), and (b)(3)(i)(C) of this section (which are adjusted for in-network cost-sharing requirements).

(A) The amount negotiated with in-network providers for the emergency service furnished, excluding any in-network copayment or coinsurance imposed with respect to the participant or beneficiary. If there is more than one amount negotiated with in-network providers for the emergency service, the amount described under this paragraph (b)(3)(i)(A) is the median of these amounts, excluding any in-network copayment or coinsurance imposed with respect to the participant or beneficiary. In determining the median described in the preceding sentence, the amount negotiated with each in-network provider is treated as a separate amount (even if the same amount is paid to more than one provider). If there is no per-service amount negotiated with in-network providers (such as under a capitation or other similar payment arrangement), the amount under this paragraph (b)(3)(i)(A) is disregarded.

(B) The amount for the emergency service calculated using the same method the plan generally uses to determine payments for out-of-network services (such as the usual, customary, and reasonable amount), excluding any in-network copayment or coinsurance imposed with respect to the participant or beneficiary. The amount in this paragraph (b)(3)(i)(B) is determined without reduction for out-of-network cost sharing that generally applies under the plan or health insurance coverage with respect to out-of-network services. Thus, for example, if a plan generally pays 70 percent of the usual, customary, and reasonable amount for out-of-network services, the amount in this paragraph (b)(3)(i)(B) for an emergency service is the total (that is, 100 percent) of the usual, customary, and reasonable amount for the service, not reduced by the 30 percent coinsurance that would generally apply to out-of-network services (but reduced by the in-network copayment or coinsurance that the individual would be responsible for if the emergency service had been provided in-network).

(C) The amount that would be paid under Medicare (part A or part B of title XVIII of the Social Security Act, 42 U.S.C. 1395 *et seq.*) for the emergency service, excluding any in-network copayment or coinsurance imposed with respect to the participant or beneficiary.

(ii) *Other cost sharing.* Any cost-sharing requirement other than a

copayment or coinsurance requirement (such as a deductible or out-of-pocket maximum) may be imposed with respect to emergency services provided out of network if the cost-sharing requirement generally applies to out-of-network benefits. A deductible may be imposed with respect to out-of-network emergency services only as part of a deductible that generally applies to out-of-network benefits. If an out-of-pocket maximum generally applies to out-of-network benefits, that out-of-pocket maximum must apply to out-of-network emergency services.

(iii) *Examples.* The rules of this paragraph (b)(3) are illustrated by the following examples. In all of these examples, the group health plan covers benefits with respect to emergency services.

Example 1. (i) *Facts.* A group health plan imposes a 25% coinsurance responsibility on individuals who are furnished emergency services, whether provided in network or out of network. If a covered individual notifies the plan within two business days after the day an individual receives treatment in an emergency department, the plan reduces the coinsurance rate to 15%.

(ii) *Conclusion.* In this *Example 1*, the requirement to notify the plan in order to receive a reduction in the coinsurance rate does not violate the requirement that the plan cover emergency services without the need for any prior authorization determination. This is the result even if the plan required that it be notified before or at the time of receiving services at the emergency department in order to receive a reduction in the coinsurance rate.

Example 2. (i) *Facts.* A group health plan imposes a $60 copayment on emergency services without preauthorization, whether provided in-network or out-of-network. If emergency services are preauthorized, the plan waives the copayment, even if it later determines the medical condition was not an emergency medical condition.

(ii) *Conclusion.* In this *Example 2*, by requiring an individual to pay more for emergency services if the individual does not obtain prior authorization, the plan violates the requirement that the plan cover emergency services without the need for any prior authorization determination. (By contrast, if, to have the copayment waived, the plan merely required that it be notified rather than a prior authorization, then the plan would not violate the requirement that the plan cover emergency services without the need for any prior authorization determination.)

Example 3. (i) *Facts.* A group health plan covers individuals who receive emergency services with respect to an emergency medical condition from an out-of-network provider. The plan has agreements with in-network providers with respect to a certain emergency service. Each provider has agreed to provide the service for a certain amount. Among all the providers for the service: One has agreed to accept $85, two have agreed to accept $100, two have agreed to accept $110, three have agreed to accept $120, and one has agreed to accept $150. Under the agreement, the plan agrees to pay the providers 80% of the agreed amount, with the individual receiving the service responsible for the remaining 20%.

(ii) *Conclusion.* In this *Example 3*, the values taken into account in determining the median are $85, $100, $100, $110, $110, $120, $120, $120, and $150. Therefore, the median amount among those agreed to for the emergency service is $110, and the amount under paragraph (b)(3)(i)(A) of this section is 80% of $110 ($88).

Example 4. (i) *Facts.* Same facts as *Example 3*. Subsequently, the plan adds another provider to its network, who has agreed to accept $150 for the emergency service.

(ii) *Conclusion.* In this *Example 4*, the median amount among those agreed to for the emergency service is $115. (Because there is no one middle amount, the median is the average of the two middle amounts, $110 and $120.) Accordingly, the amount under paragraph (b)(3)(i)(A) of this section is 80% of $115 ($92).

Example 5. (i) *Facts.* Same facts as *Example 4*. An individual covered by the plan receives the emergency service from an out-of-network provider, who charges $125 for the service. With respect to services provided by out-of-network providers generally, the plan reimburses covered individuals 50% of the reasonable amount charged by the provider for medical services. For this purpose, the reasonable amount for any service is based on information on charges by all providers collected by a third party, on a zip-code-by-zip-code basis, with the plan treating charges at a specified percentile as reasonable. For the emergency service received by the individual, the reasonable amount calculated using this method is $116. The amount that would be paid under Medicare for the emergency service, excluding any copayment or coinsurance for the service, is $80.

(ii) *Conclusion.* In this *Example 5*, the plan is responsible for paying $92.80, 80% of $116. The median amount among those agreed to for the emergency service is $115 and the amount the plan would pay is $92 (80% of $115); the amount calculated using the same method the plan uses to determine payments for out-of-network services—$116—excluding the in-network 20% coinsurance, is $92.80; and the Medicare payment is $80. Thus, the greatest amount is $92.80. The individual is responsible for the remaining $32.20 charged by the out-of-network provider.

Example 6. (i) *Facts.* Same facts as *Example 5*. The group health plan generally imposes a $250 deductible for in-network health care. With respect to all health care provided by out-of-network providers, the plan imposes a $500 deductible. (Covered in-network claims are credited against the deductible.) The individual has incurred and submitted $260 of covered claims prior to receiving the emergency service out of network.

(ii) *Conclusion.* In this *Example 6*, the plan is not responsible for paying anything with respect to the emergency service furnished by the out-of-network provider because the covered individual has not satisfied the higher deductible that applies generally to all health care provided out of network. However, the amount the individual is required to pay is credited against the deductible.

(4) *Definitions.* The definitions in this paragraph (b)(4) govern in applying the provisions of this paragraph (b).

(i) *Emergency medical condition.* The term *emergency medical condition* means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) so that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act (42 U.S.C. 1395dd(e)(1)(A)). (In that provision of the Social Security Act, clause (i) refers to placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy; clause (ii) refers to serious impairment to bodily functions; and clause (iii) refers to serious dysfunction of any bodily organ or part.)

(ii) *Emergency services.* The term *emergency services* means, with respect to an emergency medical condition—

(A) A medical screening examination (as required under section 1867 of the Social Security Act, 42 U.S.C. 1395dd) that is within the capability of the emergency department of a hospital, including ancillary services routinely available to the emergency department to evaluate such emergency medical condition, and

(B) Such further medical examination and treatment, to the extent they are within the capabilities of the staff and facilities available at the hospital, as are required under section 1867 of the Social Security Act (42 U.S.C. 1395dd) to stabilize the patient.

(iii) *Stabilize.* The term *to stabilize*, with respect to an emergency medical condition (as defined in paragraph (b)(4)(i) of this section) has the meaning given in section 1867(e)(3) of the Social Security Act (42 U.S.C. 1395dd(e)(3)).

(c) *Effective/applicability date.* The provisions of this section apply for plan years beginning on or after September 23, 2010. *See* § 54.9815–1251T for determining the application of this section to grandfathered health plans (providing that these rules regarding patient protections do not apply to grandfathered health plans).

(d) *Expiration date.* This section expires on June 21, 2013.

PART 602—[AMENDED]

■ **Par. 8.** The authority citation for part 602 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

■ **Par. 9.** Section 602.101(b) is amended by adding the following entries in numerical order to the table to read as follows:

§ 602.101 OMB control numbers.

* * * * *

(b) * * *

CFR part or section where identified and described	Current OMB control No.
* * * * *	
54.9815–2711T	1545–2179
54.9815–2712T	1545–2180
* * * * *	
54.9815–2719AT	1545–2181
* * * * *	

Department of Labor

Employee Benefits Security Administration

29 CFR Chapter XXV

■ For reasons stated in the preamble, EBSA amends 29 CFR part 2590 as follows:

PART 2590—RULES AND REGULATIONS FOR GROUP HEALTH PLANS

■ 1. The authority citation for part 2590 continues to read as follows:

Authority: 29 U.S.C. 1027, 1059, 1135, 1161–1168, 1169, 1181–1183, 1181 note, 1185, 1185a, 1185b, 1191, 1191a, 1191b, and 1191c; sec. 101(g), Pub. L. 104–191, 110 Stat. 1936; sec. 401(b), Pub. L. 105–200, 112 Stat. 645 (42 U.S.C. 651 note); sec. 512(d), Pub. L. 110–343, 122 Stat. 3881; sec. 1001, 1201, and 1562(e), Pub. L. 111–148, 124 Stat. 119, as amended by Pub. L. 111–152, 124 Stat. 1029; Secretary of Labor's Order 6–2009, 74 FR 21524 (May 7, 2009).

Subpart B—Other Requirements

■ 2. Section 2590.701–2 is amended by revising the definition of *preexisting condition exclusion* to read as follows:

§ 2590.701–2 Definitions.

* * * * *

Preexisting condition exclusion means a limitation or exclusion of benefits (including a denial of coverage) based on the fact that the condition was present before the effective date of coverage (or if coverage is denied, the date of the denial) under a group health plan or group or individual health insurance coverage (or other coverage provided to federally eligible individuals pursuant to 45 CFR part 148), whether or not any medical advice, diagnosis, care, or treatment was recommended or received before that day. A preexisting condition exclusion includes any limitation or exclusion of benefits (including a denial of coverage) applicable to an individual as a result of information relating to an individual's health status before the individual's effective date of coverage (or if coverage is denied, the date of the denial) under a group health plan, or group or individual health insurance coverage (or other coverage provided to Federally eligible individuals pursuant to 45 CFR part 148), such as a condition identified as a result of a pre-enrollment questionnaire or physical examination given to the individual, or review of medical records relating to the pre-enrollment period.

* * * * *

■ 3. Section 2590.701–3 is amended by revising paragraph (a)(1)(i) to read as follows:

§ 2590.701–3 Limitations on preexisting condition exclusion period.

(a) * * *

(1) * * *

(i) A *preexisting condition exclusion* means a *preexisting condition exclusion* within the meaning set forth in § 2590.701–2 of this part.

* * * * *

■ 4. Section 2590.715–2704 is added to subpart C to read as follows:

§ 2590.715–2704 Prohibition of preexisting condition exclusions.

(a) *No preexisting condition exclusions*—(1) *In general.* A group health plan, or a health insurance issuer offering group health insurance coverage, may not impose any preexisting condition exclusion (as defined in § 2590.701–2 of this part).

(2) *Examples.* The rules of this paragraph (a) are illustrated by the following examples (for additional examples illustrating the definition of a preexisting condition exclusion, *see* § 2590.701–3(a)(1)(ii) of this part):

Example 1. (i) *Facts.* A group health plan provides benefits solely through an insurance policy offered by Issuer *P.* At the expiration of the policy, the plan switches coverage to a policy offered by Issuer *N. N's* policy excludes benefits for oral surgery required as a result of a traumatic injury if the injury occurred before the effective date of coverage under the policy.

(ii) *Conclusion.* In this *Example 1,* the exclusion of benefits for oral surgery required as a result of a traumatic injury if the injury occurred before the effective date of coverage is a preexisting condition exclusion because it operates to exclude benefits for a condition based on the fact that the condition was present before the effective date of coverage under the policy.

Example 2. (i) *Facts.* Individual *C* applies for individual health insurance coverage with Issuer *M. M* denies *C's* application for coverage because a pre-enrollment physical revealed that *C* has type 2 diabetes.

(ii) *Conclusion. See Example 2* in 45 CFR 147.108(a)(2) for a conclusion that *M's* denial of *C's* application for coverage is a preexisting condition exclusion because a denial of an application for coverage based on the fact that a condition was present before the date of denial is an exclusion of benefits based on a preexisting condition.

(b) *Applicability*—(1) *General applicability date.* Except as provided in paragraph (b)(2) of this section, the rules of this section apply for plan years beginning on or after January 1, 2014.

(2) *Early applicability date for children.* The rules of this section apply with respect to enrollees, including applicants for enrollment, who are under 19 years of age for plan years beginning on or after September 23, 2010.

(3) *Applicability to grandfathered health plans. See* § 2590.715–1251 of this part for determining the application of this section to grandfathered health plans (providing that a grandfathered health plan that is a group health plan or group health insurance coverage must comply with the prohibition against preexisting condition exclusions).

(4) *Example.* The rules of this paragraph (b) are illustrated by the following example:

Example. (i) *Facts.* Individual *F* commences employment and enrolls *F* and *F's* 16-year-old child in the group health plan maintained by *F's* employer, with a first day of coverage of October 15, 2010. *F's* child had a significant break in coverage because of a lapse of more than 63 days without creditable coverage immediately prior to enrolling in the plan. *F's* child was treated for asthma within the six-month period prior to the enrollment date and the plan imposes a 12-month preexisting condition exclusion for coverage of asthma. The next plan year begins on January 1, 2011.

(ii) *Conclusion.* In this *Example,* the plan year beginning January 1, 2011 is the first plan year of the group health plan beginning on or after September 23, 2010. Thus, beginning on January 1, 2011, because the child is under 19 years of age, the plan cannot impose a preexisting condition exclusion with respect to the child's asthma regardless of the fact that the preexisting condition exclusion was imposed by the plan before the applicability date of this provision.

■ 5. Section 2590.715–2711 is added to subpart C to read as follows:

§ 2590.715–2711 No lifetime or annual limits.

(a) *Prohibition*—(1) *Lifetime limits.* Except as provided in paragraph (b) of

this section, a group health plan, or a health insurance issuer offering group health insurance coverage, may not establish any lifetime limit on the dollar amount of benefits for any individual.

(2) *Annual limits*—(i) *General rule.* Except as provided in paragraphs (a)(2)(ii), (b), and (d) of this section, a group health plan, or a health insurance issuer offering group health insurance coverage, may not establish any annual limit on the dollar amount of benefits for any individual.

(ii) *Exception for health flexible spending arrangements.* A health flexible spending arrangement (as defined in section 106(c)(2) of the Internal Revenue Code) is not subject to the requirement in paragraph (a)(2)(i) of this section.

(b) *Construction*—(1) *Permissible limits on specific covered benefits.* The rules of this section do not prevent a group health plan, or a health insurance issuer offering group health insurance coverage, from placing annual or lifetime dollar limits with respect to any individual on specific covered benefits that are not essential health benefits to the extent that such limits are otherwise permitted under applicable Federal or State law. (The scope of essential health benefits is addressed in paragraph (c) of this section).

(2) *Condition-based exclusions.* The rules of this section do not prevent a group health plan, or a health insurance issuer offering group health insurance coverage, from excluding all benefits for a condition. However, if any benefits are provided for a condition, then the requirements of this section apply. Other requirements of Federal or State law may require coverage of certain benefits.

(c) *Definition of essential health benefits.* The term "essential health benefits" means essential health benefits under section 1302(b) of the Patient Protection and Affordable Care Act and applicable regulations.

(d) *Restricted annual limits permissible prior to 2014*—(1) *In general.* With respect to plan years beginning prior to January 1, 2014, a group health plan, or a health insurance issuer offering group health insurance coverage, may establish, for any individual, an annual limit on the dollar amount of benefits that are essential health benefits, provided the limit is no less than the amounts in the following schedule:

(i) For a plan year beginning on or after September 23, 2010, but before September 23, 2011, $750,000.

(ii) For a plan year beginning on or after September 23, 2011, but before September 23, 2012, $1,250,000.

(iii) For plan years beginning on or after September 23, 2012, but before January 1, 2014, $2,000,000.

(2) *Only essential health benefits taken into account.* In determining whether an individual has received benefits that meet or exceed the applicable amount described in paragraph (d)(1) of this section, a plan or issuer must take into account only essential health benefits.

(3) *Waiver authority of the Secretary of Health and Human Services.* For plan years beginning before January 1, 2014, the Secretary of Health and Human Services may establish a program under which the requirements of paragraph (d)(1) of this section relating to annual limits may be waived (for such period as is specified by the Secretary of Health and Human Services) for a group health plan or health insurance coverage that has an annual dollar limit on benefits below the restricted annual limits provided under paragraph (d)(1) of this section if compliance with paragraph (d)(1) of this section would result in a significant decrease in access to benefits under the plan or health insurance coverage or would significantly increase premiums for the plan or health insurance coverage.

(e) *Transitional rules for individuals whose coverage or benefits ended by reason of reaching a lifetime limit*—(1) *In general.* The relief provided in the transitional rules of this paragraph (e) applies with respect to any individual—

(i) Whose coverage or benefits under a group health plan or group health insurance coverage ended by reason of reaching a lifetime limit on the dollar value of all benefits for any individual (which, under this section, is no longer permissible); and

(ii) Who becomes eligible (or is required to become eligible) for benefits not subject to a lifetime limit on the dollar value of all benefits under the group health plan or group health insurance coverage on the first day of the first plan year beginning on or after September 23, 2010, by reason of the application of this section.

(2) *Notice and enrollment opportunity requirements*–(i) If an individual described in paragraph (e)(1) of this section is eligible for benefits (or is required to become eligible for benefits) under the group health plan—or group health insurance coverage—described in paragraph (e)(1) of this section, the plan and the issuer are required to give the individual written notice that the lifetime limit on the dollar value of all benefits no longer applies and that the individual, if covered, is once again eligible for benefits under the plan. Additionally, if the individual is not enrolled in the plan or health insurance coverage, or if an enrolled individual is eligible for but not enrolled in any benefit package under the plan or health insurance coverage, then the plan and issuer must also give such an individual an opportunity to enroll that continues for at least 30 days (including written notice of the opportunity to enroll). The notices and enrollment opportunity required under this paragraph (e)(2)(i) must be provided beginning not later than the first day of the first plan year beginning on or after September 23, 2010.

(ii) The notices required under paragraph (e)(2)(i) of this section may be provided to an employee on behalf of the employee's dependent. In addition, the notices may be included with other enrollment materials that a plan distributes to employees, provided the statement is prominent. For either notice, if a notice satisfying the requirements of this paragraph (e)(2) is provided to an individual, the obligation to provide the notice with respect to that individual is satisfied for both the plan and the issuer.

(3) *Effective date of coverage.* In the case of an individual who enrolls under paragraph (e)(2) of this section, coverage must take effect not later than the first day of the first plan year beginning on or after September 23, 2010.

(4) *Treatment of enrollees in a group health plan.* Any individual enrolling in a group health plan pursuant to paragraph (e)(2) of this section must be treated as if the individual were a special enrollee, as provided under the rules of § 2590.701–6(d) of this part. Accordingly, the individual (and, if the individual would not be a participant once enrolled in the plan, the participant through whom the individual is otherwise eligible for coverage under the plan) must be offered all the benefit packages available to similarly situated individuals who did not lose coverage by reason of reaching a lifetime limit on the dollar value of all benefits. For this purpose, any difference in benefits or cost-sharing requirements constitutes a different benefit package. The individual also cannot be required to pay more for coverage than similarly situated individuals who did not lose coverage by reason of reaching a lifetime limit on the dollar value of all benefits.

(5) *Examples.* The rules of this paragraph (e) are illustrated by the following examples:

Example 1. (i) *Facts.* Employer *Y* maintains a group health plan with a calendar year plan year. The plan has a single benefit package. For plan years beginning before September 23, 2010, the plan has a lifetime limit on the

dollar value of all benefits. Individual *B*, an employee of *Y*, was enrolled in *Y*'s group health plan at the beginning of the 2008 plan year. On June 10, 2008, *B* incurred a claim for benefits that exceeded the lifetime limit under *Y*'s plan and ceased to be enrolled in the plan. *B* is still eligible for coverage under *Y*'s group health plan. On or before January 1, 2011, *Y*'s group health plan gives *B* written notice informing *B* that the lifetime limit on the dollar value of all benefits no longer applies, that individuals whose coverage ended by reason of reaching a lifetime limit under the plan are eligible to enroll in the plan, and that individuals can request such enrollment through February 1, 2011 with enrollment effective retroactively to January 1, 2011.

(ii) *Conclusion.* In this *Example 1*, the plan has complied with the requirements of this paragraph (e) by providing a timely written notice and enrollment opportunity to *B* that lasts at least 30 days.

Example 2. (i) *Facts.* Employer *Z* maintains a group health plan with a plan year beginning October 1 and ending September 30. Prior to October 1, 2010, the group health plan has a lifetime limit on the dollar value of all benefits. Individual *D*, an employee of *Z*, and Individual *E*, *D*'s child, were enrolled in family coverage under *Z*'s group health plan for the plan year beginning on October 1, 2008. On May 1, 2009, *E* incurred a claim for benefits that exceeded the lifetime limit under *Z*'s plan. *D* dropped family coverage but remains an employee of *Z* and is still eligible for coverage under *Z*'s group health plan.

(ii) *Conclusion.* In this *Example 2*, not later than October 1, 2010, the plan must provide *D* and *E* an opportunity to enroll (including written notice of an opportunity to enroll) that continues for at least 30 days, with enrollment effective not later than October 1, 2010.

Example 3. (i) *Facts.* Same facts as *Example 2*, except that *Z*'s plan had two benefit packages (a low-cost and a high-cost option). Instead of dropping coverage, *D* switched to the low-cost benefit package option.

(ii) *Conclusion.* In this *Example 3*, not later than October 1, 2010, the plan must provide *D* and *E* an opportunity to enroll in any benefit package available to similarly situated individuals who enroll when first eligible. The plan would have to provide *D* and *E* the opportunity to enroll in any benefit package available to similarly situated individuals who enroll when first eligible, even if *D* had not switched to the low-cost benefit package option.

Example 4. (i) *Facts.* Employer *Q* maintains a group health plan with a plan year beginning October 1 and ending September 30. For the plan year beginning on October 1, 2009, *Q* has an annual limit on the dollar value of all benefits of $500,000.

(ii) *Conclusion.* In this *Example 4*, *Q* must raise the annual limit on the dollar value of essential health benefits to at least $750,000 for the plan year beginning October 1, 2010. For the plan year beginning October 1, 2011, *Q* must raise the annual limit to at least $1.25 million. For the plan year beginning October 1, 2012, *Q* must raise the annual limit to at least $2 million. *Q* may also impose a restricted annual limit of $2 million for the plan year beginning October 1, 2013. After the conclusion of that plan year, *Q* cannot impose an overall annual limit.

Example 5. (i) *Facts.* Same facts as *Example 4*, except that the annual limit for the plan year beginning on October 1, 2009 is $1 million and *Q* lowers the annual limit for the plan year beginning October 1, 2010 to $750,000.

(ii) *Conclusion.* In this *Example 5*, *Q* complies with the requirements of this paragraph (e). However, *Q*'s choice to lower its annual limit means that under § 2590.715–1251(g)(1)(vi)(C), the group health plan will cease to be a grandfathered health plan and will be generally subject to all of the provisions of PHS Act sections 2701 through 2719A.

(f) *Applicability date.* The provisions of this section apply for plan years beginning on or after September 23, 2010. *See* § 2590.715–1251 of this Part for determining the application of this section to grandfathered health plans (providing that the prohibitions on lifetime and annual limits apply to all grandfathered health plans that are group health plans and group health insurance coverage, including the special rules regarding restricted annual limits).

■ 6. Section 2590.715–2712 is added to subpart C to read as follows:

§ 2590.715–2712 Rules regarding rescissions.

(a) *Prohibition on rescissions*—(1) A group health plan, or a health insurance issuer offering group health insurance coverage, must not rescind coverage under the plan, or under the policy, certificate, or contract of insurance, with respect to an individual (including a group to which the individual belongs or family coverage in which the individual is included) once the individual is covered under the plan or coverage, unless the individual (or a person seeking coverage on behalf of the individual) performs an act, practice, or omission that constitutes fraud, or unless the individual makes an intentional misrepresentation of material fact, as prohibited by the terms of the plan or coverage. A group health plan, or a health insurance issuer offering group health insurance coverage, must provide at least 30 days advance written notice to each participant who would be affected before coverage may be rescinded under this paragraph (a)(1), regardless of whether the coverage is insured or self-insured, or whether the rescission applies to an entire group or only to an individual within the group. (The rules of this paragraph (a)(1) apply regardless of any contestability period that may otherwise apply.)

(2) For purposes of this section, a rescission is a cancellation or discontinuance of coverage that has retroactive effect. For example, a cancellation that treats a policy as void from the time of the individual's or group's enrollment is a rescission. As another example, a cancellation that voids benefits paid up to a year before the cancellation is also a rescission for this purpose. A cancellation or discontinuance of coverage is not a rescission if –

(i) The cancellation or discontinuance of coverage has only a prospective effect; or

(ii) The cancellation or discontinuance of coverage is effective retroactively to the extent it is attributable to a failure to timely pay required premiums or contributions towards the cost of coverage.

(3) The rules of this paragraph (a) are illustrated by the following examples:

Example 1. (i) *Facts.* Individual *A* seeks enrollment in an insured group health plan. The plan terms permit rescission of coverage with respect to an individual if the individual engages in fraud or makes an intentional misrepresentation of a material fact. The plan requires *A* to complete a questionnaire regarding *A*'s prior medical history, which affects setting the group rate by the health insurance issuer. The questionnaire complies with the other requirements of this part. The questionnaire includes the following question: "Is there anything else relevant to your health that we should know?" *A* inadvertently fails to list that *A* visited a psychologist on two occasions, six years previously. *A* is later diagnosed with breast cancer and seeks benefits under the plan. On or around the same time, the issuer receives information about *A*'s visits to the psychologist, which was not disclosed in the questionnaire.

(ii) *Conclusion.* In this *Example 1*, the plan cannot rescind *A*'s coverage because *A*'s failure to disclose the visits to the psychologist was inadvertent. Therefore, it was not fraudulent or an intentional misrepresentation of material fact.

Example 2. (i) *Facts.* An employer sponsors a group health plan that provides coverage for employees who work at least 30 hours per week. Individual *B* has coverage under the plan as a full-time employee. The employer reassigns *B* to a part-time position. Under the terms of the plan, *B* is no longer eligible for coverage. The plan mistakenly continues to provide health coverage, collecting premiums from *B* and paying claims submitted by *B*. After a routine audit, the plan discovers that *B* no longer works at least 30 hours per week. The plan rescinds *B*'s coverage effective as of the date that *B* changed from a full-time employee to a part-time employee.

(ii) *Conclusion.* In this *Example 2*, the plan cannot rescind *B*'s coverage because there was no fraud or an intentional misrepresentation of material fact. The plan may cancel coverage for *B* prospectively, subject to other applicable Federal and State laws.

(b) *Compliance with other requirements.* Other requirements of Federal or State law may apply in connection with a rescission of coverage.

(c) *Applicability date.* The provisions of this section apply for plan years beginning on or after September 23, 2010. *See* § 2590.715–1251 of this part for determining the application of this section to grandfathered health plans (providing that the rules regarding rescissions and advance notice apply to all grandfathered health plans).

■ 7. Section 2590.715–2719A is added to subpart C to read as follows:

§ 2590.715–2719A Patient protections.

(a) *Choice of health care professional*—(1) *Designation of primary care provider*—(i) *In general.* If a group health plan, or a health insurance issuer offering group health insurance coverage, requires or provides for designation by a participant or beneficiary of a participating primary care provider, then the plan or issuer must permit each participant or beneficiary to designate any participating primary care provider who is available to accept the participant or beneficiary. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant of the terms of the plan or health insurance coverage regarding designation of a primary care provider.

(ii) *Example.* The rules of this paragraph (a)(1) are illustrated by the following example:

Example. (i) *Facts.* A group health plan requires individuals covered under the plan to designate a primary care provider. The plan permits each individual to designate any primary care provider participating in the plan's network who is available to accept the individual as the individual's primary care provider. If an individual has not designated a primary care provider, the plan designates one until one has been designated by the individual. The plan provides a notice that satisfies the requirements of paragraph (a)(4) of this section regarding the ability to designate a primary care provider.

(ii) *Conclusion.* In this *Example,* the plan has satisfied the requirements of paragraph (a) of this section.

(2) *Designation of pediatrician as primary care provider*—(i) *In general.* If a group health plan, or a health insurance issuer offering group health insurance coverage, requires or provides for the designation of a participating primary care provider for a child by a participant or beneficiary, the plan or issuer must permit the participant or beneficiary to designate a physician (allopathic or osteopathic) who specializes in pediatrics as the child's primary care provider if the provider participates in the network of the plan or issuer and is available to accept the child. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant of the terms of the plan or health insurance coverage regarding designation of a pediatrician as the child's primary care provider.

(ii) *Construction.* Nothing in paragraph (a)(2)(i) of this section is to be construed to waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of pediatric care.

(iii) *Examples.* The rules of this paragraph (a)(2) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan's HMO designates for each participant a physician who specializes in internal medicine to serve as the primary care provider for the participant and any beneficiaries. Participant *A* requests that Pediatrician *B* be designated as the primary care provider for *A*'s child. *B* is a participating provider in the HMO's network.

(ii) *Conclusion.* In this *Example 1,* the HMO must permit *A*'s designation of *B* as the primary care provider for *A*'s child in order to comply with the requirements of this paragraph (a)(2).

Example 2. (i) *Facts.* Same facts as *Example 1,* except that *A* takes *A*'s child to *B* for treatment of the child's severe shellfish allergies. *B* wishes to refer *A*'s child to an allergist for treatment. The HMO, however, does not provide coverage for treatment of food allergies, nor does it have an allergist participating in its network, and it therefore refuses to authorize the referral.

(ii) *Conclusion.* In this *Example 2,* the HMO has not violated the requirements of this paragraph (a)(2) because the exclusion of treatment for food allergies is in accordance with the terms of *A*'s coverage.

(3) *Patient access to obstetrical and gynecological care*—(i) *General rights*—(A) *Direct access.* A group health plan, or a health insurance issuer offering group health insurance coverage, described in paragraph (a)(3)(ii) of this section may not require authorization or referral by the plan, issuer, or any person (including a primary care provider) in the case of a female participant or beneficiary who seeks coverage for obstetrical or gynecological care provided by a participating health care professional who specializes in obstetrics or gynecology. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology. The plan or issuer may require such a professional to agree to otherwise adhere to the plan's or issuer's policies and procedures, including procedures regarding referrals and obtaining prior authorization and providing services pursuant to a treatment plan (if any) approved by the plan or issuer. For purposes of this paragraph (a)(3), a health care professional who specializes in obstetrics or gynecology is any individual (including a person other than a physician) who is authorized under applicable State law to provide obstetrical or gynecological care.

(B) *Obstetrical and gynecological care.* A group health plan or health insurance issuer described in paragraph (a)(3)(ii) of this section must treat the provision of obstetrical and gynecological care, and the ordering of related obstetrical and gynecological items and services, pursuant to the direct access described under paragraph (a)(3)(i)(A) of this section, by a participating health care professional who specializes in obstetrics or gynecology as the authorization of the primary care provider.

(ii) *Application of paragraph.* A group health plan, or a health insurance issuer offering group health insurance coverage, is described in this paragraph (a)(3) if the plan or issuer—

(A) Provides coverage for obstetrical or gynecological care; and

(B) Requires the designation by a participant or beneficiary of a participating primary care provider.

(iii) *Construction.* Nothing in paragraph (a)(3)(i) of this section is to be construed to—

(A) Waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of obstetrical or gynecological care; or

(B) Preclude the group health plan or health insurance issuer involved from requiring that the obstetrical or gynecological provider notify the primary care health care professional or the plan or issuer of treatment decisions.

(iv) *Examples.* The rules of this paragraph (a)(3) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. Participant *A*, a female, requests a gynecological exam with Physician *B*, an in-network physician specializing in gynecological care. The group health plan requires prior authorization from *A*'s designated primary care provider for the gynecological exam.

(ii) *Conclusion.* In this *Example 1*, the group health plan has violated the requirements of this paragraph (a)(3) because the plan requires prior authorization from *A's* primary care provider prior to obtaining gynecological services.

Example 2. (i) *Facts.* Same facts as *Example 1* except that *A* seeks gynecological services from *C*, an out-of-network provider.

(ii) *Conclusion.* In this *Example 2*, the group health plan has not violated the requirements of this paragraph (a)(3) by requiring prior authorization because *C* is not a participating health care provider.

Example 3. (i) *Facts.* Same facts as *Example 1* except that the group health plan only requires *B* to inform *A's* designated primary care physician of treatment decisions.

(ii) *Conclusion.* In this *Example 3*, the group health plan has not violated the requirements of this paragraph (a)(3) because *A* has direct access to *B* without prior authorization. The fact that the group health plan requires notification of treatment decisions to the designated primary care physician does not violate this paragraph (a)(3).

Example 4. (i) *Facts.* A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. The group health plan requires prior authorization before providing benefits for uterine fibroid embolization.

(ii) *Conclusion.* In this *Example 4*, the plan requirement for prior authorization before providing benefits for uterine fibroid embolization does not violate the requirements of this paragraph (a)(3) because, though the prior authorization requirement applies to obstetrical services, it does not restrict access to any providers specializing in obstetrics or gynecology.

(4) *Notice of right to designate a primary care provider*—(i) *In general.* If a group health plan or health insurance issuer requires the designation by a participant or beneficiary of a primary care provider, the plan or issuer must provide a notice informing each participant of the terms of the plan or health insurance coverage regarding designation of a primary care provider and of the rights—

(A) Under paragraph (a)(1)(i) of this section, that any participating primary care provider who is available to accept the participant or beneficiary can be designated;

(B) Under paragraph (a)(2)(i) of this section, with respect to a child, that any participating physician who specializes in pediatrics can be designated as the primary care provider; and

(C) Under paragraph (a)(3)(i) of this section, that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology.

(ii) *Timing.* The notice described in paragraph (a)(4)(i) of this section must be included whenever the plan or issuer provides a participant with a summary plan description or other similar description of benefits under the plan or health insurance coverage.

(iii) *Model language.* The following model language can be used to satisfy the notice requirement described in paragraph (a)(4)(i) of this section:

(A) For plans and issuers that require or allow for the designation of primary care providers by participants or beneficiaries, insert:

[Name of group health plan or health insurance issuer] generally [requires/allows] the designation of a primary care provider. You have the right to designate any primary care provider who participates in our network and who is available to accept you or your family members. [If the plan or health insurance coverage designates a primary care provider automatically, insert: Until you make this designation, [name of group health plan or health insurance issuer] designates one for you.] For information on how to select a primary care provider, and for a list of the participating primary care providers, contact the [plan administrator or issuer] at [insert contact information].

(B) For plans and issuers that require or allow for the designation of a primary care provider for a child, add:

For children, you may designate a pediatrician as the primary care provider.

(C) For plans and issuers that provide coverage for obstetric or gynecological care and require the designation by a participant or beneficiary of a primary care provider, add:

You do not need prior authorization from [name of group health plan or issuer] or from any other person (including a primary care provider) in order to obtain access to obstetrical or gynecological care from a health care professional in our network who specializes in obstetrics or gynecology. The health care professional, however, may be required to comply with certain procedures, including obtaining prior authorization for certain services, following a pre-approved treatment plan, or procedures for making referrals. For a list of participating health care professionals who specialize in obstetrics or gynecology, contact the [plan administrator or issuer] at [insert contact information].

(b) *Coverage of emergency services*—(1) *Scope.* If a group health plan, or a health insurance issuer offering group health insurance coverage, provides any benefits with respect to services in an emergency department of a hospital, the plan or issuer must cover emergency services (as defined in paragraph (b)(4)(ii) of this section) consistent with the rules of this paragraph (b).

(2) *General rules.* A plan or issuer subject to the requirements of this paragraph (b) must provide coverage for emergency services in the following manner—

(i) Without the need for any prior authorization determination, even if the emergency services are provided on an out-of-network basis;

(ii) Without regard to whether the health care provider furnishing the emergency services is a participating network provider with respect to the services;

(iii) If the emergency services are provided out of network, without imposing any administrative requirement or limitation on coverage that is more restrictive than the requirements or limitations that apply to emergency services received from in-network providers;

(iv) If the emergency services are provided out of network, by complying with the cost-sharing requirements of paragraph (b)(3) of this section; and

(v) Without regard to any other term or condition of the coverage, other than—

(A) The exclusion of or coordination of benefits;

(B) An affiliation or waiting period permitted under part 7 of ERISA, part A of title XXVII of the PHS Act, or chapter 100 of the Internal Revenue Code; or

(C) Applicable cost sharing.

(3) *Cost-sharing requirements*—(i) *Copayments and coinsurance.* Any cost-sharing requirement expressed as a copayment amount or coinsurance rate imposed with respect to a participant or beneficiary for out-of-network emergency services cannot exceed the cost-sharing requirement imposed with respect to a participant or beneficiary if the services were provided in-network. However, a participant or beneficiary may be required to pay, in addition to the in-network cost sharing, the excess of the amount the out-of-network provider charges over the amount the plan or issuer is required to pay under this paragraph (b)(3)(i). A group health plan or health insurance issuer complies with the requirements of this paragraph (b)(3) if it provides benefits with respect to an emergency service in an amount equal to the greatest of the three amounts specified in paragraphs (b)(3)(i)(A), (b)(3)(i)(B), and (b)(3)(i)(C) of this section (which are adjusted for in-network cost-sharing requirements).

(A) The amount negotiated with in-network providers for the emergency service furnished, excluding any in-network copayment or coinsurance imposed with respect to the participant or beneficiary. If there is more than one amount negotiated with in-network providers for the emergency service, the amount described under this paragraph (b)(3)(i)(A) is the median of these

amounts, excluding any in-network copayment or coinsurance imposed with respect to the participant or beneficiary. In determining the median described in the preceding sentence, the amount negotiated with each in-network provider is treated as a separate amount (even if the same amount is paid to more than one provider). If there is no per-service amount negotiated with in-network providers (such as under a capitation or other similar payment arrangement), the amount under this paragraph (b)(3)(i)(A) is disregarded.

(B) The amount for the emergency service calculated using the same method the plan generally uses to determine payments for out-of-network services (such as the usual, customary, and reasonable amount), excluding any in-network copayment or coinsurance imposed with respect to the participant or beneficiary. The amount in this paragraph (b)(3)(i)(B) is determined without reduction for out-of-network cost sharing that generally applies under the plan or health insurance coverage with respect to out-of-network services. Thus, for example, if a plan generally pays 70 percent of the usual, customary, and reasonable amount for out-of-network services, the amount in this paragraph (b)(3)(i)(B) for an emergency service is the total (that is, 100 percent) of the usual, customary, and reasonable amount for the service, not reduced by the 30 percent coinsurance that would generally apply to out-of-network services (but reduced by the in-network copayment or coinsurance that the individual would be responsible for if the emergency service had been provided in-network).

(C) The amount that would be paid under Medicare (part A or part B of title XVIII of the Social Security Act, 42 U.S.C. 1395 *et seq.*) for the emergency service, excluding any in-network copayment or coinsurance imposed with respect to the participant or beneficiary.

(ii) *Other cost sharing.* Any cost-sharing requirement other than a copayment or coinsurance requirement (such as a deductible or out-of-pocket maximum) may be imposed with respect to emergency services provided out of network if the cost-sharing requirement generally applies to out-of-network benefits. A deductible may be imposed with respect to out-of-network emergency services only as part of a deductible that generally applies to out-of-network benefits. If an out-of-pocket maximum generally applies to out-of-network benefits, that out-of-pocket maximum must apply to out-of-network emergency services.

(iii) *Examples.* The rules of this paragraph (b)(3) are illustrated by the following examples. In all of these examples, the group health plan covers benefits with respect to emergency services.

Example 1. (i) *Facts.* A group health plan imposes a 25% coinsurance responsibility on individuals who are furnished emergency services, whether provided in network or out of network. If a covered individual notifies the plan within two business days after the day an individual receives treatment in an emergency department, the plan reduces the coinsurance rate to 15%.

(ii) *Conclusion.* In this *Example 1*, the requirement to notify the plan in order to receive a reduction in the coinsurance rate does not violate the requirement that the plan cover emergency services without the need for any prior authorization determination. This is the result even if the plan required that it be notified before or at the time of receiving services at the emergency department in order to receive a reduction in the coinsurance rate.

Example 2. (i) *Facts.* A group health plan imposes a $60 copayment on emergency services without preauthorization, whether provided in network or out of network. If emergency services are preauthorized, the plan waives the copayment, even if it later determines the medical condition was not an emergency medical condition.

(ii) *Conclusion.* In this *Example 2*, by requiring an individual to pay more for emergency services if the individual does not obtain prior authorization, the plan violates the requirement that the plan cover emergency services without the need for any prior authorization determination. (By contrast, if, to have the copayment waived, the plan merely required that it be notified rather than a prior authorization, then the plan would not violate the requirement that the plan cover emergency services without the need for any prior authorization determination.)

Example 3. (i) *Facts.* A group health plan covers individuals who receive emergency services with respect to an emergency medical condition from an out-of-network provider. The plan has agreements with in-network providers with respect to a certain emergency service. Each provider has agreed to provide the service for a certain amount. Among all the providers for the service: one has agreed to accept $85, two have agreed to accept $100, two have agreed to accept $110, three have agreed to accept $120, and one has agreed to accept $150. Under the agreement, the plan agrees to pay the providers 80% of the agreed amount, with the individual receiving the service responsible for the remaining 20%.

(ii) *Conclusion.* In this *Example 3*, the values taken into account in determining the median are $85, $100, $100, $110, $110, $120, $120, $120, and $150. Therefore, the median amount among those agreed to for the emergency service is $110, and the amount under paragraph (b)(3)(i)(A) of this section is 80% of $110 ($88).

Example 4. (i) *Facts.* Same facts as *Example 3*. Subsequently, the plan adds another provider to its network, who has agreed to accept $150 for the emergency service.

(ii) *Conclusion.* In this *Example 4*, the median amount among those agreed to for the emergency service is $115. (Because there is no one middle amount, the median is the average of the two middle amounts, $110 and $120.) Accordingly, the amount under paragraph (b)(3)(i)(A) of this section is 80% of $115 ($92).

Example 5. (i) *Facts.* Same facts as *Example 4*. An individual covered by the plan receives the emergency service from an out-of-network provider, who charges $125 for the service. With respect to services provided by out-of-network providers generally, the plan reimburses covered individuals 50% of the reasonable amount charged by the provider for medical services. For this purpose, the reasonable amount for any service is based on information on charges by all providers collected by a third party, on a zip code by zip code basis, with the plan treating charges at a specified percentile as reasonable. For the emergency service received by the individual, the reasonable amount calculated using this method is $116. The amount that would be paid under Medicare for the emergency service, excluding any copayment or coinsurance for the service, is $80.

(ii) *Conclusion.* In this *Example 5*, the plan is responsible for paying $92.80, 80% of $116. The median amount among those agreed to for the emergency service is $115 and the amount the plan would pay is $92 (80% of $115); the amount calculated using the same method the plan uses to determine payments for out-of-network services—$116—excluding the in-network 20% coinsurance, is $92.80; and the Medicare payment is $80. Thus, the greatest amount is $92.80. The individual is responsible for the remaining $32.20 charged by the out-of-network provider.

Example 6. (i) *Facts.* Same facts as *Example 5*. The group health plan generally imposes a $250 deductible for in-network health care. With respect to all health care provided by out-of-network providers, the plan imposes a $500 deductible. (Covered in-network claims are credited against the deductible.) The individual has incurred and submitted $260 of covered claims prior to receiving the emergency service out of network.

(ii) *Conclusion.* In this *Example 6*, the plan is not responsible for paying anything with respect to the emergency service furnished by the out-of-network provider because the covered individual has not satisfied the higher deductible that applies generally to all health care provided out of network. However, the amount the individual is required to pay is credited against the deductible.

(4) *Definitions.* The definitions in this paragraph (b)(4) govern in applying the provisions of this paragraph (b).

(i) *Emergency medical condition.* The term *emergency medical condition* means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) so that

a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act (42 U.S.C. 1395dd(e)(1)(A)). (In that provision of the Social Security Act, clause (i) refers to placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy; clause (ii) refers to serious impairment to bodily functions; and clause (iii) refers to serious dysfunction of any bodily organ or part.)

(ii) *Emergency services.* The term *emergency services* means, with respect to an emergency medical condition—

(A) A medical screening examination (as required under section 1867 of the Social Security Act, 42 U.S.C. 1395dd) that is within the capability of the emergency department of a hospital, including ancillary services routinely available to the emergency department to evaluate such emergency medical condition, and

(B) Such further medical examination and treatment, to the extent they are within the capabilities of the staff and facilities available at the hospital, as are required under section 1867 of the Social Security Act (42 U.S.C. 1395dd) to stabilize the patient.

(iii) *Stabilize.* The term *to stabilize,* with respect to an emergency medical condition (as defined in paragraph (b)(4)(i) of this section) has the meaning given in section 1867(e)(3) of the Social Security Act (42 U.S.C. 1395dd(e)(3)).

(c) *Applicability date.* The provisions of this section apply for plan years beginning on or after September 23, 2010. *See* § 2590.715–1251 of this part for determining the application of this section to grandfathered health plans (providing that these rules regarding patient protections do not apply to grandfathered health plans).

Department of Health and Human Services

Office of Consumer Information and Insurance Oversight

45 CFR Subtitle A

■ For the reasons stated in the preamble, the Department of Health and Human Services amends 45 CFR parts 144 and 146, and part 147, added May 13, 2010, at 75 FR 27138, effective July 12, 2010, as follows:

PART 144—REQUIREMENTS RELATING TO HEALTH INSURANCE COVERAGE

■ 1. The authority citation for part 144 continues to read as follows:

Authority: Secs. 2701 through 2763, 2791, and 2792 of the Public Health Service Act, 42 U.S.C. 300gg through 300gg–63, 300gg–91, and 300gg–92.

■ 2. Section 144.103 is amended by revising the definition of *preexisting condition exclusion* to read as follows:

§ 144.103 Definitions.

* * * * *

Preexisting condition exclusion means a limitation or exclusion of benefits (including a denial of coverage) based on the fact that the condition was present before the effective date of coverage (or if coverage is denied, the date of the denial) under a group health plan or group or individual health insurance coverage (or other coverage provided to Federally eligible individuals pursuant to 45 CFR part 148), whether or not any medical advice, diagnosis, care, or treatment was recommended or received before that day. A preexisting condition exclusion includes any limitation or exclusion of benefits (including a denial of coverage) applicable to an individual as a result of information relating to an individual's health status before the individual's effective date of coverage (or if coverage is denied, the date of the denial) under a group health plan, or group or individual health insurance coverage (or other coverage provided to Federally eligible individuals pursuant to 45 CFR part 148), such as a condition identified as a result of a pre-enrollment questionnaire or physical examination given to the individual, or review of medical records relating to the pre-enrollment period.

* * * * *

Subpart B—Requirements Relating to Access and Renewability of Coverage, and Limitations on Preexisting Condition Exclusion Periods

■ 3. Section 146.111(a)(1)(i) is revised to read as follows:

§ 146.111 Limitations on preexisting condition exclusion period.

(a) * * *

(1) * * *

(i) A *preexisting condition exclusion* means a *preexisting condition exclusion* within the meaning set forth in § 144.103 of this part.

* * * * *

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 4. The authority citation for part 147 continues to read as follows:

Authority: 2701 through 2763, 2791, and 2792 of the Public Health Service Act (42 USC 300gg through 300gg–63, 300gg–91, and 300gg–92), as amended.

■ 5. Add § 147.108 to read as follows:

§ 147.108 Prohibition of preexisting condition exclusions.

(a) *No preexisting condition exclusions*—(1) *In general.* A group health plan, or a health insurance issuer offering group or individual health insurance coverage, may not impose any preexisting condition exclusion (as defined in § 144.103).

(2) *Examples.* The rules of this paragraph (a) are illustrated by the following examples (for additional examples illustrating the definition of a preexisting condition exclusion, *see* § 146.111(a)(1)(ii)):

Example 1. (i) *Facts.* A group health plan provides benefits solely through an insurance policy offered by Issuer *P.* At the expiration of the policy, the plan switches coverage to a policy offered by Issuer *N. N's* policy excludes benefits for oral surgery required as a result of a traumatic injury if the injury occurred before the effective date of coverage under the policy.

(ii) *Conclusion.* In this *Example 1,* the exclusion of benefits for oral surgery required as a result of a traumatic injury if the injury occurred before the effective date of coverage is a preexisting condition exclusion because it operates to exclude benefits for a condition based on the fact that the condition was present before the effective date of coverage under the policy.

Example 2. (i) *Facts.* Individual *C* applies for individual health insurance coverage with Issuer *M. M* denies *C's* application for coverage because a pre-enrollment physical revealed that *C* has type 2 diabetes.

(ii) *Conclusion.* In this *Example 2, M's* denial of *C's* application for coverage is a preexisting condition exclusion because a denial of an application for coverage based on the fact that a condition was present before the date of denial is an exclusion of benefits based on a preexisting condition.

(b) *Applicability*—(1) *General applicability date.* Except as provided in paragraph (b)(2) of this section, the rules of this section apply for plan years beginning on or after January 1, 2014; in the case of individual health insurance coverage, for policy years beginning, or applications denied, on or after January 1, 2014.

(2) *Early applicability date for children.* The rules of this section apply with respect to enrollees, including applicants for enrollment, who are

under 19 years of age for plan years beginning on or after September 23, 2010; in the case of individual health insurance coverage, for policy years beginning, or applications denied, on or after September 23, 2010.

(3) *Applicability to grandfathered health plans. See* § 147.140 of this part for determining the application of this section to grandfathered health plans (providing that a grandfathered health plan that is a group health plan or group health insurance coverage must comply with the prohibition against preexisting condition exclusions; however, a grandfathered health plan that is individual health insurance coverage is not required to comply with PHS Act section 2704).

(4) *Examples.* The rules of this paragraph (b) are illustrated by the following examples:

Example 1. (i) *Facts.* Individual *F* commences employment and enrolls *F* and *F*'s 16-year-old child in the group health plan maintained by *F*'s employer, with a first day of coverage of October 15, 2010. *F*'s child had a significant break in coverage because of a lapse of more than 63 days without creditable coverage immediately prior to enrolling in the plan. *F*'s child was treated for asthma within the six-month period prior to the enrollment date and the plan imposes a 12-month preexisting condition exclusion for coverage of asthma. The next plan year begins on January 1, 2011.

(ii) *Conclusion.* In this *Example 1*, the plan year beginning January 1, 2011, is the first plan year of the group health plan beginning on or after September 23, 2010. Thus, beginning on January 1, 2011, because the child is under 19 years of age, the plan cannot impose a preexisting condition exclusion with respect to the child's asthma regardless of the fact that the preexisting condition exclusion was imposed by the plan before the applicability date of this provision.

Example 2. (i) *Facts.* Individual *G* applies for a policy of family coverage in the individual market for *G*, *G*'s spouse, and *G*'s 13-year-old child. The issuer denies the application for coverage on March 1, 2011 because *G*'s 13-year-old child has autism.

(ii) *Conclusion.* In this *Example 2*, the issuer's denial of *G*'s application for a policy of family coverage in the individual market is a preexisting condition exclusion because the denial was based on the child's autism, which was present before the date of denial of coverage. Because the child is under 19 years of age and the March 1, 2011, denial of coverage is after the applicability date of this section, the issuer is prohibited from imposing a preexisting condition exclusion with respect to *G*'s 13-year-old child.

■ 6. Add § 147.126 to read as follows:

§ 147.126 No lifetime or annual limits.

(a) *Prohibition*—(1) *Lifetime limits.* Except as provided in paragraph (b) of this section, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, may not establish any lifetime limit on the dollar amount of benefits for any individual.

(2) *Annual limits*—(i) *General rule.* Except as provided in paragraphs (a)(2)(ii), (b), and (d) of this section, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, may not establish any annual limit on the dollar amount of benefits for any individual.

(ii) *Exception for health flexible spending arrangements.* A health flexible spending arrangement (as defined in section 106(c)(2) of the Internal Revenue Code) is not subject to the requirement in paragraph (a)(2)(i) of this section.

(b) *Construction*—(1) *Permissible limits on specific covered benefits.* The rules of this section do not prevent a group health plan, or a health insurance issuer offering group or individual health insurance coverage, from placing annual or lifetime dollar limits with respect to any individual on specific covered benefits that are not essential health benefits to the extent that such limits are otherwise permitted under applicable Federal or State law. (The scope of essential health benefits is addressed in paragraph (c) of this section).

(2) *Condition-based exclusions.* The rules of this section do not prevent a group health plan, or a health insurance issuer offering group or individual health insurance coverage, from excluding all benefits for a condition. However, if any benefits are provided for a condition, then the requirements of this section apply. Other requirements of Federal or State law may require coverage of certain benefits.

(c) *Definition of essential health benefits.* The term "essential health benefits" means essential health benefits under section 1302(b) of the Patient Protection and Affordable Care Act and applicable regulations.

(d) *Restricted annual limits permissible prior to 2014*—(1) *In general.* With respect to plan years (in the individual market, policy years) beginning prior to January 1, 2014, a group health plan, or a health insurance issuer offering group or individual health insurance coverage, may establish, for any individual, an annual limit on the dollar amount of benefits that are essential health benefits, provided the limit is no less than the amounts in the following schedule:

(i) For a plan year (in the individual market, policy year) beginning on or after September 23, 2010, but before September 23, 2011, $750,000.

(ii) For a plan year (in the individual market, policy year) beginning on or after September 23, 2011, but before September 23, 2012, $1,250,000.

(iii) For plan years (in the individual market, policy years) beginning on or after September 23, 2012, but before January 1, 2014, $2,000,000.

(2) *Only essential health benefits taken into account.* In determining whether an individual has received benefits that meet or exceed the applicable amount described in paragraph (d)(1) of this section, a plan or issuer must take into account only essential health benefits.

(3) *Waiver authority of the Secretary.* For plan years (in the individual market, policy years) beginning before January 1, 2014, the Secretary may establish a program under which the requirements of paragraph (d)(1) of this section relating to annual limits may be waived (for such period as is specified by the Secretary) for a group health plan or health insurance coverage that has an annual dollar limit on benefits below the restricted annual limits provided under paragraph (d)(1) of this section if compliance with paragraph (d)(1) of this section would result in a significant decrease in access to benefits under the plan or health insurance coverage or would significantly increase premiums for the plan or health insurance coverage.

(e) *Transitional rules for individuals whose coverage or benefits ended by reason of reaching a lifetime limit*—(1) *In general.* The relief provided in the transitional rules of this paragraph (e) applies with respect to any individual—

(i) Whose coverage or benefits under a group health plan or group or individual health insurance coverage ended by reason of reaching a lifetime limit on the dollar value of all benefits for any individual (which, under this section, is no longer permissible); and

(ii) Who becomes eligible (or is required to become eligible) for benefits not subject to a lifetime limit on the dollar value of all benefits under the group health plan or group or individual health insurance coverage on the first day of the first plan year (in the individual market, policy year) beginning on or after September 23, 2010, by reason of the application of this section.

(2) *Notice and enrollment opportunity requirements*—(i) If an individual described in paragraph (e)(1) of this section is eligible for benefits (or is required to become eligible for benefits) under the group health plan—or group or individual health insurance coverage—described in paragraph (e)(1) of this section, the plan and the issuer

are required to give the individual written notice that the lifetime limit on the dollar value of all benefits no longer applies and that the individual, if covered, is once again eligible for benefits under the plan. Additionally, if the individual is not enrolled in the plan or health insurance coverage, or if an enrolled individual is eligible for but not enrolled in any benefit package under the plan or health insurance coverage, then the plan and issuer must also give such an individual an opportunity to enroll that continues for at least 30 days (including written notice of the opportunity to enroll). The notices and enrollment opportunity required under this paragraph (e)(2)(i) must be provided beginning not later than the first day of the first plan year (in the individual market, policy year) beginning on or after September 23, 2010.

(ii) The notices required under paragraph (e)(2)(i) of this section may be provided to an employee on behalf of the employee's dependent (in the individual market, to the primary subscriber on behalf of the primary subscriber's dependent). In addition, for a group health plan or group health insurance coverage, the notices may be included with other enrollment materials that a plan distributes to employees, provided the statement is prominent. For either notice, with respect to a group health plan or group health insurance coverage, if a notice satisfying the requirements of this paragraph (e)(2) is provided to an individual, the obligation to provide the notice with respect to that individual is satisfied for both the plan and the issuer.

(3) *Effective date of coverage.* In the case of an individual who enrolls under paragraph (e)(2) of this section, coverage must take effect not later than the first day of the first plan year (in the individual market, policy year) beginning on or after September 23, 2010.

(4) *Treatment of enrollees in a group health plan.* Any individual enrolling in a group health plan pursuant to paragraph (e)(2) of this section must be treated as if the individual were a special enrollee, as provided under the rules of § 146.117(d). Accordingly, the individual (and, if the individual would not be a participant once enrolled in the plan, the participant through whom the individual is otherwise eligible for coverage under the plan) must be offered all the benefit packages available to similarly situated individuals who did not lose coverage by reason of reaching a lifetime limit on the dollar value of all benefits. For this purpose, any difference in benefits or cost-sharing requirements constitutes a different benefit package. The individual also cannot be required to pay more for coverage than similarly situated individuals who did not lose coverage by reason of reaching a lifetime limit on the dollar value of all benefits.

(5) *Examples.* The rules of this paragraph (e) are illustrated by the following examples:

Example 1. (i) *Facts.* Employer *Y* maintains a group health plan with a calendar year plan year. The plan has a single benefit package. For plan years beginning before September 23, 2010, the plan has a lifetime limit on the dollar value of all benefits. Individual *B*, an employee of *Y*, was enrolled in *Y*'s group health plan at the beginning of the 2008 plan year. On June 10, 2008, *B* incurred a claim for benefits that exceeded the lifetime limit under *Y*'s plan and ceased to be enrolled in the plan. *B* is still eligible for coverage under *Y*'s group health plan. On or before January 1, 2011, *Y*'s group health plan gives *B* written notice informing *B* that the lifetime limit on the dollar value of all benefits no longer applies, that individuals whose coverage ended by reason of reaching a lifetime limit under the plan are eligible to enroll in the plan, and that individuals can request such enrollment through February 1, 2011 with enrollment effective retroactively to January 1, 2011.

(ii) *Conclusion.* In this *Example 1*, the plan has complied with the requirements of this paragraph (e) by providing a timely written notice and enrollment opportunity to *B* that lasts at least 30 days.

Example 2. (i) *Facts.* Employer *Z* maintains a group health plan with a plan year beginning October 1 and ending September 30. Prior to October 1, 2010, the group health plan has a lifetime limit on the dollar value of all benefits. Individual *D*, an employee of *Z*, and Individual *E*, *D*'s child, were enrolled in family coverage under *Z*'s group health plan for the plan year beginning on October 1, 2008. On May 1, 2009, *E* incurred a claim for benefits that exceeded the lifetime limit under *Z*'s plan. *D* dropped family coverage but remains an employee of *Z* and is still eligible for coverage under *Z*'s group health plan.

(ii) *Conclusion.* In this *Example 2*, not later than October 1, 2010, the plan must provide *D* and *E* an opportunity to enroll (including written notice of an opportunity to enroll) that continues for at least 30 days, with enrollment effective not later than October 1, 2010.

Example 3. (i) *Facts.* Same facts as *Example 2*, except that *Z*'s plan had two benefit packages (a low-cost and a high-cost option). Instead of dropping coverage, *D* switched to the low-cost benefit package option.

(ii) *Conclusion.* In this *Example 3*, not later than October 1, 2010, the plan must provide *D* and *E* an opportunity to enroll in any benefit package available to similarly situated individuals who enroll when first eligible. The plan would have to provide *D* and *E* the opportunity to enroll in any benefit package available to similarly situated individuals who enroll when first eligible, even if *D* had not switched to the low-cost benefit package option.

Example 4. (i) *Facts.* Employer *Q* maintains a group health plan with a plan year beginning October 1 and ending September 30. For the plan year beginning on October 1, 2009, *Q* has an annual limit on the dollar value of all benefits of $500,000.

(ii) *Conclusion.* In this *Example 4*, *Q* must raise the annual limit on the dollar value of essential health benefits to at least $750,000 for the plan year beginning October 1, 2010. For the plan year beginning October 1, 2011, *Q* must raise the annual limit to at least $1.25 million. For the plan year beginning October 1, 2012, *Q* must raise the annual limit to at least $2 million. *Q* may also impose a restricted annual limit of $2 million for the plan year beginning October 1, 2013. After the conclusion of that plan year, *Q* cannot impose an overall annual limit.

Example 5. (i) *Facts.* Same facts as *Example 4*, except that the annual limit for the plan year beginning on October 1, 2009, is $1 million and *Q* lowers the annual limit for the plan year beginning October 1, 2010 to $750,000.

(ii) *Conclusion.* In this *Example 5*, *Q* complies with the requirements of this paragraph (e). However, *Q*'s choice to lower its annual limit means that under § 147.140(g)(1)(vi)(C), the group health plan will cease to be a grandfathered health plan and will be generally subject to all of the provisions of PHS Act sections 2701 through 2719A.

Example 6. (i) *Facts.* For a policy year that began on October 1, 2009, Individual *T* has individual health insurance coverage with a lifetime limit on the dollar value of all benefits of $1 million. For the policy year beginning October 1, 2010, the issuer of *T*'s health insurance coverage eliminates the lifetime limit and replaces it with an annual limit of $1 million dollars. In the policy year beginning October 1, 2011, the issuer of *T*'s health insurance coverage maintains the annual limit of $1 million dollars.

(ii) *Conclusion.* In this *Example 6*, the issuer's replacement of a lifetime limit with an equal dollar annual limit allows it to maintain status as a grandfathered health policy under § 147.140(g)(1)(vi)(B). Since grandfathered health plans that are individual health insurance coverage are not subject to the requirements of this section relating to annual limits, the issuer does not have to comply with this paragraph (e).

(f) *Applicability date.* The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after September 23, 2010. *See* § 147.140 of this part for determining the application of this section to grandfathered health plans (providing that the prohibitions on lifetime and annual limits apply to all grandfathered health plans that are group health plans and group health insurance coverage, including the special rules regarding restricted annual limits, and the prohibition on lifetime limits apply to individual health

insurance coverage that is a grandfathered health plan but the rules on annual limits do not apply to individual health insurance coverage that is a grandfathered health plan).

■ 7. Add § 147.128 to read as follows:

§ 147.128 Rules regarding rescissions.

(a) *Prohibition on rescissions*—(1) A group health plan, or a health insurance issuer offering group or individual health insurance coverage, must not rescind coverage under the plan, or under the policy, certificate, or contract of insurance, with respect to an individual (including a group to which the individual belongs or family coverage in which the individual is included) once the individual is covered under the plan or coverage, unless the individual (or a person seeking coverage on behalf of the individual) performs an act, practice, or omission that constitutes fraud, or unless the individual makes an intentional misrepresentation of material fact, as prohibited by the terms of the plan or coverage. A group health plan, or a health insurance issuer offering group or individual health insurance coverage, must provide at least 30 days advance written notice to each participant (in the individual market, primary subscriber) who would be affected before coverage may be rescinded under this paragraph (a)(1), regardless of, in the case of group coverage, whether the coverage is insured or self-insured, or whether the rescission applies to an entire group or only to an individual within the group. (The rules of this paragraph (a)(1) apply regardless of any contestability period that may otherwise apply.)

(2) For purposes of this section, a rescission is a cancellation or discontinuance of coverage that has retroactive effect. For example, a cancellation that treats a policy as void from the time of the individual's or group's enrollment is a rescission. As another example, a cancellation that voids benefits paid up to a year before the cancellation is also a rescission for this purpose. A cancellation or discontinuance of coverage is not a rescission if—

(i) The cancellation or discontinuance of coverage has only a prospective effect; or

(ii) The cancellation or discontinuance of coverage is effective retroactively to the extent it is attributable to a failure to timely pay required premiums or contributions towards the cost of coverage.

(3) The rules of this paragraph (a) are illustrated by the following examples:

Example 1. (i) *Facts.* Individual *A* seeks enrollment in an insured group health plan. The plan terms permit rescission of coverage with respect to an individual if the individual engages in fraud or makes an intentional misrepresentation of a material fact. The plan requires *A* to complete a questionnaire regarding *A's* prior medical history, which affects setting the group rate by the health insurance issuer. The questionnaire complies with the other requirements of this part and part 146. The questionnaire includes the following question: "Is there anything else relevant to your health that we should know?" *A* inadvertently fails to list that *A* visited a psychologist on two occasions, six years previously. *A* is later diagnosed with breast cancer and seeks benefits under the plan. On or around the same time, the issuer receives information about *A's* visits to the psychologist, which was not disclosed in the questionnaire.

(ii) *Conclusion.* In this *Example 1*, the plan cannot rescind *A's* coverage because *A's* failure to disclose the visits to the psychologist was inadvertent. Therefore, it was not fraudulent or an intentional misrepresentation of material fact.

Example 2. (i) *Facts.* An employer sponsors a group health plan that provides coverage for employees who work at least 30 hours per week. Individual *B* has coverage under the plan as a full-time employee. The employer reassigns *B* to a part-time position. Under the terms of the plan, *B* is no longer eligible for coverage. The plan mistakenly continues to provide health coverage, collecting premiums from *B* and paying claims submitted by *B*. After a routine audit, the plan discovers that *B* no longer works at least 30 hours per week. The plan rescinds *B's* coverage effective as of the date that *B* changed from a full-time employee to a part-time employee.

(ii) *Conclusion.* In this *Example 2*, the plan cannot rescind *B's* coverage because there was no fraud or an intentional misrepresentation of material fact. The plan may cancel coverage for *B* prospectively, subject to other applicable Federal and State laws.

(b) *Compliance with other requirements.* Other requirements of Federal or State law may apply in connection with a rescission of coverage.

(c) *Applicability date.* The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after September 23, 2010. *See* § 147.140 of this part for determining the application of this section to grandfathered health plans (providing that the rules regarding rescissions and advance notice apply to all grandfathered health plans).

■ 8. Add § 147.138 to read as follows:

§ 147.138 Patient protections.

(a) *Choice of health care professional*—(1) *Designation of primary care provider*—(i) *In general.* If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, requires or provides for designation by a participant, beneficiary, or enrollee of a participating primary care provider, then the plan or issuer must permit each participant, beneficiary, or enrollee to designate any participating primary care provider who is available to accept the participant, beneficiary, or enrollee. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a primary care provider.

(ii) *Example.* The rules of this paragraph (a)(1) are illustrated by the following example:

Example. (i) *Facts.* A group health plan requires individuals covered under the plan to designate a primary care provider. The plan permits each individual to designate any primary care provider participating in the plan's network who is available to accept the individual as the individual's primary care provider. If an individual has not designated a primary care provider, the plan designates one until one has been designated by the individual. The plan provides a notice that satisfies the requirements of paragraph (a)(4) of this section regarding the ability to designate a primary care provider.

(ii) *Conclusion.* In this *Example*, the plan has satisfied the requirements of paragraph (a) of this section.

(2) *Designation of pediatrician as primary care provider*—(i) *In general.* If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, requires or provides for the designation of a participating primary care provider for a child by a participant, beneficiary, or enrollee, the plan or issuer must permit the participant, beneficiary, or enrollee to designate a physician (allopathic or osteopathic) who specializes in pediatrics as the child's primary care provider if the provider participates in the network of the plan or issuer and is available to accept the child. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a pediatrician as the child's primary care provider.

(ii) *Construction.* Nothing in paragraph (a)(2)(i) of this section is to be construed to waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of pediatric care.

(iii) *Examples.* The rules of this paragraph (a)(2) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan's HMO designates for each participant a physician who specializes in internal medicine to serve as the primary care provider for the participant and any beneficiaries. Participant *A* requests that Pediatrician *B* be designated as the primary care provider for *A*'s child. *B* is a participating provider in the HMO's network.

(ii) *Conclusion.* In this *Example 1*, the HMO must permit *A*'s designation of *B* as the primary care provider for *A*'s child in order to comply with the requirements of this paragraph (a)(2).

Example 2. (i) *Facts.* Same facts as *Example 1*, except that *A* takes *A*'s child to *B* for treatment of the child's severe shellfish allergies. *B* wishes to refer *A*'s child to an allergist for treatment. The HMO, however, does not provide coverage for treatment of food allergies, nor does it have an allergist participating in its network, and it therefore refuses to authorize the referral.

(ii) *Conclusion.* In this *Example 2*, the HMO has not violated the requirements of this paragraph (a)(2) because the exclusion of treatment for food allergies is in accordance with the terms of *A*'s coverage.

(3) *Patient access to obstetrical and gynecological care*—(i) *General rights*—(A) *Direct access.* A group health plan, or a health insurance issuer offering group or individual health insurance coverage, described in paragraph (a)(3)(ii) of this section may not require authorization or referral by the plan, issuer, or any person (including a primary care provider) in the case of a female participant, beneficiary, or enrollee who seeks coverage for obstetrical or gynecological care provided by a participating health care professional who specializes in obstetrics or gynecology. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology. The plan or issuer may require such a professional to agree to otherwise adhere to the plan's or issuer's policies and procedures, including procedures regarding referrals and obtaining prior authorization and providing services pursuant to a treatment plan (if any) approved by the plan or issuer. For purposes of this paragraph (a)(3), a health care professional who specializes in obstetrics or gynecology is any individual (including a person other than a physician) who is authorized under applicable State law to provide obstetrical or gynecological care.

(B) *Obstetrical and gynecological care.* A group health plan or health insurance issuer described in paragraph (a)(3)(ii) of this section must treat the provision of obstetrical and gynecological care, and the ordering of related obstetrical and gynecological items and services, pursuant to the direct access described under paragraph (a)(3)(i)(A) of this section, by a participating health care professional who specializes in obstetrics or gynecology as the authorization of the primary care provider.

(ii) *Application of paragraph.* A group health plan, or a health insurance issuer offering group or individual health insurance coverage, is described in this paragraph (a)(3) if the plan or issuer—

(A) Provides coverage for obstetrical or gynecological care; and

(B) Requires the designation by a participant, beneficiary, or enrollee of a participating primary care provider.

(iii) *Construction.* Nothing in paragraph (a)(3)(i) of this section is to be construed to—

(A) Waive any exclusions of coverage under the terms and conditions of the plan or health insurance coverage with respect to coverage of obstetrical or gynecological care; or

(B) Preclude the group health plan or health insurance issuer involved from requiring that the obstetrical or gynecological provider notify the primary care health care professional or the plan or issuer of treatment decisions.

(iv) *Examples.* The rules of this paragraph (a)(3) are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. Participant *A*, a female, requests a gynecological exam with Physician *B*, an in-network physician specializing in gynecological care. The group health plan requires prior authorization from *A*'s designated primary care provider for the gynecological exam.

(ii) *Conclusion.* In this *Example 1*, the group health plan has violated the requirements of this paragraph (a)(3) because the plan requires prior authorization from *A*'s primary care provider prior to obtaining gynecological services.

Example 2. (i) *Facts.* Same facts as *Example 1* except that *A* seeks gynecological services from *C*, an out-of-network provider.

(ii) *Conclusion.* In this *Example 2*, the group health plan has not violated the requirements of this paragraph (a)(3) by requiring prior authorization because *C* is not a participating health care provider.

Example 3. (i) *Facts.* Same facts as *Example 1* except that the group health plan only requires *B* to inform *A*'s designated primary care physician of treatment decisions.

(ii) *Conclusion.* In this *Example 3*, the group health plan has not violated the requirements of this paragraph (a)(3) because *A* has direct access to *B* without prior authorization. The fact that the group health plan requires notification of treatment decisions to the designated primary care physician does not violate this paragraph (a)(3).

Example 4. (i) *Facts.* A group health plan requires each participant to designate a physician to serve as the primary care provider for the participant and the participant's family. The group health plan requires prior authorization before providing benefits for uterine fibroid embolization.

(ii) *Conclusion.* In this *Example 4*, the plan requirement for prior authorization before providing benefits for uterine fibroid embolization does not violate the requirements of this paragraph (a)(3) because, though the prior authorization requirement applies to obstetrical services, it does not restrict access to any providers specializing in obstetrics or gynecology.

(4) *Notice of right to designate a primary care provider*—(i) *In general.* If a group health plan or health insurance issuer requires the designation by a participant, beneficiary, or enrollee of a primary care provider, the plan or issuer must provide a notice informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a primary care provider and of the rights—

(A) Under paragraph (a)(1)(i) of this section, that any participating primary care provider who is available to accept the participant, beneficiary, or enrollee can be designated;

(B) Under paragraph (a)(2)(i) of this section, with respect to a child, that any participating physician who specializes in pediatrics can be designated as the primary care provider; and

(C) Under paragraph (a)(3)(i) of this section, that the plan may not require authorization or referral for obstetrical or gynecological care by a participating health care professional who specializes in obstetrics or gynecology.

(ii) *Timing.* In the case of a group health plan or group health insurance coverage, the notice described in paragraph (a)(4)(i) of this section must be included whenever the plan or issuer provides a participant with a summary plan description or other similar description of benefits under the plan or health insurance coverage. In the case of individual health insurance coverage, the notice described in paragraph (a)(4)(i) of this section must be included whenever the issuer provides a primary subscriber with a policy, certificate, or contract of health insurance.

(iii) *Model language.* The following model language can be used to satisfy

the notice requirement described in paragraph (a)(4)(i) of this section:

(A) For plans and issuers that require or allow for the designation of primary care providers by participants, beneficiaries, or enrollees, insert:

[Name of group health plan or health insurance issuer] generally [requires/allows] the designation of a primary care provider. You have the right to designate any primary care provider who participates in our network and who is available to accept you or your family members. [If the plan or health insurance coverage designates a primary care provider automatically, insert: Until you make this designation, [name of group health plan or health insurance issuer] designates one for you.] For information on how to select a primary care provider, and for a list of the participating primary care providers, contact the [plan administrator or issuer] at [insert contact information].

(B) For plans and issuers that require or allow for the designation of a primary care provider for a child, add:

For children, you may designate a pediatrician as the primary care provider.

(C) For plans and issuers that provide coverage for obstetric or gynecological care and require the designation by a participant, beneficiary, or enrollee of a primary care provider, add:

You do not need prior authorization from [name of group health plan or issuer] or from any other person (including a primary care provider) in order to obtain access to obstetrical or gynecological care from a health care professional in our network who specializes in obstetrics or gynecology. The health care professional, however, may be required to comply with certain procedures, including obtaining prior authorization for certain services, following a pre-approved treatment plan, or procedures for making referrals. For a list of participating health care professionals who specialize in obstetrics or gynecology, contact the [plan administrator or issuer] at [insert contact information].

(b) *Coverage of emergency services*—(1) *Scope.* If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, provides any benefits with respect to services in an emergency department of a hospital, the plan or issuer must cover emergency services (as defined in paragraph (b)(4)(ii) of this section) consistent with the rules of this paragraph (b).

(2) *General rules.* A plan or issuer subject to the requirements of this paragraph (b) must provide coverage for emergency services in the following manner—

(i) Without the need for any prior authorization determination, even if the emergency services are provided on an out-of-network basis;

(ii) Without regard to whether the health care provider furnishing the emergency services is a participating network provider with respect to the services;

(iii) If the emergency services are provided out of network, without imposing any administrative requirement or limitation on coverage that is more restrictive than the requirements or limitations that apply to emergency services received from in-network providers;

(iv) If the emergency services are provided out of network, by complying with the cost-sharing requirements of paragraph (b)(3) of this section; and

(v) Without regard to any other term or condition of the coverage, other than—

(A) The exclusion of or coordination of benefits;

(B) An affiliation or waiting period permitted under part 7 of ERISA, part A of title XXVII of the PHS Act, or chapter 100 of the Internal Revenue Code; or

(C) Applicable cost sharing.

(3) *Cost-sharing requirements*—(i) *Copayments and coinsurance.* Any cost-sharing requirement expressed as a copayment amount or coinsurance rate imposed with respect to a participant, beneficiary, or enrollee for out-of-network emergency services cannot exceed the cost-sharing requirement imposed with respect to a participant, beneficiary, or enrollee if the services were provided in-network. However, a participant, beneficiary, or enrollee may be required to pay, in addition to the in-network cost-sharing, the excess of the amount the out-of-network provider charges over the amount the plan or issuer is required to pay under this paragraph (b)(3)(i). A group health plan or health insurance issuer complies with the requirements of this paragraph (b)(3) if it provides benefits with respect to an emergency service in an amount equal to the greatest of the three amounts specified in paragraphs (b)(3)(i)(A), (b)(3)(i)(B), and (b)(3)(i)(C) of this section (which are adjusted for in-network cost-sharing requirements).

(A) The amount negotiated with in-network providers for the emergency service furnished, excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee. If there is more than one amount negotiated with in-network providers for the emergency service, the amount described under this paragraph (b)(3)(i)(A) is the median of these amounts, excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee. In determining the median described in the preceding sentence, the amount negotiated with each in-network provider is treated as a separate amount (even if the same amount is paid to more than one provider). If there is no per-service amount negotiated with in-network providers (such as under a capitation or other similar payment arrangement), the amount under this paragraph (b)(3)(i)(A) is disregarded.

(B) The amount for the emergency service calculated using the same method the plan generally uses to determine payments for out-of-network services (such as the usual, customary, and reasonable amount), excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee. The amount in this paragraph (b)(3)(i)(B) is determined without reduction for out-of-network cost sharing that generally applies under the plan or health insurance coverage with respect to out-of-network services. Thus, for example, if a plan generally pays 70 percent of the usual, customary, and reasonable amount for out-of-network services, the amount in this paragraph (b)(3)(i)(B) for an emergency service is the total (that is, 100 percent) of the usual, customary, and reasonable amount for the service, not reduced by the 30 percent coinsurance that would generally apply to out-of-network services (but reduced by the in-network copayment or coinsurance that the individual would be responsible for if the emergency service had been provided in-network).

(C) The amount that would be paid under Medicare (part A or part B of title XVIII of the Social Security Act, 42 U.S.C. 1395 *et seq.*) for the emergency service, excluding any in-network copayment or coinsurance imposed with respect to the participant, beneficiary, or enrollee.

(ii) *Other cost sharing.* Any cost-sharing requirement other than a copayment or coinsurance requirement (such as a deductible or out-of-pocket maximum) may be imposed with respect to emergency services provided out of network if the cost-sharing requirement generally applies to out-of-network benefits. A deductible may be imposed with respect to out-of-network emergency services only as part of a deductible that generally applies to out-of-network benefits. If an out-of-pocket maximum generally applies to out-of-network benefits, that out-of-pocket maximum must apply to out-of-network emergency services.

(iii) *Examples.* The rules of this paragraph (b)(3) are illustrated by the following examples. In all of these examples, the group health plan covers

benefits with respect to emergency services.

Example 1. (i) *Facts.* A group health plan imposes a 25% coinsurance responsibility on individuals who are furnished emergency services, whether provided in network or out of network. If a covered individual notifies the plan within two business days after the day an individual receives treatment in an emergency department, the plan reduces the coinsurance rate to 15%.

(ii) *Conclusion.* In this *Example 1,* the requirement to notify the plan in order to receive a reduction in the coinsurance rate does not violate the requirement that the plan cover emergency services without the need for any prior authorization determination. This is the result even if the plan required that it be notified before or at the time of receiving services at the emergency department in order to receive a reduction in the coinsurance rate.

Example 2. (i) *Facts.* A group health plan imposes a $60 copayment on emergency services without preauthorization, whether provided in network or out of network. If emergency services are preauthorized, the plan waives the copayment, even if it later determines the medical condition was not an emergency medical condition.

(ii) *Conclusion.* In this *Example 2,* by requiring an individual to pay more for emergency services if the individual does not obtain prior authorization, the plan violates the requirement that the plan cover emergency services without the need for any prior authorization determination. (By contrast, if, to have the copayment waived, the plan merely required that it be notified rather than a prior authorization, then the plan would not violate the requirement that the plan cover emergency services without the need for any prior authorization determination.)

Example 3. (i) *Facts.* A group health plan covers individuals who receive emergency services with respect to an emergency medical condition from an out-of-network provider. The plan has agreements with in-network providers with respect to a certain emergency service. Each provider has agreed to provide the service for a certain amount. Among all the providers for the service: one has agreed to accept $85, two have agreed to accept $100, two have agreed to accept $110, three have agreed to accept $120, and one has agreed to accept $150. Under the agreement, the plan agrees to pay the providers 80% of the agreed amount, with the individual receiving the service responsible for the remaining 20%.

(ii) *Conclusion.* In this *Example 3,* the values taken into account in determining the median are $85, $100, $100, $110, $110, $120, $120, $120, and $150. Therefore, the median amount among those agreed to for the emergency service is $110, and the amount under paragraph (b)(3)(i)(A) of this section is 80% of $110 ($88).

Example 4. (i) *Facts.* Same facts as *Example 3.* Subsequently, the plan adds another provider to its network, who has agreed to accept $150 for the emergency service.

(ii) *Conclusion.* In this *Example 4,* the median amount among those agreed to for the emergency service is $115. (Because there is no one middle amount, the median is the average of the two middle amounts, $110 and $120.) Accordingly, the amount under paragraph (b)(3)(i)(A) of this section is 80% of $115 ($92).

Example 5. (i) *Facts.* Same facts as *Example 4.* An individual covered by the plan receives the emergency service from an out-of-network provider, who charges $125 for the service. With respect to services provided by out-of-network providers generally, the plan reimburses covered individuals 50% of the reasonable amount charged by the provider for medical services. For this purpose, the reasonable amount for any service is based on information on charges by all providers collected by a third party, on a zip code by zip code basis, with the plan treating charges at a specified percentile as reasonable. For the emergency service received by the individual, the reasonable amount calculated using this method is $116. The amount that would be paid under Medicare for the emergency service, excluding any copayment or coinsurance for the service, is $80.

(ii) *Conclusion.* In this *Example 5,* the plan is responsible for paying $92.80, 80% of $116. The median amount among those agreed to for the emergency service is $115 and the amount the plan would pay is $92 (80% of $115); the amount calculated using the same method the plan uses to determine payments for out-of-network services—$116—excluding the in-network 20% coinsurance, is $92.80; and the Medicare payment is $80. Thus, the greatest amount is $92.80. The individual is responsible for the remaining $32.20 charged by the out-of-network provider.

Example 6. (i) *Facts.* Same facts as *Example 5.* The group health plan generally imposes a $250 deductible for in-network health care. With respect to all health care provided by out-of-network providers, the plan imposes a $500 deductible. (Covered in-network claims are credited against the deductible.) The individual has incurred and submitted $260 of covered claims prior to receiving the emergency service out of network.

(ii) *Conclusion.* In this *Example 6,* the plan is not responsible for paying anything with respect to the emergency service furnished by the out-of-network provider because the covered individual has not satisfied the higher deductible that applies generally to all health care provided out of network. However, the amount the individual is required to pay is credited against the deductible.

(4) *Definitions.* The definitions in this paragraph (b)(4) govern in applying the provisions of this paragraph (b).

(i) *Emergency medical condition.* The term *emergency medical condition* means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) so that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in a condition described in clause (i), (ii), or (iii) of section 1867(e)(1)(A) of the Social Security Act (42 U.S.C. 1395dd(e)(1)(A)). (In that provision of the Social Security Act, clause (i) refers to placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy; clause (ii) refers to serious impairment to bodily functions; and clause (iii) refers to serious dysfunction of any bodily organ or part.)

(ii) *Emergency services.* The term *emergency services* means, with respect to an emergency medical condition—

(A) A medical screening examination (as required under section 1867 of the Social Security Act, 42 U.S.C. 1395dd) that is within the capability of the emergency department of a hospital, including ancillary services routinely available to the emergency department to evaluate such emergency medical condition, and

(B) Such further medical examination and treatment, to the extent they are within the capabilities of the staff and facilities available at the hospital, as are required under section 1867 of the Social Security Act (42 U.S.C. 1395dd) to stabilize the patient.

(iii) *Stabilize.* The term *to stabilize,* with respect to an emergency medical condition (as defined in paragraph (b)(4)(i) of this section) has the meaning given in section 1867(e)(3) of the Social Security Act (42 U.S.C. 1395dd(e)(3)).

(c) *Applicability date.* The provisions of this section apply for plan years (in the individual market, policy years) beginning on or after September 23, 2010. *See* § 147.140 of this part for determining the application of this section to grandfathered health plans (providing that these rules regarding patient protections do not apply to grandfathered health plans).

[FR Doc. 2010–15278 Filed 6–22–10; 11:15 am]

BILLING CODE 4830–01–P, 4510–29–P, 4120–01–P

Federal Register

Friday,
July 30, 2010

Part II

Department of Health and Human Services

45 CFR Part 152
Pre-Existing Condition Insurance Plan Program; Interim Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 152

[OCIIO–9995–IFC]

RIN 0991–AB71

Pre-Existing Condition Insurance Plan Program

AGENCY: Office of Consumer Information and Insurance Oversight, OCIIO, Department of Health and Human Services, HHS.

ACTION: Interim final rule with comment period.

SUMMARY: Section 1101 of Title I of the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act) requires that the Secretary establish, either directly or through contracts with States or nonprofit private entities, a temporary high risk health insurance pool program to provide affordable health insurance coverage to uninsured individuals with pre-existing conditions. This program will continue until January 1, 2014, when Exchanges established under sections 1311 and 1321 of the Affordable Care Act will be available for individuals to obtain health insurance coverage. This interim final rule implements requirements in section 1101 of the Affordable Care Act. Key issues addressed in this interim final rule include administration of the program, eligibility and enrollment, benefits, premiums, funding, and appeals and oversight rules.

DATES: *Effective date:* This regulation is effective on July 30, 2010.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on September 28, 2010.

ADDRESSES: In commenting, please refer to file code OCIIO–9995–IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed)

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions under the "More Search Options" tab.

2. *By regular mail.* You may mail written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–OCIIO–IFC, P.O. Box 8010, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: OCIIO–9995–IFC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—
Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—
Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the "Collection of Information Requirements" section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Ariel Novick, (301) 492–4290.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will be also available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

A. General

Historically, public policy has addressed the challenges of people with pre-existing conditions through either high risk pools or insurance reform. In general, high risk pools provide coverage of last resort for people who, because of their health, are denied coverage by private insurers or are unable to purchase coverage in the individual market except at substantially surcharged premiums due to their health status, and are ineligible for public coverage (such as Medicare or Medicaid). Most States that permit insurers to decline coverage for health reasons have established high risk pools as an alternative coverage option in their individual market. These current pools provide safety net coverage for people who have difficulty obtaining individual health insurance because of their pre-existing conditions. First established in 1976, 35 State high risk pools currently provide coverage to approximately 200,000 individuals, or about one percent of the individual market nationwide, and vary in terms of the populations they cover and the benefits they provide.

States and the Congress through the Affordable Care Act have also elected to use insurance reforms to address the accessibility and availability of health insurance coverage for high risk populations. Seven States have adopted guaranteed issue to ensure access to coverage, and two States prohibit health status from being a factor in setting premiums.[1] The Patient Protection and Affordable Care Act of 2010, (the Affordable Care Act or "the Act"), Public Law 111–148 applies a ban on pre-existing condition exclusions and "rate-ups" based on health status starting in

[1] Kaiser Family Foundation, *State Health Facts. http://www.statehealthfacts.org/.*

2014 and prohibits the use of pre-existing condition exclusions for children starting in plan or policy years that begin on or after September 23, 2010.[2] This temporary Federal program provides coverage to uninsured Americans with pre-existing conditions until the Affordable Care Act is fully implemented in 2014.

B. Overview: Section 1101 of the Patient Protection and Affordable Care Act

The Affordable Care Act, was enacted on March 23, 2010. The Health Care and Education Reconciliation Act (the Reconciliation Act), Public Law 111–152, was enacted on March 30, 2010. Section 1101 of the Affordable Care Act requires that the Secretary of the Department of Health and Human Services (HHS) establish, either directly or through contracts with States or nonprofit private entities, a temporary high risk health insurance program to provide access to coverage for uninsured Americans with pre-existing conditions. (Hereafter, we generally refer to this program as the Pre-Existing Condition Insurance Plan program, or PCIP program, to avoid confusion with the existing State high risk pool programs, which will continue to operate separately.)

The PCIP program is intended to remain in place from the time of its establishment until the Exchanges established under sections 1311 or 1321 of the Act go into effect on January 1, 2014. This interim final regulation sets policy only for this unique, temporary Federal program with fixed Federal funding. Presented below is a general overview of the statutory requirements for the new program. More detailed descriptions of the specific requirements are included below as part of the discussion of the associated regulatory provisions set forth in this interim final rule.

II. Provisions of the Interim Final Rule

A. General Provisions (Subpart A, § 152.1 Through § 152.2)

Section 152.1 of this interim final rule specifies the general statutory authority for the ensuing regulations and the scope of the program, consistent with section 1101 of the Act. Section 152.2 provides definitions for terms that appear throughout these regulations. Generally, the definitions are self-explanatory or taken directly from section 1101 of the statute. The definitions set forth in subpart A apply to all of part 152 unless otherwise indicated and are applicable only for purposes of part 152.

The definition of "pre-existing condition exclusion" warrants a brief discussion. First, it is important to note that this definition applies only for purposes of the prohibition in section 1101(c)(2)(A) on a PCIP "impos[ing] any preexisting condition exclusion" under the coverage provided (an important protection for a program designed to offer coverage to those with a pre-existing condition), and is separate from the "guidelines" that determine pre-existing condition status under section 1101(d)(2)(3) for purposes of eligibility for enrollment in a PCIP. These latter eligibility provisions are set forth in subpart C of this rule, under section 152.14.

State laws vary with regard to the definition of a pre-existing condition exclusion. For purposes of defining a pre-existing condition exclusion, we adopted the definition of pre-existing condition currently used in the group market under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). We also took into account section 1201 of the Affordable Care Act, which prohibits denials of coverage because of a pre-existing condition. Thus, we specify that pre-existing condition exclusion has the same meaning as under 45 CFR 144.103. That is, the term refers to a denial of coverage, or limitation or exclusion of benefits, based on the fact that the individual denied coverage or benefits had a health condition that was present before the date of enrollment for the coverage (or a denial of enrollment), whether or not any medical advice, diagnosis, care, or treatment was recommended or received before that date. This would include exclusions stemming from a condition identified via a pre-enrollment questionnaire or physical examination, or the review of medical records during the pre-enrollment period.

B. PCIP Program Administration (Subpart B, § 152.6 and § 152.7)

As noted above, section 1101(b) of the Affordable Care Act provides that HHS may "carry out" the temporary high risk health insurance pool program either directly or through contracts with eligible entities, which are States and non-profit entities. Eligible entities must submit a proposal to carry out a PCIP in a time and manner, and containing such information, that the Secretary requires. Section 152.6 establishes the general rules for administration through either a State or by HHS through a non-profit private entity. Section 152.7 then describes the proposal process and specifies that in order to contract with HHS, the eligible entity's proposal must demonstrate capability to perform all functions necessary for the design and operation of a PCIP, and that its proposed PCIP is in full compliance with all of the requirements of this part.

These standards establish minimum requirements for PCIPs, and are supplemented by other requirements detailed in solicitation documents (such as the descriptions of the outreach plan and consumer information resources that each PCIP will establish) and incorporated into the final contracts with HHS.

B. Eligibility and Enrollment (Subpart C, § 152.14 Through § 152.15)

Section 1101(d) of the Affordable Care Act provides the basic eligibility criteria for the PCIP program, which are set forth under § 152.14. In addition, consistent with the Secretary's general authority under section 1101(c)(2)(D) of the Act to establish requirements for a PCIP, we set forth enrollment and disenrollment requirements in § 152.15.

Eligibility for the PCIP Program (§ 152.14)

Under section 1101(d) of the Affordable Care Act and subparagraphs (1), (2) and (3) of § 152.14(a) of this interim final rule, an individual is eligible to enroll in a PCIP if he or she: (1) Is a citizen or national of the United States or is lawfully present in the United States as determined in accordance with section 1411 of the Affordable Care Act; (2) has not been covered under creditable coverage, as defined in section 2701(c)(1) of the Public Health Service Act as of the date of enactment, during the 6-month period prior to the date on which he or she is applying for coverage through the PCIP; and (3) has a pre-existing condition, as determined in a manner consistent with guidance issued by the Secretary. We further provide in § 152.14(a)(4) that an individual must be a resident of a State that falls within the service area of a PCIP.

Eligibility Conditioned on Citizenship and Immigration Status

Eligibility for the PCIP program is limited to citizens or nationals of the United States and individuals who are lawfully present in the United States. For the purpose of this regulation, lawfully present has the meaning presently used under the Children's Health Insurance Program, provided in the State Health Official letter issued by

[2] These provisions do not apply to "grandfathered" plans. For a description of these provisions, see the interim final regulations implementing 2719A (regarding patient protections), published in the **Federal Register** on June 28, 2010 (75 FR 37188).

the Centers for Medicare and Medicaid Services (CMS) on July 1, 2010. Section 1101(d)(1) directs the Secretary to make a determination of citizenship and immigration status in accordance with section 1411 of the Act, which describes procedures to be employed for determining eligibility for the Exchanges and provides for these procedures also to be used in determining eligibility for the PCIP program. This section sets forth detailed requirements governing the type of information that applicants must provide and specific verification procedures that the Secretary of Health and Human Services, Commissioner of Social Security, and Secretary of Homeland Security would be required to follow to establish eligibility. Section 1411(c)(4) of the Affordable Care Act further provides that the Secretary shall conduct verifications and determinations "through the use of an on-line system or otherwise for the electronic submission of, and response to, the information submitted * * * with respect to an applicant," or by "such other method as is approved by the Secretary" that determines "the consistency of the information submitted with the information maintained in the records of the Secretary of the Treasury, the Secretary of Homeland Security, and the Commissioner of Social Security".

Under this authority, § 152.15(a)(3) specifies that a PCIP must verify that an individual is a United States citizen or national, or lawfully present in the United States. A PCIP can verify an individual's citizenship or immigration status through the Social Security Administration or, if applicable, the Department of Homeland Security. In many cases, States may be able to automate verification of citizenship and immigration status by leveraging existing data exchanges that are currently in place for other programs, such as Medicaid and the Children's Health Insurance Program. The Department of Homeland Security's U.S. Citizenship and Immigration Services (USCIS) Systematic Alien Verification for Entitlements (SAVE) program provides online system to verify an individual's immigration status. States can access this system after entering into the necessary Memorandum of Understanding with USCIS. An automated verification process will be used in all States where HHS is administering the PCIP program.

Some States are not able to have an automated "on-line system" or "electronic" process in place when they start accepting enrollments into their PCIPs. Therefore, these regulations provide, as an "alternative method" approved by the Secretary, that a PCIP program may instead require the individual to provide documentation that establishes citizenship or immigration status. Subject to HHS approval, States using documentation procedures may switch to an automated system in the future. If a PCIP shares such information with the Social Security Administration or the Department of Homeland Security, consistent with the Privacy Act, the regulation specifies that a PCIP must include a disclosure that the information provided on the enrollment request may be shared with other government agencies for purposes of establishing eligibility. The type(s) of documentation PCIPs may use is subject to approval by HHS under the terms of the contract.

Eligibility Based on a 6-Month Period Without Insurance Coverage

Eligibility for the PCIP program is limited to individuals with no creditable coverage during the 6-month period prior to the date on which they apply for coverage through the PCIP. Section 2701(c)(1) of the Public Health Service Act on the date of enactment and 45 CFR § 146.113(a)(1) define creditable coverage as coverage of an individual under a group health plan, health insurance coverage as defined at 45 CFR 144.103, Medicare Part A or Part B, Medicaid, the Children's Health Insurance Program, the TRICARE program, a medical care program of the Indian Health Service or of a tribal organization, a State health benefits risk pool (that is, existing State high risk pool), the Federal Employee Health Benefits program, a public health plan (for example, coverage through the Veterans Administration), or a health benefit plan offered under section 5(e) of the Peace Corps Act. Such creditable coverage includes health coverage provided to certain former employees, retirees, spouses, former spouses, and dependent children who are entitled to temporary continuation of health coverage at group rates under the Consolidated Omnibus Reconciliation Act of 1985 (COBRA). We specify under § 152.14(b)(3) that if an individual has already satisfied the requirement for a 6-month period without creditable coverage in connection with qualifying for a given PCIP under section 1101 of the Act, the individual will be considered to have satisfied this eligibility requirement for purposes of a PCIP in another State, if such individual moves to a different State and wishes to enroll in that State's PCIP.

In light of the unique circumstances presented by infants who are less than six months old, the Department will issue guidance on how the requirement that the individual not have had creditable coverage during the six-month period prior to the application for the PCIP program applies to and can be satisfied by such infants. Factors to be considered in this guidance include whether coverage in the hospital under the mother's plan at birth counts, current practices regarding insurers' coverage of newborns, and the anti-dumping rules that direct the Secretary to prevent disenrollment of individuals from existing insurance due to their health status.

Eligibility Based on Having a Pre-Existing Condition

Under section 1101(d)(3), eligibility for the PCIP program is conditioned on individuals having a pre-existing condition, as "determined in a manner consistent with guidance issued by the Secretary." We specify at § 152.14(c)(1) that a PCIP in a State, or the PCIP run by a non-profit in States that are not carrying out the PCIP program, may determine that an individual has a pre-existing condition, for purposes of PCIP eligibility, based on satisfying any one or more of the following criteria, subject to HHS approval: (1) The individual provides documented evidence that an insurer has refused, or has provided clear indication that it would refuse, to issue individual coverage on grounds related to the individual's health; (2) the individual provides documented evidence that he or she has been offered individual coverage but only with a rider that excludes coverage of benefits associated with a pre-existing condition; (3) the individual provides documented evidence that he or she has a medical or health condition specified by the State and approved by the Secretary; or (4) other criteria as defined by the PCIP and approved by HHS.

We believe that these criteria are fully consistent with the intent of section 1101(d)(3) of the Act and address the problems that individuals with pre-existing conditions face when applying for insurance coverage in the individual market. That is, individuals with pre-existing conditions are often unable to obtain coverage for reasons that include an outright denial and an exclusion of coverage for the pre-existing condition. This includes instances when an individual applies for coverage and is informed by the carrier's representative or Web site that they would be denied for coverage by the carrier due to the pre-existing condition. Providing States and non-profit entities operating a PCIP

the option of using these manifestations of having a pre-existing condition, rather than relying on a list of medical conditions, is consistent with the PCIP program goal of covering people who both have a pre-existing condition and otherwise cannot access insurance. We note that in some cases, individuals with pre-existing conditions are unable to obtain outright written coverage denials, but instead are told that carriers will not accept their applications. These regulations will permit PCIPs to exercise flexibility in determining exactly what type of communication constitutes a refusal to issue coverage.

Under § 152.14(c)(3), we specify that a PCIP may determine that an individual has a pre-existing condition based on evidence of the existence or history of certain medical or health conditions, as approved by the Secretary. This provision comports with our intention to permit the continuing use of eligibility standards that States use in their existing high risk pools, and permits a State that has guaranteed issue and community rated premiums to use an alternative test to showing a denial of coverage.

Finally, we provide at § 152.14(c)(4) that HHS may approve other criteria for meeting the definition of pre-existing condition under a given PCIP.

We anticipate that the first two criteria will be used in all States where individuals may be denied coverage or offered coverage with exclusionary riders. In the PCIP program serving States that have elected not to play a role in operating a PCIP program, only the first two criteria will be used, except with respect to individuals who are guaranteed to be issued a policy. PCIPs administered by States or non-profit entities may choose to utilize the additional criteria with HHS approval.

Eligibility for a PCIP Conditioned on Residing in the Plan's Service Area

Eligibility for a PCIP is limited to individuals who reside in the service area of the PCIP. At § 152.14(a)(4), we provide that an individual must be a resident of one of the 50 States or the District of Columbia which constitutes or is within the service area of the PCIP.

The statute explicitly acknowledges the role of a State (defined in section 1304(d) of the Act as the 50 States and the District of Columbia) with respect to the administration of PCIP, with no reference to "Territories" (see 1101(b)(2) and (3), 1101(e)(3), 1101(g)(3)(A) and (5)). Unlike section 1204(a) of the Health Care and Education Reconciliation Act of 2010, (which amended the Affordable Care Act and clearly specified a role for territories in the operation of Exchanges), the Congress made no similar reference to Territories in connection with the PCIP program.

Enrollment and Disenrollment Process (§ 152.15)

Under our authority in section 1101(c)(2)(D) of the Act to impose "appropriate" requirements that PCIPs would be required to meet, § 152.15(a) and (b) require PCIPs to establish a process for enrolling and disenrolling individuals that is approved by HHS. Our intent is to permit the use of established enrollment policies and procedures in place under existing State high risk pools, to the extent that they are consistent with the statute.

Section 152.15(a)(2) of this interim final rule specifies that a PCIP must allow an individual to remain enrolled unless the individual is disenrolled under specified circumstances (for example, the individual moves out of the service area or obtains other creditable coverage) or the PCIP program is terminated. Our intent is to promote continuity of coverage for individuals who enroll in a PCIP until they are able to obtain coverage through the Exchange, under which participating insurers cannot exclude individuals with pre-existing conditions. We understand, however, that to the extent individuals can obtain other coverage, for example, by becoming entitled to Medicare or enrolling in employer-based health insurance, such coverage would obviate the need for coverage provided by the PCIP. Leveraging the availability of such coverage, by exiting the PCIP, enables other qualified individuals to enroll.

A PCIP is required to establish, consistent with § 152.15(b) of this interim final rule, a disenrollment process that is approved by HHS. As noted above, we seek to support States' ability to participate in this program by allowing them to adopt policies and procedures in use under existing high risk pool programs. We understand that current practice in State high risk pools is that an individual who does not pay his or her premiums on a timely basis may be disenrolled. We provide in § 152.15(b)(2) that, under these circumstances, the enrollee will receive sufficient notice and reasonable grace period for payment prior to any disenrollment taking effect not to exceed 61 days (the longest period currently provided for by States). The consequence of failing to pay premiums and any subsequent disenrollment is that an individual loses access to coverage and may not be able to re-enroll for 6 months. Thus, we believe that it is the PCIP's responsibility to inform its enrollees prior to making a disenrollment effective. There are other circumstances in which involuntary disenrollment is appropriate and thus we establish at § 152.15(b)(3) that a PCIP must disenroll an individual in cases of death, where an individual obtains creditable coverage or no longer resides in the PCIP's service area, and other exceptional circumstances as established by HHS. We envision that such circumstances would include cases of fraud or intentional misrepresentation of material fact, and it is our intent to work with PCIPs to develop policies in these areas via sub-regulatory guidance. As we explain under our discussion of eligibility, an individual who is disenrolled because he or she no longer resides in the service area of a PCIP does not have to satisfy another 6-month continuous period without creditable coverage before applying to enroll in a PCIP in the new State of residence.

Section 152.15(c) requires that a PCIP establish rules governing effective dates of enrollments and disenrollments. In particular, a PCIP program must specify the deadline for receiving an enrollment application that would take effect on the first of the following month. In general, an individual who submits a complete enrollment request by an eligible individual by the 15th day of a month could access coverage by the 1st day of the following month. Exceptions to this policy will be subject to approval by HHS.

Finally, given the capped appropriation for this program, we recognize that PCIPs need sufficient programmatic flexibility to manage their costs and enrollment, to help ensure that the PCIP program's funding allocation is sufficient to cover claims and other program costs for the entire duration of the program. Thus, we establish authority under § 152.15(d) for a PCIP program to employ strategies to manage enrollment over the course of the program that may include enrollment capacity limits, phased-in (delayed) enrollment, premium and benefit adjustments that indirectly affect enrollment, and other measures, as defined by the PCIP and approved by HHS.

Benefits—(Subpart D, Sections 152.19 Through 152.22)

Covered Benefits (§ 152.19)

Required Benefits (§ 152.19(a))

The required benefit list in § 152.19(a) builds off of the essential health benefits under the new section 2707 of the Public Health Service Act, as enacted in the Affordable Care Act, for which

guidance has yet to be issued. The list is consistent with the most commonly covered services offered in existing State high risk pools, according to a survey conducted by the National Association of State Comprehensive Health Insurance Plans (NASCHIP) in 2009. Its benefits are also parallel to the benefits offered by the Federal Employees Health Benefits Plan (FEHBP).

Excluded Services (§ 152.19(b))

Section 152.19(b) sets forth a list of services that shall not be covered by any PCIP. While the specific benefits to be included and excluded by any PCIP are generally subject to HHS approval and review through the PCIP contracting process, this excluded services list addresses several areas where providing coverage is unequivocally prohibited. This list of excluded services parallels that of FEHBP.

The subject of Federal funding of abortion services with respect to the Affordable Care Act was addressed in the Executive Order issued by the President on March 24, 2010: The enactment of the Affordable Care Act left in place current restrictions that prohibit the use of Federal funds for abortion services, except in cases of rape or incest, or where the life of the woman would be endangered. Exec. Order No. 13,535, 75 FR 15,599 (Mar. 24, 2010). These restrictions currently apply to certain Federal programs that are similar to the PCIP program. The PCIP program is Federally-created, funded, and administered (whether directly or through contract); it is a temporary Federal insurance program in which the risk is borne by the Federal government up to a fixed appropriation. As such, the services covered by the PCIP program shall not include abortion services except in the case of rape or incest, or where the life of the woman would be endangered.

Pre-Existing Conditions Exclusions (§ 152.20)

Section 1101(c)(2)(A) of the Act requires that a PCIP established under this section not impose any pre-existing condition exclusions with respect to covered services. The Health Insurance Portability and Accountability Act of 1996 (HIPAA) includes limitations for pre-existing conditions in the group market. This protection was expanded under section 1201 of the Affordable Care Act, which prohibits any pre-existing condition exclusions from being imposed by group health plans or group and individual health insurance coverage beginning January 1, 2014. The interim final rules issued pursuant to section 2704 of the Public Health Service Act (as amended by the Affordable Care Act) under § 147 adopt, with minor modifications, the definition of pre-existing condition currently used under HIPAA.

Similarly, our rule prohibits PCIPs from applying any pre-existing condition exclusion to covered services, and consistent with the regulations implementing section 1201 of the Act, defines a pre-existing condition exclusion as a limitation or exclusion of benefits based on the fact that the condition was present before the date of enrollment in coverage (or a denial of enrollment), whether or not any medical advice, diagnosis, care, or treatment was recommended or received before that date.

Pursuant to the authority provided to the Secretary under section 1101(c)(2)(D), this interim final rule also prohibits PCIPs from imposing any type of coverage waiting period upon eligible individuals. For purposes of this rule, a waiting period is defined as the period immediately following the effective date of enrollment in which some or all benefits in the coverage are not provided. Accordingly, once an individual is enrolled in a PCIP consistent with the rules set forth in subpart C, full coverage must be provided to the individual starting with the effective date of enrollment.

Premiums and Cost-Sharing (§ 152.21)

Standard Rate

Section 1101(c)(2)(C)(iii) of the Act requires that premium rates charged for coverage under the high risk pool program be established at "a standard rate for a standard population". The National Association of Insurance Commissioners (NAIC) Model Health Plan for Uninsurable Individuals Act suggests that high risk pool plans "determine a standard risk rate by considering the premium rates charged by other insurers offering health insurance coverage to individuals." Furthermore, section 2245(g)(2) of the Public Health Service Act (PHSA), which governs the existing Federal high risk pool grant program, defines the "standard risk rate" for the high risk pools to mean a rate that: (1) Is determined under the State high risk pool by considering the premium rates charged by other health insurers offering health insurance coverage to individuals in the insurance market served; (2) is established using reasonable actuarial techniques; and (3) reflects anticipated claims experience and expenses for the coverage involved.

In keeping with the methodology suggested by the NAIC Model Act and the Federal grant program, § 152.21 of this interim final rule generally interprets the phrase "standard rate for a standard population" to refer to the premium rates offered in the individual market in a given State. While existing State high risk pools' premiums vary between 105–250 percent of the standard rate of the individual market, the Act requires that premiums in the PCIP program be at the standard rate, rather than a higher proportion of that rate. Therefore, this rule provides that a PCIP established under this section must not offer enrollees premiums at a rate that exceeds 100 percent of the standard individual market rate in the PCIP service area.

This interim final rule does not mandate a specific formula for calculating the standard rate. Instead, we specify that a PCIP may calculate the standard rate using reasonable actuarial techniques, as approved by the Secretary, that reflect anticipated experience and expenses. This requirement should accommodate reasonable variations in the methods that PCIPs may use to calculate a standard risk rate.

We also recognize that individual market rates in each State can vary as a consequence of individual State insurance laws. For example, some States require that insurers issue all applicants a policy or offer coverage at a community rate. In such situations, the standard individual rate may be considerably higher than in a State that permits insurers to reject applicants or set premiums on the basis of health status or other factors. To account for these variations, § 152.21(a) of these rules provides that, subject to approval by HHS, a PCIP may use other methods of determining the standard rate in the State. The exact methodology must be submitted and approved through the proposal process as specified in § 152.8 of this part.

Premium Variation

Section 1101(c)(2)(C)(ii) of the Act specifies that premium rates in a PCIP can vary on the basis of age by a factor not greater than 4 to 1. Section 2701(a)(3) of the PHSA as amended by the Affordable Care Act requires HHS, in consultation with NAIC, to define permissible age bands for rating purposes in the individual and group markets. However, the rating bands established under section 2701 will not be effective until January 1, 2014, and no such requirement exists for the PCIP program. Given these factors, this rule does not establish standard age bands

for the PCIP program beyond the statutory requirements. Thus, § 152.21(a)(2) of this rule simply follows the statutory requirement of section 1101(c)(2)(C)(ii) of the Act and provides that premiums charged in the PCIP can vary by age on a factor of not greater than 4 to 1. Specific age band rating will be established through the PCIP contracting process.

Section 1101(c)(2)(C)(i) of the Act requires that premiums in the PCIP program may vary only as provided under section 2701 of the PHSA, other than what is allowed in section 1101. Section 2701 permits premiums rates to vary in the individual and group markets by a finite number of factors. Gender rating, for example, is prohibited in the PCIP program.

Limits on Enrollee Costs

Section 1101(c)(2)(B) of the Act sets limits on enrollee costs in the PCIP program. Specifically, the issuer's share of the total allowed costs of benefits provided under such coverage cannot be less than 65 percent of such costs, subject to actuarial review and approval by the Secretary. Section 152.21(b)(1) of this rule provides that coverage under a plan offered by a PCIP must at a minimum meet this 65 percent threshold.

Section 1101(c)(2)(B)(ii) of the Act requires that coverage provided by PCIPs not have an out-of-pocket limit greater than the applicable amount described in section 223(c)(2) of the Internal Revenue Code, which sets the out-of-pocket limit for high deductible health plans associated with a tax favored health savings accounts. (This amount is $5,950 for 2010.) Under § 152.2, we define out-of-pocket costs as the sum of the annual deductible and the other annual out-of-pocket expenses, other than for premiums, required to be paid under the plan. Section 152.21(b)(2) also notes that, consistent with IRS rules, the out-of-pocket limit may be applied only for in-network providers, consistent with the terms of PCIP plan benefit package.

Access to Services (§ 152.22)

As noted above, section 1101(c)(2)(D) of the Act provides that coverage offered via a PCIP must meet any other requirements determined appropriate by the Secretary of HHS. Section 152.22 provides that the PCIP may specify the network of providers from whom enrollees may obtain services, provided that the PCIP demonstrates to HHS that it has a sufficient number and range of providers to ensure that all covered services are reasonably available and accessible under such coverage. Section 152.22(b) makes clear that, in the case of emergency room services, such services must be covered out of network and out of area if (1) the enrollee had a reasonable concern that failure to obtain immediate treatment could present a serious risk to his or her life or health; and (2) the services were required to assess whether a condition requiring immediate treatment exists, or to provide such immediate treatment where warranted. We believe these requirements are in keeping with generally accepted standards with respect to the provision of emergency services in plans with network limits, such as those in place in the Medicare Advantage program under title XVIII of the Social Security Act and the commercial health insurance market.

E. Oversight (Subpart E, Sections 152.26 Through 152.28)

Appeals Procedures (§ 152.26)

Section 1101(f)(1) of the Act requires the establishment of an appeals process to enable individuals to appeal determinations under the PCIP program. We are interpreting this provision to apply both to determinations with respect to benefit coverage determinations and determinations with respect to an individual's eligibility for the program, including whether an individual is a citizen or national of the United States, or lawfully present in the United States.

Rather than establishing detailed, proscriptive requirements with respect to appeals procedures, § 152.26 of this interim final rule establishes minimum requirements that all PCIPS must meet. Section 152.26(b) specifies that a PCIP must provide for a timely redetermination of an eligibility or coverage determination; coverage determinations include both whether an item or service is covered and the amount paid by the PCIP. For coverage determinations, § 152.26(b)(3) further specifies that an enrollee has the right to a timely second-level appeal, or "reconsideration," by an independent entity.

The requirement for independent review of a plan's coverage redetermination ensures that the entity providing the reconsideration would have no stake of any kind in the outcome, and was not involved in the initial or reconsidered determination being reviewed. This requirement could be satisfied under a variety of arrangements, including (1) An existing appeal mechanism provided for under State law; (2) in the case of a State-administered PCIP, a review process created by the State; or (3) an independent contractor, such as the independent review entities with which HHS contracts to review coverage determinations under the Medicare program.

These requirements are intended to permit States to use existing appeals or review mechanisms provided for under State law, and to permit other non-profit entities to utilize their existing internal appeals mechanisms. The actual appeals mechanisms will be subject to the Secretary's approval as part of the contracting process. Given both the temporary nature of the program and the statutory implementation timeframe for the new program, we believe that using these existing mechanisms is necessary and appropriate.

Fraud, Waste, and Abuse (§ 152.27)

Section 1101(f)(2) of the Affordable Care Act requires the Secretary to establish procedures to protect against fraud, waste, and abuse. To that end, § 152.27(a) of this interim final rule requires the PCIP to develop, implement, and execute operating procedures to prevent, detect, recover payments (when applicable or allowable), and promptly report to HHS incidences of waste, fraud, and abuse. These procedures are required to include identifying situations in which enrollees, potential enrollees, or their family members had access to employer-based coverage, and may have been discouraged from enrolling in that coverage. Should HHS become aware of instances involving fraud, waste, or abuse within the PCIP's operation, HHS will take appropriate action within the terms of the contract, or as otherwise provided by law. As stated in § 152.27(b), the PCIP shall cooperate with Federal law enforcement and oversight authorities in cases involving waste, fraud and abuse, and shall report cases in which an individual may have been discouraged from enrolling in other coverage to appropriate authorities. For example, if the coverage was an employer group health plan subject to ERISA, which prohibits discrimination based on health status, the matter should be reported to the Department of Labor for investigation and possible enforcement action.

Preventing Insurer Dumping (§ 152.28)

There is an incentive for employers and issuers to single out high risk and thus high-cost individuals and offer incentives for them to disenroll from their coverage and obtain coverage in PCIPs which offer such individuals guaranteed access to coverage without pre-existing condition exclusion at a standard premium, if they are uninsured

for at least six months. Congress recognized this potential issue and directed the Secretary under section 1101(e)(2) of the Act to establish criteria for determining whether health insurance issuers and employment-based health plans have discouraged individuals from remaining enrolled in prior coverage based on the health status of those individuals, and specifies certain criteria that shall be included in those established by the Secretary. Section 152.28 of this interim final rule thus sets forth these criteria, and requires that PCIPs establish procedures to identify and report to HHS instances where health insurance issuers or group health plans are discouraging high-risk individuals from remaining enrolled in their current coverage, in instances where such individuals subsequently are eligible to enroll in the PCIP.

Consistent with section 1101(e)(2) of the Affordable Care Act, section 152.28(c) of the interim final rule provides that if, in applying the criteria in section 152.28(b), it is determined that a dumping under section 152.28(a) has occurred, the Secretary may bill the issuer or group health plan for any medical expenses incurred by the PCIP for such enrollees. In these situations, the interim final rule also makes clear that the issuer or group health plan will be referred to appropriate Federal and State authorities for other enforcement action that may be warranted depending on the facts and circumstances. Finally, section 152.28(d) specifies that nothing in the subsection may be construed as constituting exclusive remedies for violations of the section or preventing States from applying or enforcing this section or other provisions of law with respect to health insurance issuers, consistent with section 1101(c)(3) of the Affordable Care Act. Additional guidance will be issued to prevent "dumping" from public programs like Medicaid and the Children's Health Insurance Program.

F. Funding (Subpart F, Sections 152.32 Through 152.35)

Use of Funds (§ 152.32)

Section 1101(g) of the Affordable Care Act appropriates $5,000,000,000 to pay the claims and administrative costs of the PCIP program established under this section that are in excess of the amount of premiums collected from enrollees. Traditionally, in State high risk pools, as well as other insurance programs, the funds collected from enrollees as premiums and other funding streams are expended across two chief areas. The majority of funds collected as premiums are expended to pay the health expenses for covered services incurred by enrollees. Administrative expenses, the costs of operating the program, make up the second major expense category. Section 152.32(a) of this interim final rule thus provides that all funds awarded under this program must be used exclusively to pay the allowable claims and administrative costs of a PCIP established under this section. Such costs include those incurred in the development and operation of the PCIP program, to the extent that those costs are in excess of the amounts or premiums collected from individuals enrolled in the program. PCIP program funds are not available for any other uses, such as to pay expenses or defray premiums of existing State high risk pools.

Although the Act does not specify the amount that a PCIP can spend on administrative expenses, § 152.32(b) of this rule permits PCIPs to spend no more than 10 percent of its total allotted funds towards administrative expenses. The 10 percent limitation is similar to what is imposed under the Children's Health Insurance Program (CHIP). Typical examples of the types of administrative costs and expenses that we expect to be incurred by PCIPs include: Start-up and program implementation activities, the production and distribution of information and outreach materials, eligibility determination and enrollment processing, claims processing, costs associated with prevention and detection of fraud, waste and abuse, and other ancillary services such as operation of a customer service call center, account maintenance, and appeals. We note that, given the start-up costs for the new PCIPs established under this program, and the need for expeditious implementation, this 10 percent cap applies to the total allotment for the duration of the program, as opposed to spending in a given year.

Initial Allocation of Funds (§ 152.33)

Section 1101(g) of the Act does not specify exactly how HHS should allocate funds for the purpose of this program. At the outset of the program, as specified under section 152.33, the Secretary has established initial allotment ceilings for PCIPs in each State using a methodology consistent with the funding allocation methodology used in CHIP, as set forth under 42 CFR Part 457, subpart F, Payment to States. (Note that, subject to these allocation ceilings, the estimated funding amounts available under the PCIP program contracts are established through the contracting process based on the projected number of PCIP enrollees and their projected claims costs. Actual payments to PCIPs will be based on their reported cost statements during the life of the contract.)

Thus, the initial ceilings on PCIP funding allocations are based on a blended formula based on the State population, number of uninsured individuals under 65, and geographic health care costs. Under this formula, one half of the available funds are allocated based on the number of the nonelderly population in each State, compared to the total U.S. nonelderly population. This gives more populous States more funding and does not penalize those States that employ mechanisms to reduce the number of uninsured persons in their States.

The health care cost index that HHS will use to adjust the funding allocations will be based on the wages of employees in the health services industry, and is consistent with what we have used under the Children's Health Insurance Program. These wage data were developed by the Bureau of Labor Statistics of the Department of Labor through its Quarterly Census of Employment and Wages. This will include a weighted average of the wages in the health services industry represented by ambulatory health care services, hospitals, and nursing and residential care facilities. As in the CHIP formula, 15 percent of the cost factor is held constant, while 85 percent reflects how each State's average wage compares to the U.S. average. In order to insure that the geographic variation and cost adjustments accurately reflect statistics on population and the number of uninsured, the same year of data will be used to calculate population, number of uninsured, geographic health care costs, and cost adjustments.

Reallocation of Funds (§ 152.34)

As noted above, over time, spending under the PCIP program will be determined based on the actual enrollment and cost experience of the PCIPs across the country. Thus, we recognize that there may be a need to reallocate funds if actual experience indicates that, in a given State, not all of funds available under the allocation formula will be used. Section 152.34 accounts for this possibility by giving HHS explicit authority to reallocate funds among States if HHS determines that the PCIP in a given State will not make use of the total estimated funding originally allotted to that State. HHS will be receiving monthly reports on the program costs of each PCIP and will consult closely with PCIPs in evaluating these reports and making any decisions

with respect to the need for reallocations.

Insufficient Funds (§ 152.35)

Section 1101(g)(2) of the Affordable Care Act states that if HHS estimates for any fiscal year that the aggregate amounts available for the payment of the expenses of the high risk pool will be less than the actual amount of such expenses, HHS shall make such adjustments as are necessary to eliminate this deficit. Further, section 1101(g)(4) of this Act states that HHS has the authority to stop taking applications for participation in the program to comply with the funding limitations. Accordingly, § 152.35(c) of this rule provides that the PCIP, subject to HHS approval, may adjust premiums, alter required benefits, limit PCIP applications or take other measures to eliminate a projected deficit. Particularly in view of the capped appropriation for the PCIP program, HHS is committed to working very closely with the PCIPs to monitor PCIP enrollment and claims experience. To that end, the PCIP contracts include detailed reporting responsibilities with respect to PCIP enrollment and spending, as well as spelling out PCIP responsibilities for the development of mitigation strategies and recommended adjustments should the amounts available under a contract be less than the projected expenses. Lastly, § 152.35(d) ensures that, if the Secretary estimates that aggregate amounts available for PCIP expenses will be less than the actual amount of expenses, HHS reserves the right to make such adjustments as are necessary to eliminate such deficit, consistent with the terms of the PCIP contract.

G. Relationship to Existing Laws and Programs (Subpart G, § 152.39 Through § 152.40)

Relationship to Other Federal Health Insurance Regulation

We note that subtitles A and C of Title I of the Affordable Care Act contain new requirements that apply to group health plans and issuers of health insurance in the individual health insurance market which are governed by title XXVII of the PHSA. Some of these provisions address the same areas as the above provisions in section 1101 governing the PCIP program (*e.g.*, premium amounts, beneficiary out-of-pocket expenses, and pre-existing conditions). These insurance reforms do not apply to the PCIP established under section 1101 of the Affordable Care Act and implemented in this interim final rule since the high risk pools do not meet the definition of a group health plan or a health insurance issuer pursuant to sections 2791(a)(1) and 2791(b)(2) of the PHS Act.

Maintenance of Effort (§ 152.39)

Section 1101(b)(3) of the new law imposes a maintenance of effort requirement, which specifies that in order for a State to enter into a contract to administer a PCIP, a State must agree not to reduce the annual amount it expended on the operation of an existing State high risk pool in the year preceding the year in which a PCIP contract begins. We believe that the clear intent of this provision is to prohibit the shifting of costs of existing State high risk pools to the Federal government. The maintenance of effort requirement both ensures that the fixed $5 billion in funding is used to meet the PCIP program goals and also reinforces the limitation of eligibility to individuals who are uninsured, as opposed to those already insured through a State high risk pool. At the same time, we recognize that States now use different sources of funds to support the operation of existing high risk pools. For example, many States rely upon assessments on the health insurance industry or health insurance providers to support their high risk pools, and States also commonly allow insurers to reduce premium tax payments by all or a percentage of such assessment.

Given the various funding models that are now in place in different States, we believe it is appropriate to permit States some latitude in terms of ways in which they can satisfy this requirement subject to Secretarial approval. Accordingly, section 152.39(a) specifies that in order for a State to enter into a contract with the Secretary it must comply with the maintenance of effort requirement set forth in section 1101(b)(3) of the Affordable Care Act in a manner approved by the Secretary. We anticipate that permissible methods of meeting this requirement would include, but are not limited to, maintaining either the total amount or the total per capita amount of State funding for the operation of an existing high risk pool (given that a State would be maintaining its effort per enrollee, and cannot control disenrollment), maintaining the same formula for providing funding for a State high risk pool, or establishing an altered formula that the Secretary determines will not reduce the total funds expended on the existing high risk pool. (Note that options such as the per capita approach would need to be evaluated in terms of other policies in effect in a State that could negatively influence enrollment in an existing State high risk pool.) Again, all such approaches are subject to the approval of the Secretary.

Section 152.39(b) specifies that in situations where a State enters into a contract with HHS under this part, HHS shall take appropriate action, such as terminating the PCIP contract, against any State that fails to maintain funding levels for existing State high risk pools.

Relation to State Laws (§ 152.40)

Section 152.40 of this interim final rule reflects the provision in section 1101(g)(5) that specifies State standards that might otherwise apply to the coverage offered under a PCIP program are pre-empted, with the exception of laws relating to licensing or solvency. This language tracks similar language that applies to State regulation of health plans offering Medicare Advantage plans under Medicare Part C or drug coverage under Medicare Part D under title XVIII of the Social Security Act, and we would expect to interpret the language for purposes of the PCIP program in a manner similar to the way HHS has applied it under those programs.

H. Transition to Exchanges (Subpart H, § 152.44 Through § 152.45)

End of PCIP Coverage (§ 152.44)

Section of 152.44 of this interim final rule specifies that, consistent with section 1101(g)(3)(A) of the Affordable Care Act, enrollee coverage under the PCIP program will end effective January 1, 2014, because affordable coverage will be available under the Exchanges and insurance plans will no longer be permitted to exclude coverage for pre-existing conditions. Note that PCIP program contracts will remain in effect to provide for appropriate contractual close out periods, but coverage of claims under the PCIP program will extend only to the costs of covered services provided up through December 31, 2013.

Transition to the Exchanges (§ 145.45)

As provided by section 1101(g)(3)(B) of the Affordable Care Act, HHS will develop procedures to transition PCIP enrollees to the Exchanges (exchanges) that are established under sections 1311 or 1321 of the Act, in order to ensure there are no lapses in coverage for individuals enrolled in the PCIP program. Since these exchanges are still in the developmental stages, we believe it would be premature to specify transition procedures in this interim final rule. Thus, section 152.45 simply establishes that HHS will develop such transition procedures, and we encourage

comments on the best ways to carry out the transition.

III. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

IV. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking (NPRM) in the **Federal Register** and invite public comment on the proposed rule before publishing a final rule that responds to comments and sets forth final regulations that generally take effect sixty days later. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

The Affordable Care Act was enacted on March 23, 2010, and requires that a temporary high risk pool program be in place "not later than 90 days" after enactment. The publication of proposed regulations in an NPRM could not govern implementation of the high risk pool program, as they would constitute mere proposals with no force of law. The normal sixty-day public comment period provided for in the case of regulations proposed in an NPRM would by itself consume two-thirds of the time the statute provides for implementation. Under these circumstances, it would be impracticable and contrary to the public interest to delay putting regulations into effect that are necessary to implement the program until the rules have been subjected to prior notice and comment procedures.

Therefore, we find good cause to waive the notice of proposed rulemaking and to issue this final rule on an interim basis. We are providing a 60-day public comment period. Also, because these regulations need to be in effect in order to undertake full implementation of the program, we also find good cause for waiving the normal delay in effective date that would apply, and these regulations are effective on July 30, 2010.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

A. ICRs Regarding Proposal Process (§ 152.7)

Section 152.7 states that a proposal from a State or from a nonprofit private entity shall demonstrate that the eligible entity has the capacity and technical capability to perform all functions necessary for the design and operation of a Pre-Existing Condition Insurance Plan (PCIP), and that its proposed PCIP is in full compliance with all of the requirements of this part. Specifically, the proposal shall demonstrate that the proposed PCIP satisfies at least the conditions listed at § 152.7(a)(1) through (9).

If there are States that do not submit acceptable proposals as described in § 152.7, HHS will solicit proposals from nonprofit entities to contract with HHS to operate a PCIP in those States. Nonprofits may submit proposals to contract directly with HHS to operate a PCIP program.

The burden associated with this requirement is the time and effort necessary for a State or nonprofit entity to develop and submit a proposal to operate a PCIP, which is a one-time information collection burden. We estimate that it would take a State or nonprofit entity 684 hours to compile the necessary information to comply with this requirement. While this one-time requirement is subject to the PRA, the associated burden is approved under OMB control number 0938–1085.

B. ICRs Regarding Eligibility (§ 152.14)

Section 152.14 discusses eligibility to enroll in a PCIP program. An individual who enrolls in a PCIP must meet both the requirements listed at § 152.14(a)(1), demonstrating they are a citizen or national of the United States or lawfully present in the United States and § 152.14(a)(3), providing evidence that they have a pre-existing condition as established under paragraph (c) of this section. The burden associated with this requirement includes the process of obtaining such information and forwarding the information to the appropriate party at the PCIP. We estimate this information could be submitted either electronically or hard copy in accordance with directions furnished by the PCIP and approved by HHS. We estimate that it will take approximately 30 minutes per applicant to obtain, review and submit the above proof(s) of eligibility. Although the Department has not estimated program participation, for the purpose of this calculation, we assume that within the first six months of the program approximately 100,000 potential enrollees will submit eligibility information to the PCIP program. The estimated one-time burden associated with this requirement is 50,000 hours. As the program progresses beyond 2010, we assume that we will receive fewer inquiries based on the experience with existing State high risk pool programs. In 2011 and beyond, we assume that approximately 50,000 potential enrollees will submit eligibility information to the PCIP program. The estimated annual burden associated with this requirement is 25,000 hours.

C. ICRs Regarding Enrollment and Disenrollment Process (§ 152.15)

Section 152.15(a) and (b) require a PCIP to develop and implement enrollment and disenrollment processes, respectively. The burden associated with these requirements is the time and effort necessary for a PCIP program to establish enrollment and disenrollment procedures. The burden associated with the establishment of enrollment and disenrollment procedures is a one-time burden that was included in the 684 burden hour estimate in our earlier discussion of § 152.7. While these requirements are subject to the PRA, the associated burden is approved under OMB control number 0938–1085.

In regards to ongoing reporting under the PCIP contract, any State or entity selected to administer the PCIP program may later decide it is in the best interest of their State to propose amendments to

the previously agreed upon contract. We estimate that, while uncommon, such instances may occur and permissible proposed changes would be allowed. When considering all aspects of the contract, which would include the enrollment and disenrollment process, access to services, and the appeals process, we estimate that it will take approximately 24 hours per contractor to submit a revised proposal and implement any approved amendments. The estimated annual burden associated with this requirement is 1,224 hours at a cost of $28,152.

D. ICRs Regarding Access to Services (§ 152.22)

Section § 152.22(a) states that a PCIP may specify the networks of providers from whom enrollees may obtain plan services. The PCIP must demonstrate to HHS that it has a sufficient number and range of providers to ensure that all covered services are reasonably available and accessible to its enrollees. The burden associated with this requirement is the time and effort necessary for a PCIP to demonstrate to HHS that it has a sufficient number and range of providers to ensure that all covered services are reasonably available and accessible to its enrollees. The burden associated with these requirements is included in the 684 burden hour estimate for compiling the necessary information to comply with this requirement as stated in our earlier discussion of § 152.7.

In regards to ongoing reporting under the PCIP contract, any State or entity selected to administer the PCIP program may later decide it is in the best interest of their state to propose amendments to the previously agreed upon contract. We estimate that while uncommon, such instances may occur, and permissible proposed changes would be allowed. When considering all aspects of the contract, which would include access to covered services, we estimate that it will take approximately 24 hours per contractor to submit a revised proposal and implement any approved amendments. The estimated annual burden associated with this requirement is 1,224 hours at a cost of $28,152.

E. ICRs Regarding Appeals Procedures (§ 152.26)

Section 152.26(a) requires a PCIP to establish and maintain procedures for individuals to appeal eligibility and coverage determinations. Section 152.26(b) lists the minimum requirements for appeals procedures. The burden associated with this requirement is the time and effort necessary for a PCIP to develop and maintain appeals procedures. The burden associated with these requirements is included in the 684 burden hour estimate for compiling the necessary information to comply with this requirement as stated in our earlier discussion of § 152.7. The aforementioned information collection requirements and associated burden are currently approved under OMB control number 0938–1085.

In regards to ongoing reporting under the PCIP contract, any state or entity selected to administer the PCIP program may later decide it is in the best interest of their state to propose amendments to the previously agreed upon contract. We estimate that while uncommon, such instances may occur, and permissible proposed changes would be allowed. When considering all aspects of the contract, which would include the appeals process, we estimate that it will take approximately 24 hours per contractor to submit a revised proposal and implement any approved amendments. The estimated annual burden associated with this requirement is 1,224 hours at a cost of $28,152.

F. ICRs Regarding Fraud, Waste, and Abuse (§ 152.27)

As stated in § 152.27(a), a PCIP shall develop, implement, and execute operating procedures to prevent, detect, recover (when applicable or allowable), and promptly report to HHS incidences of waste, fraud and abuse. Additionally, § 152.27(b) states that a PCIP program shall cooperate with Federal law enforcement authorities in cases involving waste, fraud, and abuse. The burden associated with the requirement contained in § 152.27 is the time and effort necessary to submit the required information on an ongoing basis. We estimate that it will take PCIPs 4 hours each month, per State, to report all required information to HHS and/or Federal law enforcement authorities which would include any identified instances of waste, fraud, and abuse. The estimated annual burden associated with this requirement is 2,448 hours at a cost of $56,304.

G. ICRs Regarding Preventing Insurer Dumping (§ 152.28)

Section 152.28(b) requires a PCIP to establish procedures to identify and report to HHS instances in which health insurance issuers or group health plans are discouraging high-risk individuals from remaining enrolled in their current coverage and in instances in which such individuals subsequently are eligible to enroll in the qualified high risk pool. The required procedures shall include methods to identify circumstances described in § 152.28(b)(1) through (4). The burden associated with this requirement is the time and effort necessary for a PCIP to establish procedures for identifying insurer dumping and for reporting dumping practices to HHS. We estimate that it will take PCIPs 8 hours each month, per State, to develop and report information to HHS of any health insurance issuer or group health plan they have identified as discouraging an individual from remaining enrolled in coverage offered by such issuer or health plan based on the individual's health status. The estimated annual burden associated with this requirement is 4,896 hours at a cost of $110,160.

H. ICRs Regarding Use of Funds (§ 152.32)

Section 152.32 states that all funds awarded through the contracts established under this program must be used exclusively to pay allowable claims and administrative costs incurred in the development and operation of the PCIP that are in excess of the amounts of premiums collected from individuals enrolled in the program. The burden associated with this requirement is the time and effort necessary for a State to collect allowable cost information, review and submit such information to HHS for payment. We estimate that it will take each PCIPs 16 hours each month, per State to comply with this requirement. The estimated annual burden associated with this requirement is 9,792 hours at a cost of $323,136.

I. ICRs Regarding Maintenance of Effort (§ 152.39)

Section 152.39(a) requires a State that enters into a contract with HHS under this part to demonstrate, subject to approval by HHS, that it will continue to provide funding of any existing high risk pools in the State at a level that is not reduced from the amount provided for in the year prior to the year in which the contract is entered. The burden associated with this requirement is the time and effort necessary for a State to demonstrate maintenance of effort to HHS. The burden associated with this one-time requirement is included in the 684 burden hour estimate for compiling the necessary information to comply with the proposal requirement as stated in our earlier discussion of § 152.7. While this requirement is subject to the PRA, the associated burden is approved under OMB control number 0938–1085.

TABLE 1—ANNUAL REPORTING AND RECORDKEEPING BURDEN

Regulation Section(s)	OMB Control No.	Respondents	Responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting ($)	Total labor cost of reporting ($)	Total capital/ maintenance costs ($)	Total cost ($)
§ 152.7, § 152.15, § 152.22, § 152.26, § 152.39	0938–1085	51	51	684	34,884	**	1,421,268	0	1,421,268
§ 152.15, § 152.22, § 152.26	0938–1100	51	51	24	1,224	**	28,152	0	28,152
§ 152.14	0938–1095	100,000	100,000	.5	50,000	**	N/A	0	N/A
§ 152.27	0938–1100	51	612	4	2,448	**	56,304	0	56,304
§ 152.28	0938–1100	51	612	8	4,896	**	110,160	0	110,160
§ 152.32	0938–1100	51	612	16	9,792	**	323,136	0	323,136
Total		100,051	101,887		103,244				1,939,020

**Wage rates vary by level of staff involved in complying with information collection request (ICR). Wage rates are detailed in the Supporting Statement Part A for this (ICR). Wage rates vary from $12 to $60 hourly salary. Supporting Statement Part A for this (ICR).

We will accept comments for both the new information collection requirements contained in this interim final rule and the requirements previously approved under 0938–1085 and 0938–1095, respectively, for 60 days from the date of display for this interim final rule. At the conclusion of the 60-day comment period, we will publish an additional notice announcing the submission of the information collection request associated with this final rule for OMB approval. At that time, the public will have an additional 30 days to submit public comments to OMB for consideration.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget,

Attention: CMS Desk Officer, [OCIIO–9995–IFC]

Fax: (202) 395–6974; or

E-mail: *OIRA_submission@omb.eop.gov.*

VI. Regulatory Impact Analysis

A. Summary and Need for Regulatory Action

Section 1101 of Title I of the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act), Public Law 111–148, requires that the Secretary establish, either directly or through contracts with States or nonprofit private entities, a temporary high risk health insurance pool program to provide affordable health insurance coverage to uninsured individuals with pre-existing conditions. (We generally refer to this program as the Pre-Existing Condition Insurance Plan program, or PCIP program, to avoid confusion with the existing State high risk pool programs, which will continue to operate separately.) This program will continue until January 1, 2014, when Exchanges established under sections 1311 and 1321 of the Affordable Care Act will be available for individuals to obtain health insurance coverage without regard to their pre-existing condition. This interim final rule sets forth the initial regulations with respect to this new program, and is needed for its implementation. The rule addresses key issues regarding administration of the program, eligibility and enrollment, benefits, premiums, funding, appeals rules, and enforcement provisions related to anti-dumping and fraud waste and abuse.

Executive Order 12866 explicitly requires agencies to take account of "distributive impacts" and "equity." Offering health coverage to uninsured Americans with pre-existing conditions at an affordable premium is needed to provide the opportunity for coverage to individuals that cannot otherwise obtain insurance in the market. It is a temporary program to provide a transition to the Affordable Care Act policies that take effect in 2014 that ban the use of pre-existing conditions in determining access, benefit and premiums. The $5 billion in Federal funding appropriated for this program will yield a meaningful increase in equity, and is a benefit of this interim final regulation.

B. Executive Order 12866

Under Executive Order 12866 (58 FR 51735), a "significant" regulatory action is subject to review by the Office of Management and Budget (OMB). Section 3(f) of the Executive Order defines a "significant regulatory action" as an action that is likely to result in a rule (1) having an annual effect on the economy of $100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as "economically significant"); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. OMB has determined that this regulation is economically significant within the meaning of section 3(f)(1) of the Executive Order, because it is likely to have an annual effect on the economy of $100 million in any one year. Accordingly, OMB has reviewed this rule pursuant to the Executive Order.

The Department provides an assessment of the potential costs, benefits, and transfers associated with these interim final regulations, summarized in the following table.

TABLE 1.1—ACCOUNTING TABLE

Benefits	
Qualitative: The Pre-existing Condition Insurance Plan will provide uninsured Americans with preexisting conditions that have been denied coverage or otherwise excluded from purchasing insurance coverage with an opportunity to obtain coverage. Providing this insurance option will increase access to health care and reduce financial strain for participants. It is also likely to improve health outcomes and worker productivity. Individuals who are especially vulnerable as a result of existing health problems and financial status may receive the greatest benefit from this program.	
Costs	$1,939,020 annually for reporting and recordkeeping.
Qualitative: To the extent PCIP increases access to health care services, increased health care utilization and costs will result due to increased uptake. Administrative costs include: the cost of contractors to apply, the time cost for individuals to apply, and the contractors' costs of complying with program rules (*e.g.*, conducting appeals, preventing fraud).	
Transfers	$5,000,000,000 for the period from July 1, 2010 to December 31, 2013.
Qualitative: The $5 billion in Federal funds is a transfer from the Secretary to contractors to aid in administering the program.	

a. Estimated Number of Affected Entities

This rule provides guidance for the States and nonprofit private entities that contract with HHS to establish PCIPs to provide affordable health insurance coverage to uninsured individuals with pre-existing conditions within each State. The States or nonprofit private entities that voluntarily participate in the PCIP program will be directly affected by this regulation as well as the terms of their contracts.

There are 35 State-based high risk pool programs today.[3] First created in the 1970s, States adopted these programs to address insurance market failures for people with pre-existing conditions. The number of such existing State programs grew with the enactment of a Federal law, the Health Insurance Portability and Accountability Act of 1996 (HIPAA), that requires States to provide either guaranteed issue policies in the individual market to a certain set of people who have been continuously covered or access to an acceptable alternative mechanism, such as a high risk pool. In addition, beginning in 2002, Federal grants provided seed money and a limited amount of loss subsidies for such programs. Ongoing financial support for State-based high risk pools varies, but is generally provided through assessments on issuers, enrollee premiums, State general revenue, and, recently, Federal grants. Each program also has different eligibility rules, benefits, premiums, and/or cost controls (*e.g.*, pre-existing condition waiting lists, disease management). As of the end of 2008, there were approximately 200,000 enrollees in the 35 State high risk pools. The Government Accountability Office (GAO) estimated that there were approximately 4 million uninsured people with health problems in States with high risk pools.[4]

The Affordable Care Act establishes a program that is similar in some respects to these programs, but has notable differences in terms of eligibility criteria, benefits, and premiums. These differences make it difficult to extrapolate potential enrollment in the PCIP program from the experience of existing State high risk pools.

First, none of the existing pools limit eligibility to people who have been uninsured for a minimum of six months whereas this is a pre-requisite for enrollment in the PCIP program. In general, the uninsured have different health problems, economic statuses, and demands for health care and health insurance than the insured population.[5]

Second, while the State programs and Federal program cover roughly the same benefit categories, the PCIP program bars both benefit carve-outs and waiting periods for pre-existing conditions, which 30 State programs employ.[6] In addition, PCIP limits annual out-of-pocket spending to $5,950 nationwide, whereas two State programs have no specified annual limits and six States have limits that exceed $5,950 within each State's most popular high risk pool plan.[7] These distinctions in benefits affect both the cost of health insurance per capita as well as the mix of enrollees. For example, a person with cancer may decide it is not worth the premiums to sign up for a State high risk pool that will not cover her chemotherapy in the first year of enrollment due to a waiting period. Immediate coverage of pre-existing conditions should increase demand in the new program relative to the existing pools, and may also lead to a somewhat less favorable mix of health risks, because people with problems requiring substantial medical care will receive more benefit from the new program than the existing pools.

Third, all State high risk pools set their premiums at a higher percent of the standard rate in the individual market than the PCIP program. In the existing pools, premiums average 140 percent of standard rate, and range from 105 percent to 250 percent of the standard rate or higher.[8] The PCIP program's premiums are set at 100 percent of standard rate. PCIP's lower premium is expected to increase the number of people who will want to purchase coverage. One study estimated that lowering all State high risk pool premiums to 125 percent of the standard rate would increase enrollment by one-third.[9] The lower premium may lead to a more favorable health mix of enrollees, because the higher premiums in existing pools make the pools less

[3] U.S. Government Accountability Office, *Health Insurance: Enrollment, Benefits, Funding, and Other Characteristics of State High Risk Health Insurance Pools* (2009), *http://www.gao.gov/new.items/d09730r.pdf.*

[4] U.S. Government Accountability Office, *Health Insurance: Enrollment, Benefits, Funding, and Other Characteristics of State High Risk Health Insurance Pools* (2009), *http://www.gao.gov/new.items/d09730r.pdf.* This estimate was based on the number of individuals with at least one chronic condition, from the 2006 Medical Expenditure Panel Survey (MEPS), applied to the Current Population Survey estimates of the population in States with high risk pools.

[5] "The Uninsured: A Primer," *Kaiser Commission on Medicaid and the Uninsured* (2006), *http://www.kff.org/uninsured/upload/7451.pdf.*

[6] Tanya Schwartz, "State High Risk Pools: An Overview," *Kaiser Commission on Medicaid and the Uninsured.* (2010), *http://www.kff.org/uninsured/8041.cfm.*

[7] U.S. Government Accountability Office, *Health Insurance: Enrollment, Benefits, Funding, and Other Characteristics of State High Risk Health Insurance Pools* (2009), *http://www.gao.gov/new.items/d09730r.pdf.*

[8] National Association of State Comprehensive Health Insurance Plans. *Comprehensive Health Insurance for High-Risk Individuals: A State-by-State Analysis, 2009/2010.*

[9] Austin Frakt, Steve Pizer, and Martin Wrobel, "Insuring the Uninsurable: The Growth in High-Risk Pools," *Abt Associates, HSRE Working Paper* (2002), *http://www.abtassociates.com/reports/HSRE-W12-highrisk.pdf.*

attractive to individuals with fewer health problems. Lower premiums may also attract individuals who are in poor health, but are unable to afford the premiums in the existing pools.

Fourth, fifteen States and the District of Columbia lack a high risk pool program today. These States do not have a high risk pool for a variety of reasons. Some States, such as New York, Massachusetts, and Vermont, have enacted insurance reforms that require plans to accept people with pre-existing conditions into the individual insurance market (through guaranteed issue and rating rules) instead of segregating them into high risk pools. Others, like Arizona and Nevada, do not have extensive insurance reforms. There is no common profile to States that lack high risk pools today.

Lastly, there is no clear correlation between high risk pool enrollment and need. One measure of need is the number and rate of uninsured residents. A State that provides protections for its residents with high risk or low income should have a relatively low number and rate of uninsured residents, and vice versa. As such, among States that offer such pools, there should be a relatively constant relationship between a State's number of uninsured and its enrollees in high risk pools. However, experience suggests otherwise. The difference between the highest and lowest ratio of a State's uninsured population to its high risk pool enrollees is 27 to one. This is substantially larger than the disparity in the ratio of uninsured to Medicaid enrollees in a State, which is six to one.[10] A report that examined current State high risk pools, estimated a participation rate of 0.05 to 0.33 percent of the State population in those programs.[11] For these reasons, the Department concludes that the experience in existing high risk pools is not a good basis for estimating PCIP enrollment.

Several reports have estimated the likely number of enrollees in the PCIP program by using survey data and applying a participation rate to the approximate number of people eligible for the PCIP program. One analysis was conducted by the Center for Studying Health System Change.[12] Using the Medical Expenditure Panel Survey (MEPS), the analysis identified individuals who were uninsured and had at least one chronic condition deemed "high cost," meaning spending exceeds 1.5 times of the average cost of the condition. This methodology generated 5.6 to 7 million people who could potentially qualify for the program. Assuming that the annual Federal cost per person is $6,000 to $7,000 and the $5 billion in Federal funding is capped in each year over the three and a half year period (roughly $1.3 to $1.4 billion per year), the analysis estimated that 200,000 people per year through 2013 could be covered.

Second, the Centers for Medicare and Medicaid Services' Office of the Actuary (OAct) estimated participation based on demand, without assuming that Federal funding would be limited to $1.3 to $1.4 billion in each year. It estimated that participation in the program in 2010 would be 375,000, assuming the program would be fully implemented within the year. Given this enrollment rate, it projected that the $5 billion in Federal funding would not last through 2013.

Third, the Congressional Budget Office (CBO) conducted two analyses. In a December 2008 report, CBO estimated the cost and coverage of a national high risk pool program. This program would require that all States establish high risk pool programs, with full Federal subsidies for enrollees. Its premiums would be higher than PCIP—150 versus 100 percent of the standard rate—but its enrollment would be broader—significantly, it would not require that applicants have been uninsured for the previous six months. CBO estimated that 175,000 uninsured would gain coverage in this program, and the Federal cost would be $5.4 billion over five years (with offsetting receipts from changes in employer coverage).[13]

In addition, in June, 2010, CBO provided information on PCIP in response to a request from Congress.[14] Its methodology was not explained in its letter, but it calculated that 200,000 people could be enrolled in the program for the 2010–2013 period given the fixed $5 billion appropriation. If the Federal funding cap were lifted, CBO estimated that enrollment would be 400,000 in 2011 rising to about 600,000 or 700,000 in 2013. CBO underscored the uncertainty of the estimates due to the potential variation in eligibility rules, benefits, and premiums. Since this interim final rule preserves variation and flexibility in program parameters across States, CBO's observations continue to be relevant and there may be a wide range of potential enrollees. CBO would probably continue to estimate a wide range of potential enrollees taking this interim final rule into account.

For purpose of this analysis, the Department has not produced its own estimates of the number of individuals likely to enroll in the PCIP program but believes that it will fall in the range of the other estimates, from 200,000 to 400,000. The lower bound of this range is consistent with the numbers estimated by the Center for Studying Health System Change and by CBO in June 2010. The upper bound of this range is approximately the enrollment estimate from the Office of the Actuary and CBO when they assume that PCIPs do not immediately impose enrollment constraints to extend the limited Federal funding. We expect that efficient program implementation, effective cost control, targeted benefit design, and enrollment patterns that are different than projected will mitigate the need for enrollment constraints, and Federal funding will be sufficient to meet program demand. Even assuming the lower estimate of enrollment of 200,000, the PCIP program could double the number of Americans with pre-existing conditions insured through high risk pool programs.

c. Benefits

A key premise for the establishment of the Pre-Existing Condition Insurance Plan is that those who are unable to purchase health insurance in the private sector due to medical underwriting and are not eligible for public insurance programs are potentially disadvantaged through both poor health and loss of income. We expect that the PCIP program will help such individuals by providing access to affordable health insurance coverage.

This interim final regulation could generate significant benefits to consumers. These benefits could take the form of reductions in mortality and morbidity, reductions in medical expenditure risk, increases in worker productivity, and decreases in the cross-subsidy in premiums to offset uncompensated care, sometimes referred to as the "hidden tax." Each of these effects is described below.

A first type of benefit is reductions in mortality and morbidity. While the empirical literature leaves many questions unresolved, a growing body of evidence convincingly demonstrates that health can be improved by

[10] Data from State Health Facts.org, Kaiser Family Foundation.

[11] "State High Risk Pools: An Overview." *State Health Access Data Assistance Center* (2008).

[12] Mark Merlis, "Health Coverage for the High-Risk Uninsured: Policy Options for Design of the Temporary High-Risk Pool," *National Institute for Health Care Reform, Center for Studying Health System Change* (2010).

[13] Congressional Budget Office. *Health Care Budget Options Volume I.* December 2008.

[14] Congressional Budget Office Director Douglas W. Elmendorf, letter to Senator Michael B. Enzi, June 21, 2010.

spending more on at-risk individuals and by expanding health insurance coverage. For example, Almond *et al.*[15] find that newborns classified just below a medical threshold for "very low birthweight" have *lower* mortality rates than newborns classified as just above the threshold, despite an association between low birth weight and higher mortality in general, because they tend to receive timely and appropriate medical care. In a study of severe automobile accidents, Doyle[16] found that uninsured individuals receive less care and have a substantially higher mortality rate. Currie and Gruber[17] found that increased eligibility for Medicaid coverage expanded utilization of care for otherwise uninsured children, leading to a sizeable and significant reduction in child mortality. A study of Medicare by Card *et al.*[18] found that individuals just old enough to qualify for coverage have lower mortality rates—despite similar illness severity—than do those just too young for eligibility. Finally, a report by the Institute of Medicine (IOM)[19] found mortality risks for uninsured individuals that were 25 percent higher than those of observably similar insured individuals. In addition to the prospect that expanded insurance coverage will result in reductions in mortality, it will almost certainly significantly reduce morbidity, as demonstrated in extensive reviews of the literature by Hadley and the IOM.[20]

This interim final regulation will expand access to currently uninsured individuals with pre-existing conditions. These newly insured populations will likely achieve both mortality and morbidity reductions from the regulation greater than those found in the studies, since these populations are, on average, in worse health than the population at large and thus likely to benefit even more from insurance coverage than uninsured individuals in general.

A second type of benefit from the cumulative effects of this interim final regulation is a reduction in financial burden faced by the uninsured on account of onerous medical costs. Various studies have documented two related phenomena: (1) Averted healthcare utilization among the uninsured due to cost and (2) financial strain due to medical expenditures among the uninsured. Recent data show that 24 percent of the uninsured went without needed health care due to cost compared to 4 percent of those with private or employer-based insurance.[21] Given the population targeted by the PCIP program—uninsured people with pre-existing conditions—individuals currently without insurance may not be able to simply forgo needed care, leading to substantial financial strain. Approximately half of the more than 500,000 personal bankruptcies in the U.S. in 2007 were in part due to very high medical expenses.[22] In a Commonwealth Fund report[23] on medical debt, 60 percent of those having no insurance reported having difficulties paying medical care costs. In the past 12 months, they had incurred medical bills they either could not pay, were forced to make significant changes in their life styles in order to meet their obligations, had been contacted by a bill collection agency, or were forced to pay medical bills over an extended period. Exclusions from health insurance coverage based on preexisting conditions expose the uninsured to the aforementioned financial risks.

The Pre-Existing Condition Insurance Plan is designed to reduce the uncertainty and hardship associated with these financial risks by limiting the extent to which individuals must bear the entire cost of medical care by themselves. One study found that people who are uninsured for a full year pay for over a third of their care (35 percent) out-of-pocket, while individuals who are insured for a full or partial year paid just under 20 percent of their care out-of-pocket.[24] Moreover, because the PCIP program is targeted to individuals who are likely to have extensive medical needs, it is likely to have especially large economic benefits in terms of reducing financial risk. For example, uninsured individuals with two chronic conditions spent $908 out of pocket annually compared to $304 annually among the uninsured with no chronic conditions and $259 annually among the privately insured with no chronic conditions.[25] This program and the interim final regulation that implements it will help insurance companies more effectively protect patients from the financial hardship of illness, including bankruptcy and reduced funds for non-medical purposes.

A third type of benefit from the PCIP program and this interim final regulation is improved workplace productivity. This interim final regulation will benefit employers and workers by increasing workplace productivity and reducing absenteeism, low productivity at work due to preventable illness, and "job-lock." A June 2009 report by the Council of Economic Advisers found that increased access to health insurance coverage improves labor market outcomes by improving worker health.[26] The health benefits of offering health insurance to uninsured people with pre-existing conditions will help to reduce disability, low productivity at work due to preventable illness, and absenteeism in the work place, thereby increasing workplace productivity and labor supply. Economic theory suggests that these benefits would likely be shared by workers, employers, and consumers.

Fourth, the PCIP will reduce cost shifting of uncompensated care to the privately insured, which contributes to higher premiums. The program will help expand the number of individuals who are insured and reduce the likelihood that individuals who have insurance do not bankrupt themselves by paying medical bills. Both effects will help reduce the amount of uncompensated care that imposes a "hidden tax" on consumers of health care since the costs of this care are

[15] Douglas Almond *et al.*, "Estimating Marginal Returns to Medical Care: Evidence from At-Risk Newborns," *The Quarterly Journal of Economics* 125, No. 2 (2010): 591–634, *http://www.mit.edu/~jjdoyle/vlbw.pdf.*

[16] Joseph J. Doyle, "Health Insurance, Treatment and Outcomes: Using Auto Accidents as Health Shocks." *The Review of Economics and Statistics* 87, No. 2 (2005): 256–270, *http://www.mitpressjournals.org/doi/abs/10.1162/0034653053970348.*

[17] Janet Currie and J. Gruber, "Health Insurance Eligibility, Utilization of Medical Care, and Child Health," *The Quarterly Journal of Economics* 111, No. 2 (1996): 431–466, *http://www.jstor.org/stable/2946684?cookieSet=1.*

[18] David Card, C. Dobkin, and N. Maestas, "Does Medicare Save Lives?" *The Quarterly Journal of Economics* 124, No. 2 (2009): 597–636, *http://www.mitpressjournals.org/doi/abs/10.1162/qjec.2009.124.2.597.*

[19] Institute of Medicine, "Care Without Coverage: Too Little, Too Late," (2002), *http://books.nap.edu/openbook.php?record_id=10367&page=R1.*

[20] Institute of Medicine, op. cit. J. Hadley, "Sicker and Poorer: The Consequences of Being Uninsured," *Medical Care Research and Review* 60 (No. 2): 3S–75S, (2003).

[21] Kaiser Family Foundation, "The Uninsured A Primer," (2009), *http://www.kff.org/uninsured/upload/7451-05.pdf.*

[22] David Himmelstein *et al.*, "Medical Bankruptcy in the United States, 2007: Results of a National Study," *The American Journal of Medicine* (2009), *http://www.pnhp.org/new_bankruptcy_study/Bankruptcy-2009.pdf.*

[23] Collins *et al.*, "The Affordability Crisis In U.S. Health Care: Findings From The Commonwealth Fund Biennial Health Insurance Survey," *(2004): 17.*

[24] Jack Hadley and John Holohan, "The Cost of Care for the Uninsured," *The Kaiser Commission on Medicaid and the Uninsured* (2004), *http://www.kff.org/uninsured/upload/The-Cost-of-Care-for-the-Uninsured-What-Do-We-Spend-Who-Pays-and-What-Would-Full-Coverage-Add-to-Medical-Spending.pdf.*

[25] Hwang et al, "Out of Pocket Medical Spending for Care of Chronic Conditions," *Health Affairs* (2001), *http://www.partnershipforsolutions.org/DMS/files/Out-of-pocket2002.pdf.*

[26] Council of Economic Advisers. "The Economic Case for Health Reform." (2009).

shifted to those who are able to pay for services in the form of higher prices.

In their analysis of the interim final regulations implementing patient protections, the Departments of Labor, the Treasury, and Health and Human Services estimated an order of magnitude for the compensatory reduction in cost-shifting of uncompensated care associated with the expansion of coverage of those interim final regulations.[27] The analysis assumed that induced utilization due to expanded coverage would be relatively low since the uninsured populations affected by these interim final regulations tend to have worse health, greater needs for health care, and less ability to reduce utilization when they are uninsured. Second, on the basis of the economics literature on the subject,[28] the Departments estimated that two-thirds of the previously uncovered costs would have been uncompensated care, 25 percent of which would have been paid for by private sources. Assuming that reductions in privately-financed uncompensated care lower insurance premiums charged to consumers, the Departments estimated the patient protections' regulations' increased insurance coverage could result in reductions in insurance premiums of up to $1 billion in 2013.[29]

Assuming an enrollment range of 200,000 to 400,000 in the PCIP program, the effect on uncompensated care could be over twice to four times as high as prior estimates associated with the patient protections. This increased impact is due to the fact that the primary effect on coverage of the patient protections interim final regulations was the ban on pre-existing condition exclusions for children. Those rules estimated that 90,000 children would gain coverage. Given the differing scopes of these two interim final regulations, it is likely that more uninsured will be helped by PCIP than the patient protections policies and interim final regulations. Moreover, savings per person will likely be higher for the PCIP population compared to children with pre-existing conditions. This is because most enrollees in PCIP are likely to be adults, whose average cost of health care is higher than that of children.

In addition, we believe that PCIP will help local and State governments. Since much of the uncompensated health care is provided through State and locally funded public health facilities, by enabling a portion of those who would seek care at a public facility to enroll in the high risk pool, the program could help reduce the drain on scarce State and local resources. We welcome public comment on this analysis.

d. Costs and Transfers

Under section 1101 of the Affordable Care Act, HHS is authorized to disperse $5 billion for the purpose of funding the PCIP program, including administrative costs and contracts with States and non-profit third party administrators. This Federal funding is used to offset the cost of providing health care to enrollees that exceeds the premium revenue. According to independent studies, the Federal share of total costs could be roughly 35 to 40 percent of total spending.[30]

There will also be administrative costs associated with the PCIP program. This takes the form of the cost to contractors to apply, the time cost for individuals to apply, and the contractors' costs of complying with program rules (for example, conducting appeals, preventing fraud). The Department estimates that the annual administrative cost would be $1.9 million. Note that any State administrative costs incurred that are allowable under this program may be paid for by Federal and premium funds.

e. Conclusion

Under section 1101 of the Affordable Care Act, the Department is authorized to spend $5 billion via States and third party administrators for the purpose of funding the PCIP program. The transfer of this amount of funds will have a significant, positive financial impact on individuals who enroll in the program, States, and health care providers. We anticipate that individuals who are currently uninsured will benefit from having lower out-of-pocket costs for health care, less financial strain, and improved access to health services. We also anticipate that insured individuals will benefit indirectly through paying lower premiums because of a reduced burden on the plans to subsidize uncompensated care. In addition, we believe that establishing the PCIP program will reduce the burden on local and State governments to pay health care providers for uncompensated care.

The direct costs of this regulation is a transfer of $5 billion from the Federal government to the PCIPs that will be established in each State. Administrative costs are expected to be $1.9 million per year. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

VII. Other Sections

Regulatory Alternatives

Under the Executive Order, we must consider alternatives to issuing regulations and alternative regulatory approaches. Section 1101 establishes broad requirements regarding contracting, eligibility, benefits, payments, insurer dumping, and the control of fraud, waste, and abuse.

We considered implementing the PCIP through some form of guidance to States and other interested parties. However, we believe that it is in the best interest of States, contractors, enrollees, and other interested parties to establish this program through the rulemaking process. As discussed in detail above, there are several areas where the statute clearly anticipates that the Secretary will exercise discretion in implementing the program, most notably the definition of a pre-existing condition for purpose of establishing eligibility. We also need to issue regulations to establish the legal framework for the contracting mechanism that sets the specific terms for the State-administered pools and for the organizations that will operate the pools in the States that do not contract with HHS. Establishing these rules through rulemaking ensures that the public has ample opportunity to understand and comment on these rules and establishes clear authority to enforce them.

The Department considered regulatory alternatives for program design, and often referred to the design features in existing State high risk pool and the Children's Health Insurance Program (CHIP) given their similarities to the PCIP goals and features. We

[27] **Federal Register** June 28, 2010: *http://frwebgate1.access.gpo.gov/cgi-bin/TEXTgate.cgi?WAISdocID=3HyQcj/5/1/0&WAISaction=retrieve.*

[28] Jack Hadley *et al*, "Covering the Uninsured in 2008: Current Costs, Sources of Payment, and Incremental Costs," Health Affairs 27, No. 5 (2008): 399–415.

[29] The Departments first estimated the proportion of the population in group and individual markets using the Medical Expenditure Panel Survey (2008). Next, information from 75 FR 34538 (June 17, 2010) was used to estimate the proportion of employer and individual plans that maintain or lose grandfather status by 2013. Projections of national health expenditures from the National Health Expenditure Accounts to 2013 were distributed among these groups, and premium impacts as discussed in this regulatory impact analysis were applied. Potential premium reductions secondary to reductions in the cost-shifting of uncompensated care were then calculated using the information from the economic literature as presented in this discussion. The Departments note that to the extent that not all of the reductions in uncompensated care costs are passed onto insured populations, these estimates may be an overestimate.

[30] Mark Merlis, "Health Coverage for the High-Risk Uninsured: Policy Options for Design of the Temporary High-Risk Pool," *National Institute for Health Care Reform, Center for Studying Health System Change* (2010).

explored setting uniform rules for eligibility for all PCIPs but rejected this approach since it did not take into account the existing markets and programs in each State.

Given the fixed Federal funding for the PCIP program, these regulatory alternatives will not affect Federal outlays. They are also unlikely to have measurable national health spending implications since the Federal funding constraint is accompanied by a fixed standard for private premiums—100 percent of a standard rate for benefits that cover at least 65 percent of the cost of coverage.

Regulatory Flexibility Act

The RFA requires agencies that issue a regulation to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. The Act generally defines a "small entity" as (1) A proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a nonprofit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of "small entity." These regulations apply to the States, both those that contract with HHS to establish PCIPs and those States in which HHS contracts with another entity to establish the program, no small entities will be affected. Therefore, the Secretary certifies that the regulations will not have significant impact on a substantial number of small entities.

Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates would require spending in any one year $100 million in 1995 dollars, updated annually for inflation. In 2010, that threshold is approximately $135 million.

UMRA does not address the total cost of a rule. Rather, it focuses on certain categories of cost, mainly those "Federal mandate" costs resulting from: (1) Imposing enforceable duties on State, local, or tribal governments, or on the private sector; or (2) increasing the stringency of conditions in, or decreasing the funding of, State, local, or tribal governments under entitlement programs.

Under the Affordable Care Act, States may choose to participate in the PCIPs and receive Federal funding for administering and paying benefits. If they do not choose to participate, the Federal government will establish a PCIPs in the State. Thus, the law and these regulations do not impose an unfunded mandate on States.

Individuals will have to pay a premium and incur out-of-pocket expenses to join the PCIPs that either a State or the Federal government establishes. However, individuals are free to join based on their evaluation of the costs and benefits of belonging to the program. There is no automatic enrollment and no requirement to join a PCIP. Thus, the law, and these regulations do not impose an unfunded mandate on the private sector.

Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications.

This rule does not impose any direct costs on State or local governments. Consistent with section 1101(g)(5) of the Act, § 152.40 of this interim final rule specifies that State standards that might otherwise apply to the coverage offered under a PCIP are preempted, with the exception of laws relating to licensing or solvency. This language tracks similar language that applies to State regulation of health plans offering Medicare Advantage plans under Medicare Part C or drug coverage under Medicare Part D under title XVIII of the Social Security Act, and we would expect to interpret the language for purposes of the high risk pool program in a manner similar to the way HHS has applied it under those programs. We do not anticipate that this regulation will have significant implications, particularly since only individuals who are not now insured, and thus not directly subject to existing State insurance laws, may enroll in the program.

List of Subjects in 45 CFR Part 152

Administrative practice and procedure, Health care, Health insurance, Penalties, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, the Department of Health and Human Services amends 45 CFR subtitle A, subchapter B, by adding a new part 152 to read as follows:

PART 152—PRE-EXISTING CONDITION INSURANCE PLAN PROGRAM

Subpart A—General Provisions

Sec.
152.1 Statutory basis.
152.2 Definitions.

Subpart B—PCIP Program Administration

152.6 Program administration.
152.7 PCIP proposal process.

Subpart C—Eligibility and Enrollment

152.14 Eligibility.
152.15 Enrollment and disenrollment process.

Subpart D—Benefits

152.19 Covered benefits.
152.20 Prohibitions on pre-existing condition exclusions and waiting periods.
152.21 Premiums and cost-sharing.
152.22 Access to services.

Subpart E—Oversight

152.26 Appeals procedures.
152.27 Fraud, waste, and abuse.
152.28 Preventing insurer dumping.

Subpart F—Funding

152.32 Use of funds.
152.33 Initial allocation of funds.
152.34 Reallocation of funds.
152.35 Insufficient funds.

Subpart G—Relationship to Existing Laws and Programs

152.39 Maintenance of effort.
152.40 Relation to State laws.

Subpart H—Transition to Exchanges

152.44 End of PCIP program coverage.
152.45 Transition to the exchanges.

Authority: Sec. 1101 of the Patient Protection and Affordable Care Act (Pub. L. 111–148).

Subpart A—General Provisions

§ 152.1 Statutory basis.

(a) *Basis.* This part establishes provisions needed to implement section 1101 of the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act), which requires the Secretary of the Department of Health and Human Services to establish a temporary high risk health insurance pool program to provide health insurance coverage for individuals described in § 152.14 of this part.

(b) *Scope.* This part establishes standards and sets forth the requirements, limitations, and procedures for the temporary high risk health insurance pool program, hereafter referred to as the "Pre-Existing Condition Insurance Plan" (PCIP) program.

§ 152.2 Definitions.

For purposes of this part the following definitions apply:

Creditable coverage means coverage of an individual as defined in section 2701(c)(1) of the Public Health Service Act as of March 23, 2010 and 45 CFR 146.113(a)(1).

Enrollee means an individual receiving coverage from a PCIP established under this section.

Lawfully present means

(1) A qualified alien as defined in section 431 of the Personal Responsibility and Work Opportunity Act (PRWORA) (8 U.S.C. 1641);

(2) An alien in nonimmigrant status who has not violated the terms of the status under which he or she was admitted or to which he or she has changed after admission;

(3) An alien who has been paroled into the United States pursuant to section 212(d)(5) of the Immigration and Nationality Act (INA) (8 U.S.C. 1182(d)(5)) for less than 1 year, except for an alien paroled for prosecution, for deferred inspection or pending removal proceedings;

(4) An alien who belongs to one of the following classes:

(i) Aliens currently in temporary resident status pursuant to section 210 or 245A of the INA (8 U.S.C. 1160 or 1255a, respectively);

(ii) Aliens currently under Temporary Protected Status (TPS) pursuant to section 244 of the INA (8 U.S.C. 1254a), and pending applicants for TPS who have been granted employment authorization;

(iii) Aliens who have been granted employment authorization under 8 CFR 274a.12(c)(9), (10), (16), (18), (20), (22), or (24);

(iv) Family Unity beneficiaries pursuant to section 301 of Public Law 101–649 as amended;

(v) Aliens currently under Deferred Enforced Departure (DED) pursuant to a decision made by the President;

(vi) Aliens currently in deferred action status;

(vii) Aliens whose visa petitions have been approved and who have a pending application for adjustment of status;

(5) A pending applicant for asylum under section 208(a) of the INA (8 U.S.C. 1158) or for withholding of removal under section 241(b)(3) of the INA (8 U.S.C. 1231) or under the Convention Against Torture who has been granted employment authorization, and such an applicant under the age of 14 who has had an application pending for at least 180 days;

(6) An alien who has been granted withholding of removal under the Convention Against Torture; or

(7) A child who has a pending application for Special Immigrant Juvenile status as described in section 101(a)(27)(J) of the INA (8 U.S.C. 1101(a)(27)(J)).

Out-of-pocket costs means the sum of the annual deductible and the other annual out-of-pocket expenses, other than for premiums, required to be paid under the program.

Pre-Existing condition exclusion has the meaning given such term in 45 CFR 144.103.

Pre-Existing Condition Insurance Plan (PCIP) means the temporary high risk health insurance pool plan (sometimes referred to as a "qualified high risk pool") that provides coverage in a State, or combination of States, in accordance with the requirements of section 1101 of the Affordable Care Act and this part. The term "PCIP program" is generally used to describe the national program the Secretary is charged with carrying out, under which States or non-profit entities operate individual PCIPs.

Resident means an individual who has been legally domiciled in a State.

Service Area refers to the geographic area encompassing an entire State or States in which PCIP furnishes benefits.

State refers each of the 50 States and the District of Columbia.

Subpart B—PCIP Program Administration

§ 152.6 Program administration.

(a) *General rule.* Section 1101(b)(1) of the Affordable Care Act requires that HHS carry out the Pre-Existing Condition Insurance Plan program directly or through contracts with eligible entities, which are States or nonprofit private entities.

(b) *Administration by State.* A State (or its designated non-profit private entity) may submit a proposal to enter into a contract with HHS to establish and administer a PCIP in accordance with section 1101 of the Affordable Care Act and this part.

(1) At the Secretary's discretion, a State may designate a nonprofit entity or entities to contract with HHS to administer a PCIP.

(2) As part of its administrative approach, a State or designated entity may subcontract with either a for-profit or nonprofit entity.

(c) *Administration by HHS.* If a State or its designated entity notifies HHS that it will not establish or continue to administer a PCIP, or does not submit an acceptable or timely proposal to do so, HHS will contract with a nonprofit private entity or entities to administer a PCIP in that State.

(d) *Transition in administration.* The Secretary may consider a request from a State to transition from administration by HHS to administration by a State or from administration by a State to administration by HHS. Such transitions shall be approved only if the Secretary determines that the transition is in the best interests of the PCIP enrollees and potential PCIP enrollees in that state, consistent with § 152.7(b) of this part.

§ 152.7 PCIP proposal process.

(a) *General.* A proposal from a State or nonprofit private entity to contract with HHS shall demonstrate that the eligible entity has the capacity and technical capability to perform all functions necessary for the design and operation of a PCIP, and that its proposed PCIP is in full compliance with all of the requirements of this part.

(b) *Special rules for transitions in administration.* (1) Transitions from HHS administration of a PCIP to State administration must take effect on January 1 of a given year.

(2) A State's proposal to administer a PCIP must meet all the requirements of this section.

(3) Transitions from State administration to HHS administration must comply with the termination procedures of the PCIP contract in effect with the State or its designated entity.

(4) The Secretary may establish other requirements needed to ensure a seamless transition of coverage for all existing enrollees.

Subpart C—Eligibility and Enrollment

§ 152.14 Eligibility.

(a) *General rule.* An individual is eligible to enroll in a PCIP if he or she:

(1) Is a citizen or national of the United States or lawfully present in the United States;

(2) Subject to paragraph (b) of this section, has not been covered under creditable coverage for a continuous 6-month period of time prior to the date on which such individual is applying for PCIP;

(3) Has a pre-existing condition as established under paragraph (c) of this section; and

(4) Is a resident of one of the 50 States or the District of Columbia which constitutes or is within the service area of the PCIP. A PCIP may not establish any standards with regard to the duration of residency in the PCIP service area.

(b) *Satisfaction of 6-month creditable coverage requirement when an enrollee leaves the PCIP service area.* An individual who becomes ineligible for a PCIP on the basis of no longer residing in the PCIP's service area as described in paragraph (a)(4) of this section is deemed to have satisfied the requirement in paragraph (a)(2) of this section for purposes of applying to enroll in a PCIP in the new service area.

(c) *Pre-existing condition requirement.* For purposes of establishing a process for determining eligibility, and subject

to HHS approval, a PCIP may elect to apply any one or more of the following criteria in determining whether an individual has a pre-existing condition for purposes of this section:

(1) *Refusal of coverage.* Documented evidence that an insurer has refused, or a clear indication that the insurer would refuse, to issue coverage to an individual on grounds related to the individual's health.

(2) *Exclusion of coverage.* Documented evidence that such individual has been offered coverage but only with a rider that excludes coverage of benefits associated with an individuals' identified pre-existing condition.

(3) *Medical or health condition.* Documented evidence of the existence or history of certain medical or health condition, as approved or specified by the Secretary.

(4) Other. Other criteria, as defined by a PCIP and approved by HHS.

§ 152.15 Enrollment and disenrollment process.

(a) *Enrollment process.* (1) A PCIP must establish a process for verifying eligibility and enrolling an individual that is approved by HHS.

(2) A PCIP must allow an individual to remain enrolled in the PCIP unless:

(i) The individual is disenrolled under paragraph (b) of this section;

(ii) The individual obtains other creditable coverage;

(iii) The PCIP program terminates, or is terminated; or

(iv) As specified by the PCIP program and approved by HHS.

(3) A PCIP must verify that an individual is a United States citizen or national or lawfully present in the United States by:

(i) Verifying the individual's citizenship, nationality, or lawful presence with the Commissioner of Security or Secretary of Homeland Security as applicable; or

(ii) By requiring the individual to provide documentation which establishes the individual's citizenship, nationality, or lawful presence.

(iii) The PCIP must provide an individual who is applying to enroll in the PCIP with a disclosure specifying if the information will be shared with the Department of Health and Human Services, Social Security Administration, and if necessary, Department of Homeland Security for purposes of establishing eligibility.

(b) *Disenrollment process.* (1) A PCIP must establish a disenrollment process that is approved by HHS.

(2) A PCIP may disenroll an individual if the monthly premium is not paid on a timely basis, following notice and a reasonable grace period, not to exceed 61 days from when payment is due, as defined by the PCIP and approved by HHS.

(3) A PCIP must disenroll an individual in any of the following circumstances:

(i) The individual no longer resides in the PCIP service area.

(ii) The individual obtains other creditable coverage.

(iii) Death of the individual.

(iv) Other exceptional circumstances established by HHS.

(c) *Effective dates.* A PCIP must establish rules governing the effective date of enrollment and disenrollment that are approved by HHS. A complete enrollment request submitted by an eligible individual by the 15th day of a month, where the individual is determined to be eligible for enrollment, must take effect by the 1st day of the following month, except in exceptional circumstances that are subject to HHS approval.

(d) *Funding limitation.* A PCIP may stop taking applications for enrollment to comply with funding limitations established by the HHS under section 1101(g) of Public Law 111–148 and § 152.35 of this part. Accordingly, a PCIP may employ strategies to manage enrollment over the course of the program that may include enrollment capacity limits, phased-in (delayed) enrollment, and other measures, as defined by the PCIP and approved by HHS, including measures specified under § 152.35(b).

Subpart D—Benefits

§ 152.19 Covered benefits.

(a) *Required benefits.* Each benefit plan offered by a PCIP shall cover at least the following categories and the items and services:

(1) Hospital inpatient services

(2) Hospital outpatient services

(3) Mental health and substance abuse services

(4) Professional services for the diagnosis or treatment of injury, illness, or condition

(5) Non-custodial skilled nursing services

(6) Home health services

(7) Durable medical equipment and supplies

(8) Diagnostic x-rays and laboratory tests

(9) Physical therapy services (occupational therapy, physical therapy, speech therapy)

(10) Hospice

(11) Emergency services, consistent with § 152.22(b), and ambulance services

(12) Prescription drugs

(13) Preventive care

(14) Maternity care

(b) *Excluded services.* Benefit plans offered by a PCIP shall not cover the following services:

(1) Cosmetic surgery or other treatment for cosmetic purposes except to restore bodily function or correct deformity resulting from disease.

(2) Custodial care except for hospice care associated with the palliation of terminal illness.

(3) In vitro fertilization, artificial insemination or any other artificial means used to cause pregnancy.

(4) Abortion services except when the life of the woman would be endangered or when the pregnancy is the result of an act of rape or incest.

(5) Experimental care except as part of an FDA-approved clinical trial.

§ 152.20 Prohibitions on pre-existing condition exclusions and waiting periods.

(a) *Pre-existing condition exclusions.* A PCIP must provide all enrollees with health coverage that does not impose any pre-existing condition exclusions (as defined in § 152.2) with respect to such coverage.

(b) *Waiting periods.* A PCIP may not impose a waiting period with respect to the coverage of services after the effective date of enrollment.

§ 152.21 Premiums and cost-sharing.

(a) *Limitation on enrollee premiums.* (1) The premiums charged under the PCIP may not exceed 100 percent of the premium for the applicable standard risk rate that would apply to the coverage offered in the State or States. The PCIP shall determine a standard risk rate by considering the premium rates charged for similar benefits and cost-sharing by other insurers offering health insurance coverage to individuals in the applicable State or States. The standard risk rate shall be established using reasonable actuarial techniques, that are approved by the Secretary, and that reflect anticipated experience and expenses. A PCIP may not use other methods of determining the standard rate, except with the approval of the Secretary.

(2) Premiums charged to enrollees in the PCIP may vary on the basis of age by a factor not greater than 4 to 1.

(b) *Limitation on enrollee costs.* (1) The PCIP's average share of the total allowed costs of the PCIP benefits must be at least 65 percent of such costs.

(2) The out-of-pocket limit of coverage for cost-sharing for covered services under the PCIP may not be greater than the applicable amount described in section 223(c)(2) of the Internal Revenue

code of 1986 for the year involved. If the plan uses a network of providers, this limit may be applied only for in-network providers, consistent with the terms of PCIP benefit package.

§ 152.22 Access to services.

(a) *General rule.* A PCIP may specify the networks of providers from whom enrollees may obtain plan services. The PCIP must demonstrate to HHS that it has a sufficient number and range of providers to ensure that all covered services are reasonably available and accessible to its enrollees.

(b) *Emergency services.* In the case of emergency services, such services must be covered out of network if:

(1) The enrollee had a reasonable concern that failure to obtain immediate treatment could present a serious risk to his or her life or health; and

(2) The services were required to assess whether a condition requiring immediate treatment exists, or to provide such immediate treatment where warranted.

Subpart E—Oversight

§ 152.26 Appeals procedures.

(a) *General.* A PCIP shall establish and maintain procedures for individuals to appeal eligibility and coverage determinations.

(b) *Minimum requirements.* The appeals procedure must, at a minimum, provide:

(1) A potential enrollee with the right to a timely redetermination by the PCIP or its designee of a determination regarding PCIP eligibility, including a determination of whether the individual is a citizen or national of the United States, or is lawfully present in the United States.

(2) An enrollee with the right to a timely redetermination by the PCIP or its designee of a determination regarding the coverage of a service or the amount paid by the PCIP for a service.

(3) An enrollee with the right to a timely reconsideration of a redetermination made under paragraph (b)(2) of this section by an entity independent of the PCIP.

§ 152.27 Fraud, waste, and abuse.

(a) *Procedures.* The PCIP shall develop, implement, and execute operating procedures to prevent, detect, recover (when applicable or allowable), and promptly report to HHS incidences of waste, fraud, and abuse, and to appropriate law enforcement authorities instances of fraud. Such procedures shall include identifying situations in which enrollees or potential enrollees (or their family members) are employed, and may have, or have had, access to other coverage such as group health coverage, but were discouraged from enrolling.

(b) *Cooperation.* The PCIP shall cooperate with Federal law enforcement and oversight authorities in cases involving waste, fraud and abuse, and shall report to appropriate authorities situations in which enrollment in other coverage may have been discouraged.

§ 152.28 Preventing insurer dumping.

(a) *General rule.* If it is determined based on the procedures and criteria set forth in paragraph (b) of this section that a health insurance issuer or group health plan has discouraged an individual from remaining enrolled in coverage offered by such issuer or health plan based on the individual's health status, if the individual subsequently enrolls in a PCIP under this part, the issuer or health plan will be responsible for any medical expenses incurred by the PCIP with respect to the individual.

(b) *Procedures and criteria for a determination of dumping.* A PCIP shall establish procedures to identify and report to HHS instances in which health insurance issuers or employer-based group health plans are discouraging high-risk individuals from remaining enrolled in their current coverage in instances in which such individuals subsequently are eligible to enroll in the qualified high risk pool. Such procedures shall include methods to identify the following circumstances, either through the PCIP enrollment application form or other vehicles:

(1) Situations where an enrollee or potential enrollee had prior coverage obtained through a group health plan or issuer, and the individual was provided financial consideration or other rewards for disenrolling from their coverage, or disincentives for remaining enrolled.

(2) Situations where enrollees or potential enrollees had prior coverage obtained directly from an issuer or a group health plan and either of the following occurred:

(i) The premium for the prior coverage was increased to an amount that exceeded the premium required by the PCIP (adjusted based on the age factors applied to the prior coverage), and this increase was not otherwise explained;

(ii) The health plan, issuer or employer otherwise provided money or other financial consideration to disenroll from coverage, or disincentive to remain enrolled in such coverage. Such considerations include payment of the PCIP premium for an enrollee or potential enrollee.

(c) *Remedies.* If the Secretary determines, based on the criteria in paragraph (b) of this section, that the rule in paragraph (a) of this section applies, an issuer or a group health plan will be billed for the medical expenses incurred by the PCIP. The issuer or group health plan also will be referred to appropriate Federal and State authorities for other enforcement actions that may be warranted based on the behavior at issue.

(d) *Other.* Nothing in this section may be construed as constituting exclusive remedies for violations of this section or as preventing States from applying or enforcing this section or other provisions of law with respect to health insurance issuers.

Subpart F—Funding

§ 152.32 Use of funds.

(a) *Limitation on use of funding.* All funds awarded through the contracts established under this program must be used exclusively to pay allowable claims and administrative costs incurred in the development and operation of the PCIP that are in excess of the amounts of premiums collected from individuals enrolled in the program.

(b) *Limitation on administrative expenses.* No more than 10 percent of available funds shall be used for administrative expenses over the life of the contract with the PCIP, absent approval from HHS.

§ 152.33 Initial allocation of funds.

HHS will establish an initial ceiling for the amount of the $5 billion in Federal funds allocated for PCIPs in each State using a methodology consistent with that used to established allocations under the Children's Health Insurance Program, as set forth under 42 CFR Part 457, Subpart F, Payment to States.

§ 152.34 Reallocation of funds.

If HHS determines, based on actual and projected enrollment and claims experience, that the PCIP in a given State will not make use of the total estimated funding allocated to that State, HHS may reallocate unused funds to other States, as needed.

§ 152.35 Insufficient funds.

(a) *Adjustments by a PCIP to eliminate a deficit.* In the event that a PCIP determines, based on actual and projected enrollment and claims data, that its allocated funds are insufficient to cover projected PCIP expenses, the PCIP shall report such insufficiency to HHS, and identify and implement

necessary adjustments to eliminate such deficit, subject to HHS approval.

(b) *Adjustment by the Secretary.* If the Secretary estimates that aggregate amounts available for PCIP expenses will be less than the actual amount of expenses, HHS reserves the right to make such adjustments as are necessary to eliminate such deficit.

Subpart G—Relationship to Existing Laws and Programs

§ 152.39 Maintenance of effort.

(a) *General.* A State that enters into a contract with HHS under this part must demonstrate, subject to approval by HHS, that it will continue to provide funding of any existing high risk pool in the State at a level that is not reduced from the amount provided for in the year prior to the year in which the contract is entered.

(b) *Failure to maintain efforts.* In situations where a State enters into a contract with HHS under this part, HHS shall take appropriate action, such as terminating the PCIP contract, against any State that fails to maintain funding levels for existing State high risk pools as required, and approved by HHS, under paragraph (a) of this section.

§ 152.40 Relation to State laws.

The standards established under this section shall supersede any State law or regulation, other than State licensing laws or State laws relating to plan solvency, with respect to PCIPs which are established in accordance with this section.

Subpart H—Transition to Exchanges

§ 152.44 End of PCIP program coverage.

Effective January 1, 2014, coverage under the PCIP program (45 CFR part 152) will end.

§ 152.45 Transition to the exchanges.

Prior to termination of the PCIP program, HHS will develop procedures to transition PCIP enrollees to the Exchanges, established under sections 1311 or 1321 of the Affordable Care Act, to ensure that there are no lapses in health coverage for those individuals.

Dated: July 26, 2010.

Jay Angoff,

Director, Office of Consumer Information and Insurance Oversight.

Dated: July 26, 2010.

Kathleen Sebelius,

Secretary, Department of Health and Human Services.

[FR Doc. 2010–18691 Filed 7–29–10; 8:45 am]

BILLING CODE 4150–03–P

Federal Register

Wednesday,
December 1, 2010

Part III

Department of Health and Human Services

45 CFR Part 158

Health Insurance Issuers Implementing Medical Loss Ratio (MLR) Requirements Under the Patient Protection and Affordable Care Act; Interim Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 158

[OCIIO–9998–IFC]

RIN 0950–AA06

Health Insurance Issuers Implementing Medical Loss Ratio (MLR) Requirements Under the Patient Protection and Affordable Care Act

AGENCY: Office of Consumer Information and Insurance Oversight, Department of Health and Human Services.

ACTION: Interim final rule with request for comments.

SUMMARY: This document contains the interim final regulation implementing medical loss ratio (MLR) requirements for health insurance issuers under the Public Health Service Act, as added by the Patient Protection and Affordable Care Act (Affordable Care Act).

DATES: *Effective date:* This interim final regulation is effective January 1, 2011.

Comment date: Comments are due on or before January 31, 2011.

Applicability dates: This interim final regulation generally applies beginning January 1, 2011, to health insurance issuers offering group or individual health insurance coverage.

ADDRESSES: Written comments may be submitted to the address specified below.

All comments will be made available to the public. *Warning:* Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments are posted on the Internet exactly as received, and can be retrieved by most Internet search engines. No deletions, modifications, or redactions will be made to the comments received, as they are public records. Comments may be submitted anonymously.

In commenting, please refer to file code OCIIO–9998–IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the instructions under the "More Search Options" tab.

2. *By regular mail.* You may mail written comments to the following address only: Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, Attention: OCIIO–9998–IFC, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address only: Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, Attention: OCIIO–9998–IFC, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to the following address: Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, Attention: OCIIO–9998–IFC, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the OCIIO drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the "Collection of Information Requirements" section in this document.

FOR FURTHER INFORMATION CONTACT: Carol Jimenez, Office of Consumer Information and Insurance Oversight, Department of Health and Human Services, at (301) 492–4457.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* Comments received timely will also be available for public inspection as they are received, generally beginning approximately three weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

Customer Service Information: Individuals interested in obtaining information on health reform can be found *http://www.healthcare.gov.*

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I. Background

The Patient Protection and Affordable Care Act (Pub. L. 111–148, was enacted on March 23, 2010); the Health Care and Education Reconciliation Act (Pub. L. 111–152, was enacted on March 30, 2010). In this preamble we refer to the two statutes collectively as the Affordable Care Act. The Affordable Care Act reorganizes, amends, and adds to the provisions of Part A of title XXVII of the Public Health Service Act (PHS Act) relating to group health plans and health insurance issuers in the group and individual markets.

The Department of Health and Human Services (HHS, or the Department) is issuing regulations in several phases in order to implement revisions to the PHS Act made by the Affordable Care Act. All of the previous regulations were issued jointly with the Departments of Labor and the Treasury. A request for information relating to the medical loss ratio (MLR) provisions of PHS Act section 2718 was published in the **Federal Register** on April 14, 2010 (75 FR 19297) (notice, or request for information). Additionally, a series of interim final regulations were published earlier this year implementing PHS Act provisions added by the Affordable Care Act. Specifically, interim final rules were published implementing (1) section 2714 (requiring dependent coverage of children to age 26) (75 FR 27122 (May 13, 2010)); (2) section 1251 of the Affordable Care Act (relating to status as a grandfathered health plan) (75 FR 34538 (June 17, 2010)); (3) sections 2704 (prohibiting preexisting condition exclusions), 2711 (regarding lifetime and annual dollar limits on benefits), 2712 (regarding restrictions on rescissions), and 2719A (regarding patient protections) (75 FR 37188 (June 28, 2010)); (4) section 2713 (regarding preventive health services) (75 FR 41726 (July 19, 2010)); and (5) section 2719 (regarding internal claims and appeals and external review processes) (75 FR 43330 (July 23, 2010)). Most recently, HHS, Department of Labor, and Department of the Treasury published an amendment to the interim final regulations relating to status as a grandfathered health plan (regarding change in health insurance issuers) in the **Federal Register** on November 17, 2010 (75 FR 70114). The Departments have also published sub-regulatory guidance regarding various issues related to the implementation of the Affordable Care Act, available at *http://www.dol.gov/ebsa and http://www.hhs.gov/ociio.*

This interim final regulation adopts and certifies in full all of the recommendations in the model regulation of the National Association of Insurance Commissioners (NAIC) regarding MLRs. It is being published to implement section 2718(a) through (c) of the PHS Act, relating to bringing down the cost of health care coverage through a new MLR standard. Subpart A implements the requirements for reporting the data to be considered in determining that ratio. Subpart B addresses the requirements for health insurance issuers (issuers) in the group or individual market, including grandfathered health plans, to provide an annual rebate to enrollees, if the issuer's MLR fails to meet minimum requirements: Generally, 85 percent in the large group market and 80 percent in the small group or individual market. In Subpart C, this interim final regulation provides a process and criteria for the Secretary of Health and Human Services (the Secretary) to determine whether application of the 80 percent MLR in the individual market in a State may destabilize that individual market. Finally, enforcement of the reporting and rebate requirements of section 2718(a) and (b) are addressed in Subparts D–F, as specifically authorized in section 2718(b)(3). This interim final regulation is generally applicable for plan years beginning on or after January 1, 2011. Self-insured plans are not a health insurance issuer, as defined by section 2791(b)(2) of the PHS Act, and thus are not subject to this interim final regulation.

II. Provisions of the Interim Final Rule

A. Introduction and Overview

Section 2718 of the PHS Act includes two provisions designed to achieve the objective in the section title: "Bringing down the cost of health care coverage." The first is the establishment of greater transparency and accountability around the expenditures made by health insurance issuers. The law requires that issuers publicly report on major categories of spending of policyholder premium dollars, such as clinical services provided to enrollees and activities that will improve health care quality. The second is the establishment of MLR standards for issuers, which are intended to help ensure policyholders receive value for their premium dollars. Issuers will provide rebates to enrollees when their spending for the benefit of policyholders on reimbursement for clinical services and quality improving activities, in relation to the premiums charged, is less than the MLR standards established pursuant to the statute. The rebate provisions of section 2718 are designed not just to provide value to policyholders, but also to create incentives for issuers to become more efficient in their operations. Section 2718 also contains provisions which allow for modifications to the standards under certain circumstances, which are described in this regulation. To inform decisions about definitions and methodologies for calculating MLRs, the Affordable Care Act directed the NAIC to make recommendations to the Secretary, subject to certification by the Secretary. As described below, this interim final regulation adopts to these recommendations.

As to the reporting provisions, section 2718(a) requires health insurance issuers to "submit to the Secretary a report concerning the ratio of the incurred loss (or incurred claims) plus the loss adjustment expense (or change in contract reserves) to earned premiums." The statute, as implemented by this interim final regulation, requires health insurance issuers to submit data

to the Secretary that will allow enrollees of health plans, consumers, regulators, and others to take into consideration MLRs as a measure of health insurance performance as described in section 2718 of the PHS Act. More specifically, this interim final regulation is intended to provide consumers with information needed to better understand how much of the premium paid to the issuer is used to reimburse providers for covered services, to improve health care quality, and to pay for the "non-claims," or administrative expenses, incurred by the issuer. The caption of subsection (a) reflects this purpose, which is to provide the Secretary and other parties with a "clear accounting for costs."

As quoted above, the statute requires issuers to submit a report that "concerns" the ratio of the "incurred loss" to "earned premium." The statute does not simply require the issuer to report the numeric ratio of the incurred loss to earned premium. In addition, subsection (a)(3) requires issuers to provide an explanation of the "nature" of "non-claims costs." This interim final regulation accordingly describes the type of information that is to be included in the report to the Secretary and made available to consumers, in addition to the numerical ratio. To increase transparency and avoid confusion, this interim final regulation provides that the data to be reported according to section 2718(a) of the PHS Act will include all of the elements of revenue and expenditures that will be needed to calculate the amount of rebates under subsection 2718(b).

For this information to be meaningful to consumers, the report provided to the Secretary and made available to the public must include the amount of premium revenue received as well as the amount expended on each of the types of activity identified in subparagraphs (1), (2), and (3) of section 2718(a) of the PHS Act:

(1) Reimbursement for clinical services provided to enrollees under the health insurance plan (subparagraph (1));

(2) Activities that improve health care quality for enrollees (subparagraph (2));

(3) All other "non-claims" costs (subparagraph (3)); and

(4) Federal and State taxes and licensing or regulatory fees (subparagraph (3)).

In addition, the rebate requirements established by section 2718(b) allow for a State to provide for higher ratios than those required by section 2718(b)(1)(A)(i) and (ii) of the PHS Act. In order to allow a State to do so, the reporting required of health insurance issuers under subsection (a) must be done on a State level. Section 2718(b) also requires a separate calculation of the MLR for the large group market, the small group market, and the individual market. Consequently, the data required under subsection (a) must be reported for the large group market, the small group market, and the individual market within each State.

NAIC model regulation and recommendations. Section 2718(c) of the PHS Act directs the NAIC, subject to certification by the Secretary, to establish:

(1) Uniform definitions of the activities reported under section 2718(a);

(2) standardized methodologies for calculating measures of the activities reported under section 2718(a); and

(3) definitions of which activities and in what regard such activities constitute activities that improve health care quality.

Section 2718(c) also directs that the standardized methodologies for calculating measures of the activities reported under section 2718(a) "shall be designed to take into account the special circumstances of smaller plans, different types of plans, and newer plans."

The NAIC provided its recommendations to the Secretary on October 27, 2010 regarding the above three areas, and made additional recommendations regarding other aspects of section 2718, in the form of a model regulation entitled *Regulation for Uniform Definitions and Standardized Methodologies for Calculation of the Medical Loss Ratio for Plan Years 2011, 2012 and 2013 per Section 2718(b) of the Public Health Service Act* (hereinafter "NAIC model regulation") (*http://www.naic.org/documents/committees_ex_mlr_reg_asadopted.pdf*). The NAIC model regulation is discussed in more detail in connection with the specific provisions of this interim final regulation. The NAIC, in discharging its statutory obligations, conducted a thorough and transparent process in which the views of regulators and stakeholders were discussed, analyzed, addressed and documented in numerous open forums held by staff from State insurance departments, by NAIC staff, and by the commissioners, directors, and superintendents of insurance from the States. This interim final regulation certifies and adopts the NAIC's model regulation in full.

The NAIC model regulation includes definitions to be used for purposes of reporting the types of activities mandated by section 2718(a), and standardized methodologies for calculating measures of such activities including those that improve health care quality. This interim final regulation certifies and adopts these definitions in the NAIC model regulation. Consistent with the mandate of section 2718(b), the NAIC and this interim final regulation require that health insurance issuers aggregate data at the State level by the large group market, small group market, and individual market, and define these markets. The reporting requirements, which follow NAIC's recommendations, are discussed in connection with Subpart A.

The NAIC model regulation addresses in several different ways, as does this interim final regulation, the statutory requirement that the methodologies used to calculate the measures of the activities reported "shall be designed to take into account the special circumstances of smaller plans, different types of plans, and newer plans." The NAIC recommendations address the special circumstance of newer plans and smaller plans. They address newer plans by adjusting when newer plans' experience is to be reported, which is addressed in Subpart A. The special circumstance of smaller plans, which do not have sufficient experience to be statistically valid for purposes of the rebate provisions, are addressed by the NAIC through credibility adjustments to the calculation of the MLR. Because credibility adjustments are necessary to calculate the rebates under section 2718(b), they are addressed in Subpart B of this interim final regulation. The NAIC model regulation does not address the special circumstances of different types of plans such as so-called mini-med plans or expatriate plans, although it does address expatriate plans in a letter to the Secretary. HHS addresses both mini-med plans and expatriate plans in this interim final regulation, and discusses them in connection with Subpart A.

The NAIC model regulation details the MLR rebate calculation for each of the next three MLR reporting years and notes the incurred claims and expenses related to improving health care quality that may be included. HHS has adopted these provisions in Subpart B.

As noted above, the statute directs the NAIC, subject to certification by the Secretary, to establish uniform definitions and methodologies for calculating measures of activities that are used to calculate an issuer's MLR. HHS has reviewed these recommended definitions and methodologies and has decided to certify and adopt the NAIC recommendations in its October 27 model regulation. The NAIC held public, weekly meetings for several months during which interested parties

were encouraged to provide both written and oral comments, and the details surrounding the reporting requirements were thoroughly analyzed. In making the determination to certify the NAIC's recommendations, HHS also considered the NAIC's Issue Resolution Documents, which were produced as a result of the NAIC's process and which contain the NAIC's position regarding numerous related issues. In addition, HHS considered the public comments received by the NAIC as well as comments submitted to HHS in response to its request for information published on April 14, 2010 in the **Federal Register**. HHS also considered the letters submitted by the NAIC to the Secretary with respect to MLR issues, which are also public records.

Organization of this regulation. The basis, scope, applicability, and definitions for this interim final regulation are set forth in §§ 158.101 through 158.103. The structure of Subpart A of this interim final regulation follows the organization of section 2718(a). The obligation to report is established in § 158.110. The way in which issuers are to aggregate data in the required reports is explained in § 158.120. The special circumstances of mini-med plans and expatriate plans are also included in § 158.120. Newer experience is addressed in § 158.121. Section 158.130 addresses provisions that relate to premium revenue. Section 158.140 clarifies what may be reported as reimbursement for clinical services provided to enrollees, also known as incurred claims. Sections 158.150 through 158.151 explain the criteria for determining whether expenditures are for activities that improve health care quality, allocation of such expenses, and treatment of health information technology (HIT) expenses required to accomplish such activities. Section 158.160 clarifies reporting of non-claims costs. Sections 158.161 and 158.162 address the Federal and State taxes and licensing or regulatory fees that may be excluded from non-claims costs pursuant to PHS Act section 2718(a)(3). Section 158.170 addresses allocation of expenses among categories reported as well as an issuer's lines of business.

Similarly, the structure of Subpart B of this interim final regulation follows the organization of section 2718(b). The applicable MLR standards for the large group, small group and individual markets are addressed in § 158.210. States are permitted to establish a higher MLR standard than provided by the Affordable Care Act, and if a State has done so, the State's standard applies, as stated in § 158.211. Section 158.220 explains which MLR reporting year's data is to be used to calculate an issuer's MLR, and § 158.221 directs which data elements should be in the ratio's numerator and which should be in the denominator. Credibility adjustments are delineated in § 158.230, and the details as to how to calculate them are addressed in § 158.231 and § 158.232. Sections 158.240 through 158.242 provide that enrollees must receive a rebate if the applicable MLR standard is not met, and establish who receives the rebate in certain circumstances, and the manner in which the rebate must be made. The de minimis amount below which a rebate need not be provided and how to handle de minimis rebates are addressed in § 158.243. Section 158.250 establishes a requirement for issuers to provide rebate recipients with an explanatory notice, while § 158.260 establishes a requirement for issuers to report to the Secretary data regarding rebate payments.

Subpart C of this interim final regulation addresses the Secretary's discretion in section 2718(b)(A)(ii) to adjust the MLR percentage for the individual market in a State if the Secretary determines that application of an 80 percent MLR standard may destabilize the individual market in such State. This interim final regulation provides that such determinations will be made pursuant to a State request and based on standards that include recommendations made to HHS in a letter from the NAIC on October 13, 2010.

Subparts D, E and F of this interim final regulation implement section 2718(b)(3), Enforcement, which directs the Secretary to promulgate regulations for enforcing section 2718, and allows for providing appropriate penalties as part of the enforcement scheme. Subpart D addresses the enforcement scheme. Subpart E sets forth the requirements for maintaining records and information. Subpart F, Federal Civil Penalties, details the basis for imposing civil penalties, factors that HHS will consider in assessing civil penalties, the amount of the penalties, and the process for assessing them.

B. Scope, Applicability and Definitions

1. Scope and Applicability (§§ 158.101 Through 158.102)

Section 158.101 sets forth the topics and issues covered in Part 158 of this interim final regulation.

Section 158.102 provides that Part 158 applies to health insurance issuers offering group or individual health insurance coverage. Section 2718(a) of the PHS Act expressly provides that this includes grandfathered health plans. Grandfathered health plans are defined in 26 CFR 54.9815–1251T, 29 CFR §§ 2590.715 through 1251, and 45 CFR 147.140, which implements the provisions in the Affordable Care Act regarding status as a grandfathered health plan (see Interim Final Rules for Group Health Plans and Health Insurance Coverage Relating to Status as a Grandfathered Health Plan Under the Affordable Care Act, 75 FR 34538 (June 17, 2010), as amended, 75 FR 70114 (November 17, 2010)).

Although Section 2718(a) of the PHS Act does not exempt specific categories of plans from its requirements, subparagraph (c) requires that the reporting requirements and methodologies for calculating measures of the activities reported "be designed to take into account the special circumstances of smaller plans, different types of plans, and newer plans." Smaller plans, different types of plans, and newer plans are subject to this interim final rule, and their special circumstances are addressed through the reporting requirements and calculation of the MLR provisions in Subparts A and B.

2. Definitions (§ 158.103)

Section 2718(c) of the PHS Act directs the NAIC, subject to certification by the Secretary, to "establish uniform definitions of the activities reported under subsection (a) and standardized methodologies for calculating measures of such activities, including definitions of which activities, and in what regard such activities, constitute activities described in section (a)(2)."

The NAIC model regulation includes definitions of the activities reportable under section 2718(a) of the PHS Act and this interim final regulation adopts those definitions. Many of the terms defined in the NAIC model regulation refer to specific lines on NAIC financial reporting forms that are broader than the reporting required for the PHS Act MLR provisions.

Any defined term that is used in only one section of this Subpart is defined in that section and is not also contained in the "Definitions" section of the regulation. Such terms include "aggregation," "incurred claims," and "quality improving activities." Thus, these terms are discussed in the preamble section regarding that topic, rather than here. For example, "aggregation" is addressed in § 158.120, "incurred claims" is defined in § 158.140, and "quality improving activities" is defined in § 158.150. Each of these terms is discussed in the section of the preamble regarding the regulation pertaining to it.

Definitions that are used in the regulation as commonly used in the health care industry are not of particular note and therefore are not discussed here. We do discuss several definitions that are unique to this regulation or that may be of particular interest to enrollees, health plans, consumers, regulators and others. The definitions in § 158.103 apply to all of Part 158. Also, in the public comments regarding uniform definitions for activities reported on under section 2718(a) of the PHS Act, the only definition we received any significant amount of comments on is "plan year." Those comments are discussed below with regard to MLR reporting year. Finally, we note that the interim final regulation uses the term "market" as it is used in the statute, to differentiate the small group, large group, and individual market, even if in some contexts these are also referred to as "market segments."

"MLR reporting year." Section 2718(a) requires each health insurance issuer to submit a report to the Secretary "with respect to each plan year." The NAIC has recommended, and HHS concurs, that for purposes of MLR reporting and calculation, the term "plan year" in section 2718 should be interpreted to refer to the calendar year for that plan, and not necessarily the plan year that applies for other purposes. In adopting the NAIC's definition, HHS uses the term "MLR reporting year." Accordingly, this regulation interprets "plan year," as used in section 2718(a), as referring to the "MLR reporting year," and defines the MLR reporting year as the calendar year. We recognize that this definition is different than the definition of the term "plan year" currently in the regulations implementing the PHS Act. This current regulatory definition of "plan year" would continue to apply for all purposes other than the period to be used for MLR reporting and rebate calculation. Specifically, for purposes other than the period for MLR reporting and rebate calculation, the term plan year is defined as "the year that is designated as the plan year in the plan document of a group health plan," although the plan year may under certain conditions be the deductible year, the policy year, the employer's tax year, or the calendar year. We also note that, in the case of individual health insurance coverage, a similar term—"policy year"—is defined. Under these definitions, the "plan year" or "policy year" is specific to the group or individual policy, and can be determined by the issuer. The NAIC recognized that requiring reporting of MLR data for each plan year under this generally applicable definition would be problematic. Meaningful reporting of the data required by section 2718 of the PHS Act requires aggregation of an issuer's experience across health insurance policies and policy forms in each State's large group, small group, and individual markets.

As stated above, the NAIC recommends and requires calendar-year reporting and we adopt this recommendation and require reporting on a calendar-year basis. Issuers will report the premium earned, claims, quality improvement expenses and other non-claims costs incurred under health insurance that is in force during the calendar year. Calendar year reporting will increase the reliability of the experience data that will be reported and that will be used as the basis for rebate calculations. It will reduce the reporting burden on issuers, as they will be required to prepare and file a single loss ratio report and to calculate and pay rebates only once each calendar year. All enrollees under any of the health insurance coverage whose experience is reflected in the report to the Secretary will be eligible for rebates on the premiums paid during that calendar year. To avoid confusion with other uses of the term "plan year," and to make for a clearer presentation and discussion of the MLR reporting requirements, we have adopted the term "MLR reporting year" to refer to the "plan year" referenced in section 2718 for use in the regulation.

The Secretary invited the public to comment on uniform definitions for activities to be reported to the Secretary pursuant to section 2718(a). The only comments received regarding the terms defined in § 158.103 were with respect to "plan year."

Since section 2718 of the PHS Act uses the term "plan year" without specifying whether it means a plan-specific year or a generally applicable reporting period, several commenters requested that we simply clarify its meaning. As explained above, we have done so. A minority of commenters preferred reporting to correspond to the effective dates of each health plan, arguing that non-calendar year plans may have difficulty gathering data on a calendar year basis as health plans are issued at various times throughout the calendar year. However, the calendar year reporting method used in this regulation was supported by several State regulators, health insurance issuers and others because it allows issuers to combine experiences across all policies and will therefore produce more uniform and reliable premium, claims and cost data. They also supported such a calendar-year based reporting period because it is consistent with current industry financial reporting practices, is simpler for consumers to comprehend, and allows States to get the data at one time.

"Enrollee." Section 158.103 defines the term "enrollee" as "an individual who is enrolled, within the meaning of 45 CFR 144.103, in group health insurance coverage, or an individual who is covered by individual insurance coverage, at any time during an MLR reporting year." The NAIC does not define the term "enrollee." However, we believe it is important to clarify that, for reporting purposes, "enrollee" refers to anyone covered by a group plan, including dependents of the subscriber or employee, as well as anyone covered by an individual policy, despite the fact that this term is not ordinarily used in the individual market.

"Small group market" and *"Large group market."* The reporting regulations require in general that issuers report data for the large group market, small group market, and individual market, as that separation of data will be required in order to calculate the ratios and rebates provided for in PHS Act section 2718(b). There is currently more than one option for how to distinguish the small group market and the large group market. The small and large group markets, respectively, refer to coverage sold to a "small employer" or a "large employer." The determination of whether an employer is large or small depends on how many employees it has at particular times. Prior to the Affordable Care Act, the PHS Act defined a small group in terms of 2–50 employees, and a large group in terms of 51 or more employees, while a group with only one employee was considered to be in the individual market. However, the States were permitted to regulate very small groups ("groups of one") in the small group market rather than the individual market. While most States used the statutory definition, several States have chosen to regulate these very small groups in the small group market.

Section 1304(b) of the Affordable Care Act amended the definitions of large and small employer in the PHS Act, defining a small employer as 1–100 employees and a large employer as 101 or more employees. However, section 1304(b)(3) of the Affordable Care Act also allows States to continue to define an employer with up to 50 employees as a "small employer" until 2016.

This interim final regulation provides that for purposes of section 2718 of the PHS Act, consistent with the provisions

in the Affordable Care Act, until 2016 a State may continue to provide a definition of small group as having a maximum of 50 members, and that for States that do so, that definition shall apply to the MLR reporting and rebate requirements set forth in section 2718. This regulation does not address the definition of the term "small employer" as used in ERISA or the Internal Revenue Code, or how the definition in these statutes interact with the definition in the PHS Act for purposes other than the MLR provisions in section 2718. We anticipate that these provisions will be addressed in future guidance.

C. Subpart A—Disclosure and Reporting

1. Reporting Requirements (§ 158.110)

Section 2718(a) of the statute requires issuers to submit a report to the Secretary for each plan year concerning information related to earned premiums and expenditures in various categories, including reimbursement for clinical services provided to enrollees, activities that improve health care quality, and all other non-claims costs. In § 158.110 of this interim final regulation, HHS requires that the report be submitted to the Secretary by June 1 of the year following the end of an MLR reporting year. This allows issuers to include in the report claims for services provided during the MLR reporting year that are processed and paid in the three months following the end of the MLR reporting year, as provided in § 158.140(a)(1), and gives issuers another two months to compile and submit the required data. As discussed in sections 4. and 5. below, mini-med plans and expatriate plans wishing to receive the "special circumstances" adjustment discussed in those sections would be required under § 158.110(b)(1) to submit data on an accelerated schedule.

The precise form and content of the data that issuers must report to the Secretary will be announced in a subsequent **Federal Register** notice. It is anticipated that the data to be submitted will be closely coordinated with the data included on the Supplemental MLR Exhibit that is filed by issuers with State departments of insurance as part of their Annual Statement.

A common practice in insurance is the sale or transfer of blocks of policies between issuers. This practice creates two issues for the reporting requirements under section 2718 of the PHS Act. Consistent with the NAIC's recommendation, § 158.110(c) requires an issuer that has ceded all of the risk associated with a block of policies to another issuer to exclude any experience under those policies from its report. As specified in § 158.110(c), the issuer acquiring the policies must report all of the claims, premium and expenses associated with the acquired policies, including claims and costs incurred and premiums earned during the MLR reporting year by the ceding issuer prior to the effective date of the agreement to transfer responsibility for the policies. The ceding issuer must not include experience under these policies in its report to the Secretary. A second practice in insurance with implications for the reporting requirements under section 2718 of the PHS Act is the use of so-called "assumption reinsurance" to transfer a block of business or group of insurance policies from one issuer to another.

2. Aggregate Reporting (§ 158.120)

Section 158.120 of this interim final regulation requires issuers to report premium, claims and other expenses for all group and individual health insurance coverage (as defined above) on an aggregate basis by State and health insurance market. This follows the approach recommended by the NAIC. That is, a health insurance issuer will submit, for each State in which it writes coverage, data on the aggregate premiums, claims experience, quality-improvement expenditures, and non-claims costs it incurs in connection with the policies it issues in the large group, small group, and individual markets. HHS believes that reporting by State is clearly intended in section 2718 of the PHS Act, which allows a State to set a higher MLR standard than the 80 or 85 percent required by the statute. Reporting by health insurance market—*i.e.*, by large group, small group, and individual markets—is also required by section 2718 of the PHS Act, which requires that MLR standards be met for each such market. The experience for group coverage issued by a single issuer that covers employees in multiple States must be attributed to the State that regulates the insurance contract between the employer and the issuer, as stated in § 158.120(b) of this interim final regulation. Section 158.120(d) also (1) specifies how to attribute experience related to policies sold through associations and trusts, (2) establishes special rules that should be followed in reporting experience under group health insurance coverage offered by multiple affiliated issuers in connection with a single group health plan that gives participants a choice of coverage options, and (3) provides for separate reporting in 2011 for mini-med plans that have a total annual limit of $250,000 or less and for expatriate plans.

The aggregation rules adopted in the regulation are designed to accomplish several objectives. First, the data that are reported and subsequently used to calculate MLRs and rebates should be based on sufficient experience to provide a reliable estimate of the issuer's administrative performance and pricing strategy. To the extent possible, the data used to calculate the MLRs and rebates should not simply represent unpredictable fluctuations in use of services by those covered by the issuer. Second, the reported data should reflect the responsibility of State insurance departments to (1) license issuers to sell insurance within a State (and, where applicable, to approve the products that can be offered in the State by the issuer), and (2) exercise oversight over the premium amounts that are charged for coverage. Third, HHS sought to minimize the burden associated with reporting MLR data, including the quality-improvement expense and non-claims costs that would be reported in connection with each "aggregation."

In developing the regulation, a rule was considered that would disaggregate products by type of coverage—for example, HMO, PPO, and high-deductible coverage—even if offered by the same licensed issuer. The purpose of such a disaggregation would be to have the reported MLRs and rebates reflect experience under more uniform product designs, and to reduce possible inequities in the treatment of different types of plans. However, disaggregation would increase the number of reporting aggregations since one licensed issuer could have to report multiple aggregations, thus reducing the reliability of reported experience and rebates. HHS agrees with the NAIC and has decided against this type of disaggregation. In response to the Request for Comments, commenters generally supported aggregation by State and, within State, by the three market segments identified in the statute: The large group market, the small group market, and the individual market. Consumer advocacy groups generally noted that aggregation would tend to mask variations in MLRs across products. However, other commenters noted that aggregation across policies is needed to calculate reliable MLRs and to reflect the pooling of risk across policies or policy forms. After considering the arguments presented by the commenters, as well as public comments submitted to the NAIC, HHS decided to follow the recommendations submitted to the Secretary by the NAIC

and aggregate at the market level within each State, for reasons described below.

a. Attribution to State-of-Issue

The regulation requires issuers to report experience based on the State-of-issue for each policy that it writes. This requirement is intended to result in a report that describes experience under policies whose benefits and premiums either are regulated, or could be regulated, by a State, since it is at the State level that insurance regulation occurs. The regulation generally defines the State-of-issue based on the "situs" of the insurance contract between the issuer and the policyholder. HHS defines "situs" as the State in which the contract is issued or delivered as stated in the contract. Consistent with NAIC guidance, HHS interprets this as the State that has primary jurisdiction over, or governs, the policy. Special rules that apply to determining the "situs" of a policy marketed to individuals and employers through associations or trusts are discussed below.

The NAIC concluded, and the Department agrees with its conclusion, that the State is the appropriate level of geographic aggregation. Regulation of insurance has been and continues to be primarily the responsibility of States. Benefits offered, premiums, and marketing activities are all regulated under State law. It is the States that review and approve rates, and oversee solvency, and rebates are essentially a retrospective adjustment or correction to premiums. In addition, the statute specifically provides an opportunity for individual States to adopt loss ratio standards that are higher than those required by section 2718(b). It also allows for State-by-State adjustments to the medical loss ratio standard when justified by potential destabilization in the individual market. Applying State-level and State-specific MLR standards would be difficult if experience were aggregated across States that may have different MLR standards. Adopting the State as the basic unit of geographic aggregation will make the reports submitted under section 2718 more meaningful to the exchanges. The Department agrees with the NAIC determination and has decided not to aggregate the experience of a single issuer across States. A rule that would permit aggregation of experience across issuers with common ownership was also considered. Under such a rule, the experience of all issuers owned by a common holding company or corporate group would be combined. Aggregation across such affiliated issuers would have two possible advantages: It would increase the total experience used to prepare the report, thereby increasing the reliability of the data for smaller issuers; and it would combine similar coverage provided in the same market by two related companies. However, aggregation across affiliated issuers might also combine the experience of issuers offering dissimilar coverage or that use different pricing policies. HHS has concluded, as did the NAIC, that reporting should not be done at the level of the holding company in this interim final regulation.

In response to both the April request for information notice and the NAIC's solicitation of comments, extensive comments were received from issuers, regulators, and consumers. In general, comments received from regulators and consumers supported aggregation at no higher than the State level. The reasons given for State aggregation included consistency with the statute, greater meaningfulness of State-level information to consumers and purchasers, consistency with the responsibility of the States for regulation of issuers and oversight of insurance premiums, and the calculation of rebates that appropriately reflect the relationship between premium and claims experience. Many health issuers also recommended aggregation at the State level, although some recommended aggregation at the national level for coverage sold to large employers. Advocates of aggregation at a national level pointed to the greater reliability of reported loss ratios when based on the experience of the combined national enrollment of an issuer and, in the case of large group coverage, the use of experience rating for national or regional employers, and the complexity of allocating certain expenses, particularly Federal taxes, to experience within a single State. Several comments addressed aggregation at a geographic region smaller than a State. Reasons identified for regional aggregation within a State included claims of geographic variations within States of utilization and expenditure patterns and differences across issuers in geographic adjustments that are used to set premiums.

The NAIC considered the arguments made for different approaches to geographic aggregation, including the issues related to multi-State level employers, and decided that aggregation should be at the State level. HHS agrees with and adopts the NAIC's approach. As discussed previously, particularly as to the individual and small group markets, State aggregation is most consistent with the requirements of the statute, particularly provisions permitting State-level exceptions to the minimum loss ratio, and will result in information that is more meaningful to consumers. In addition, aggregation at a national level would preclude States' flexibility to set higher MLR standards as prescribed in the Affordable Care Act. Aggregation at the State level will also ensure value for their health care dollars for consumers in every State.

Some issuers have expressed concern that the reporting and rebate requirements recommended by the NAIC, and adopted in this regulation, would disadvantage large or multi-state employers, including those with a small number of employees in one State and a larger presence in another. This regulation does not require these businesses to change the manner in which they operate, and accommodates issuers that provide coverage to such employers in a number of ways.

First, where an issuer insures employees of a business located in multiple States, the NAIC recommended and HHS agrees that MLR reporting should be based on the "situs of the contract." Under this approach, incorporated in this regulation, the premiums and claims experience attributable to employees in multiple States are combined and reported by the issuer in the MLR report for the State identified in the insurance policy or certificate as having primary jurisdiction over the policy—often the headquarters of the company. This avoids separating the experience of employees from a single company in multiple States.

Second, the NAIC recommended, and HHS adopts, combined reporting across affiliates for "dual contracts." Under these types of insurance contracts, a single group health plan obtains coverage from two affiliated issuers, one providing in-network coverage, and a second affiliate providing out-of-network benefits to the plan. The experience of these two affiliated issuers providing coverage to a single employer can be combined and reported on a consolidated basis as if it were entirely provided by the in-network issuer. This maintains the experience of employees in a single reporting entity.

Thirdly, where affiliated issuers offer blended insurance rates to an employer—rates based on the combined experience of the affiliates serving the employer—the NAIC recommended and HHS agrees that the incurred claims and expenses for quality improving activities can be adjusted among affiliates to reflect the experience of the employer as a whole.

Taken together, these provisions recommended by the NAIC and adopted by HHS are a reasonable

accommodation of the needs of affiliated issuers and the multi-state employers for which the issuers provide coverage.

b. Attribution to Health Insurance Markets Within States

The interim final regulation requires issuers to report experience within a State for each of the three markets referenced by the statute: The individual market, the small group market and the large group market. Experience under a health insurance policy or certificate is to be attributed to the individual market if the policy is not offered in connection with a group health plan, as defined by the PHS Act.

In response to the April request for information notice, HHS received extensive comments on a separate aggregation question: Whether to combine the small group and individual markets. In general, comments supported separate reporting for the individual, small group, and large group markets. Concern was expressed that merging any of these markets would tend to conceal differences in medical loss ratios and perpetuate the pricing of individual or small group policies to achieve a medical loss ratio substantially below the minimums specified in the statue. On the other hand, HHS received comments from both regulators and industry supporting the consolidation of the individual and small group markets, and some comments recommended giving issuers the option of combining or not combining the individual and small group markets. Consolidated reporting could increase the reliability of reported loss ratios by reflecting a larger base of experience. However, it could also deprive consumers in one of these markets of the value of the statutory MLR standard.

The NAIC, in its model regulation, permits an issuer to combine the individual and small group markets for purposes of calculating the MLR rebate if the State in which the coverage is issued requires that the two markets be combined for rating purposes. HHS adopts this approach. This exception is consistent with section 1312(c)(3) of the Affordable Care Act, which allows a State to require the merger of the individual and small group markets. Under such a merger, risk is pooled between individuals and small groups, and it would be appropriate to base rebates on the combined experience in the two markets. While we agree with this approach, it is important that the experience of the small group and individual markets be reported separately even if experience is combined for purposes of calculating the MLR, for a number of reasons. The statute allows the Secretary to adjust the MLR percentage in the individual market of a State if the Secretary determines that the application of the 80 percent MLR may destabilize the individual market in that State. Also, the law states that the Secretary may adjust the MLR "if the Secretary determines appropriate on account of the volatility of the individual market due to the establishment of State Exchanges." In order for the Secretary to make these determinations, reporting of data for the individual market is needed. Separately reported data will also enable HHS to evaluate the impact of the MLR standards on the market, consumers, and the industry, and to consider making changes to the interim final regulation as appropriate based on actual experience.

HHS has considered the arguments made for different approaches to aggregation across markets. It has decided to follow the recommendation to the Secretary submitted by the NAIC and require separate reporting of experience by the three markets.

c. Associations or Trusts

The aggregation rules, in § 158.120(d), adopts the NAIC's approach and also provide guidance for insurance coverage offered through associations or trusts. Under the definition of "group health insurance coverage," only coverage offered to individuals through associations or trusts that are offered in connection with a group health plan should be attributed to the group market. Coverage obtained through an association or trust that is not offered in connection with a group health plan should be attributed to the individual market. Although such coverage is generally considered to be "group" coverage under the conventions of statutory accounting, it is to be reported as individual coverage consistent with the requirements of the PHS Act. This is consistent with ERISA's definition of group health plan, as incorporated in title XXVII of the PHS Act, as well as the NAIC's recommended approach. Although such coverage is generally considered to be "group" coverage for other purposes (for example, the conventions of statutory accounting), this interim final regulation requires non-employment based coverage to be reported as individual coverage consistent with the requirements of the PHS Act. As noted earlier, this interim final regulation does not apply to self-insured plans, including self-insured plans offered through an association or trust.

d. Expatriate Plans

The NAIC model regulation does not address the special circumstances of different types of plans, such as expatriate plans and plans with low annual limits, commonly called "mini-med" plans. However, in a letter dated October 13, 2010 to the Secretary of Health and Human Services, the NAIC expressed its opinion that expatriate plans should be excluded from the requirements of section 2718. HHS has considered the NAIC's views, as well as the public comments received by HHS and by the NAIC regarding these types of plans. Expatriate policies generally cover: Employees working outside their country of citizenship; employees working outside of their country of citizenship and outside the employer's country of domicile; and citizens working in their home country. Their unique nature results in a higher percentage of administrative costs in relation to premiums than plans that provide coverage primarily within the United States, for two reasons. One, administrative costs are related to identifying and credentialing providers worldwide in countries with different licensing and other requirements from those found in the United States, processing claims submitted in various languages that follow various billing procedures and standards, providing translation and other services to enrollees, and helping subscribers locate qualified providers in different countries. Two, because these plans primarily cover care in other countries, issuers are less able to provide quality improving activities.

We note initially that some expatriate plans are not subject to the provisions of the Affordable Care Act, including the MLR reporting and rebate provisions of section 2718. Policies issued by non-U.S. issuers for services rendered outside of the U.S. are not subject to the Affordable Care Act. Therefore, if an expatriate policy is written on a form that was not filed and approved by any State insurance department, or its equivalent, experience under that policy would not be reported for purposes of calculating an issuer's MLR.

HHS agrees with the NAIC that expatriate policies that are issued by U.S. domestic issuers on forms approved by a State insurance department have special circumstances that should be addressed in this interim final regulation. Therefore, the experience of these expatriate policies is to be reported separately from other coverage, as provided in § 158.120(d)(4), and the calculation of claims and quality improving activities is to be

multiplied by a factor of two, as provided in § 158.221(b). HHS believes that this factor is sufficient to account for the special circumstances of expatriate plans, while still requiring that they meet the statutory MLR standards. However, because HHS thinks additional data is necessary to inform this adjustment, this special circumstance adjustment applies for 2011 only. Also, in order to determine whether, and if so what type of, an adjustment may be appropriate for 2012, expatriate plans that wish to avail themselves of this special circumstances adjustment in § 158.221(b)(4) for 2011 will be required to report MLR data on a quarterly schedule under § 158.110(b). We will revisit the special filing circumstances for expatriate plans after reviewing the quarterly filings.

e. "Mini-med" Plans

HHS has received requests from issuers of so-called mini-med plans to be exempted entirely from the MLR and rebate provisions of section 2718. The term "mini-med" plan does not have a statutory basis, and we use it here to generally refer to policies that often cover the same types of medical services as comprehensive medical plans but have unusually low annual benefit limits, often capping coverage on an annual basis for one or more benefits at $5,000 or $10,000, although some have limits above $50,000 or even $250,000. Our analysis of this segment of the insurance market suggests that a large majority of such plans have limits at or below $250,000. As discussed below, we therefore are using this figure as a proxy for capturing this type of plan.

Issuers of mini-med plans assert that their administrative costs are higher as a percentage of the premium collected than is the case for plans having higher annual limits and thus a higher premium base. They assert that they have special administrative burdens because the populations they serve generally have high turnover rates. This high turnover rate may also result in lower claims costs. Mini-med plans are also less likely to spend as much on quality improving activities because of their lower annual limits. Both of these factors would result in administrative costs being a higher percentage of premium dollars than for plans with higher amounts of coverage. These issuers therefore ask that mini-med coverage be exempted entirely from the requirements of section 2718, and have indicated that in the absence of an exemption some may no longer be able to offer coverage. Some consumer groups have disagreed, suggesting that mini-med plans have higher profit margins than do traditional plans with significantly higher limits and should not be exempt from the MLR standards. The Blue Cross and Blue Shield Association sent a letter to Secretary Sebelius on November 1, 2010 in which it urged that HHS not grant "any MLR exceptions for particular companies or product types." However, an issuer, which according to company materials has a relationship with the Blue Cross and Blue Shield system and provides coverage to at least one large employer, asserted that the company would be forced to drop this coverage without an exemption.

The application of the Affordable Care Act to mini-med plans has already arisen in the context of restrictions on annual benefit limits under section 2711 of the PHS Act. HHS has established a process under which certain health plans with annual limits below those established in the interim final regulation implementing section 2711 may be granted a temporary waiver from the application of higher limits if compliance with the standards would result in a significant decrease in access to benefits or a significant increase in premiums. See 26 CFR 54.9815–2711T; 29 CFR 2590.715–2711; 45 CFR 147.126; and OCIIO Sub-Regulatory Guidance (OCIIO 2010–1), September 3, 2010. Data from the applications for waivers described above suggest that over one million individuals have coverage in mini-med plans. There are little publicly available data on these plans because current financial reporting to the States does not separate mini-med experience from other experience on which issuers report.

HHS is concerned about the possibility of the over one million individuals who have coverage through mini-med plans losing that coverage. Based on this concern and the limited data that indicate mini-med plans may have a higher percentage of administrative costs due to lower claims and quality improving activities, HHS has decided to exercise its authority in section 2718(c) to "take into account the special circumstances of smaller plans, different types of plans, and newer plans."

Therefore, for the reporting year 2011, HHS will apply a methodological change to address the special circumstances of mini-med plans. The mini-med issuers, for policies that have a total of $250,000 or less in annual limits, will be permitted to apply an adjustment to their reported experience to address the unusual expense and premium structure of these plans. Specifically, under § 158.221(b)(3), in the case of a plan with a total of $250,000 or less in annual limits, the total of the incurred claims and expenditures for activities that improve health care quality reported under § 158.221(b) are multiplied by a factor of two. We believe this factor is sufficient to account for the special circumstances of mini-med plans based on the limited data available.

Because little information is available to inform this adjustment, this special circumstances adjustment applies for 2011 only. Also, in order to determine whether, and if so what type of, an adjustment may be appropriate for 2012, mini-med plans that wish to avail themselves of this special circumstances adjustment in § 158.221(b)(3) for 2011 will be required to report MLR data on a quarterly schedule under § 158.110(b). We will revisit the special filing circumstances for mini-med plans after reviewing the quarterly filings.

3. Newer Experience (§ 158.121)

Section 2718(c) specifically charges the NAIC with establishing methodologies that take into consideration the special circumstances of newer plans. HHS follows the NAIC's approach in the model regulation, which allows an issuer to defer the experience associated with newly issued health insurance policies under certain circumstances. Specifically, an issuer may defer to the next MLR reporting year the premium and claims experience, as well as the life-years, associated with policies first issued after the start of the MLR reporting period if these policies account for more than half of the issuer's experience in a market segment for an individual State. This condition means that more than half of an issuer's overall premium revenue for a market sector within a State would have to be from newly issued policies that are issued after the first of the year.

The rationale for this provision, as set forth by the NAIC and certified and adopted herein by HHS, has two parts: (1) The rationale for deferring experience under newly issued policies; and (2) the rationale for limiting the deferral of experience to issuers that derive more than half of their premium revenue from newly issued policies. The rationale for deferring experience under newly issued policies is that claims experience is generally expected to be substantially less than the premium revenue from those policies during the year in which the coverage is issued. This is particularly true for policies with substantial deductibles. Applying the rebate provision to these policies would create a substantial barrier to the entry of new issuers into a market.

The rationale for allowing the deferral of experience only when more than half of the premium revenue is derived from newly issued policies is twofold. First, if newly issued policies account for a small percentage of an issuer's total experience in a market, they would have a very limited effect on the aggregated MLR for an issuer. Second, the principal purpose of allowing the deferral of newly issued business in the MLR calculation is to reduce barriers to market entry. Because claims experience is generally low compared to premiums under newly issued policies, including new business would generally result in lowering an issuer's MLR simply because of the new business. Deferral of reporting new business encourages companies to enter new markets, and new companies to enter the market.

In response to the HHS notice requesting public comments regarding section 2718 of the PHS Act, HHS received comments from issuers, consumer advocates, and providers urging that special consideration be given to newer plans. Reasons for this included concern both about the effect on the market if newer plans are not given special consideration, and about the impact on the reliability of reported MLRs if newer plans' experience is included. HHS agrees with these concerns and addresses them by adopting, in § 158.121, the NAIC's method for recognizing the special circumstances of issuers that have substantial new business.

4. Premium Revenue (§ 158.130)

Section 2718(a) of the PHS Act requires health insurance issuers to report information concerning "earned premium," and section 2718(b) provides that these reported data would be used in determining rebates to enrollees. Section 2718(c) charges the NAIC with establishing a uniform definition of premium revenue, subject to certification by the Secretary. HHS is adopting the NAIC definition of premium revenue, as described below.

The NAIC defines "earned premium" as the sum of all monies paid by a policyholder as a condition of receiving coverage from a health insurance issuer subject to section 2718, including any fees or other contributions associated with the health plan, and accounting for unearned premiums. HHS is adopting this NAIC approach in § 158.130(a), and these adjustments to earned premium are discussed below. The NAIC calls for reporting of premium on a direct basis as set forth in § 158.130(a)(1). Earned premium is addressed in § 158.130 and includes any fees or other contributions associated with the health plan.

Adjustments to premium revenue are addressed in § 158.130. Unearned premium is that portion of the premium paid in the MLR reporting year for coverage during a period beyond the MLR reporting year. Any premium for a period outside of the MLR reporting year must not be reported in earned premium for the MLR reporting year. Earned premium is net of premiums associated with group conversion charges that the issuer collects in connection with transfers between group and individual lines of business. Group conversion charges are the portion of earned premium allocated to providing the privilege for a certificate holder terminated from a group health plan to purchase individual health insurance without providing evidence of insurability. In addition, earned premium excludes premium assessments paid to or subsidies received from Federal and State high risk pools. High risk pool subsidies include grants provided under section 2745 of the PHS Act. Earned premium excludes adjustments for experience rating refunds, as provided in § 158.130(b). Experience rating refunds are retrospective premium adjustments arising from retrospectively rated contracts.

Earned premium is to be reported prior to deducting premium refunds to enrollees for health and wellness promotion. These refunds are considered quality improvement expenditures, so they should not be double counted as a reduction in premium, as provided in § 158.130(b)(4).

We have adopted the NAIC's approach to assumption and indemnity reinsurance, in § 158.130(a)(2) and (3). Earned premium for policies that originally were issued by one entity and later assumed by another entity via assumption reinsurance are to be reported as direct earned premium by the assuming entity and are to be excluded from premium revenue reported by the ceding entity. Similarly, if a block of business was subject to indemnity reinsurance and administrative agreements effective prior to the effective date of the Affordable Care Act, such that the assuming entity is responsible for 100 percent of the ceding entity's financial risk and takes on all of the administration of the block, then the assuming entity and not the ceding entity should report the reinsured earned premium as part of its premium revenue.

Section 2718 makes specific reference to "Federal and State taxes and licensing or regulatory fees" in two places: First, in the reporting requirements of subsection (a) it excludes these items from "all other non-claims costs"; second, it excludes these costs from premium revenue in determining the ratio of expenditures on claims and activities to improve quality health care to premium revenue. For reporting purposes, therefore, taxes are excluded from "all other non-claims costs," and are addressed in §§ 158.161 and 158.162, separate from but immediately following the requirements set forth in § 158.160 related to reporting of non-claims costs. Taxes are also discussed in the section of this preamble describing calculation of the MLR.

The PHS Act section 2718(a) requires reporting of "premium revenue, after accounting for collections or receipts for risk adjustment and risk corridors and payments of reinsurance." Because this language so closely parallels the three programs added by the Affordable Care Act (the transitional reinsurance program established by section 1341; the risk-corridor program established by section 1342; and risk-adjustments under section 1343 of the Affordable Care Act), we interpret this requirement as applying exclusively to payments under those provisions, which are not effective until 2014. HHS anticipates providing guidance on these provisions at a later time. Consistent with the statute, § 158.130(b)(v) of this interim final regulation treats payments and collections under these provisions of the Affordable Care Act as adjustments to premium revenue.

In response to the HHS notice requesting public comments regarding section 2718 of the PHS Act, HHS received a number of comments from the industry regarding premium revenue. A few industry commenters recommended adjusting premium revenue for the change in unearned premium reserves. HHS agrees that changes in unearned premium reserves should be reflected in premium revenue, and has provided for this in § 158.130(a). A few industry commenters recommended adjusting premium revenue for commercial reinsurance ceded and assumed. HHS is not adjusting premium revenue for commercial reinsurance (with the exception of 100 percent assumption reinsurance) because this largely would provide a tool for issuers to manipulate reported premiums.

The NAIC considered allowing an adjustment to premium for commercial stop-loss or similar reinsurance, but rejected allowing such adjustments. We adopt the reasoning and recommendation of the NAIC. The argument for allowing such adjustments

for reinsurance was that it might increase the reliability of the medical loss ratio that is used for purposes of calculating rebates. However, the NAIC concluded that allowing adjustments for reinsurance created too much of an opportunity for manipulation of the reported loss ratio and would require extensive and complex regulation of the use of reinsurance. An industry commenter suggested subtracting experience rating refunds from premium revenue. The NAIC recommended, and HHS agrees, that there should be an adjustment for experience rating refunds. A consumer advocate suggested that total revenue (including investment income) be used in place of premium revenue, so consumers would know the universe of funds available to be spent on medical services. However, the commenter points out—and both the NAIC and we agree—that the statute instructs issuers to report "premium revenue" and not total revenue.

5. Reimbursement for Clinical Services Provided to Enrollees (§ 158.140)

Section 2718(a)(1) of the PHS Act requires reporting of "reimbursement for clinical services provided to enrollees under such coverage." The Affordable Care Act charges the NAIC with establishing a uniform definition of reimbursement for clinical services. The NAIC defines reimbursement for clinical services as direct claims paid and incurred claims during the applicable MLR reporting year. In this interim final regulation, HHS is adopting this NAIC approach, at § 158.140. The definition and guidance regarding adjustments to claims are discussed below.

The interim final regulation defines incurred claims as the sum of direct paid claims incurred in the MLR reporting year, unpaid claim reserves associated with claims incurred during the MLR reporting year, the change in contract reserves, reserves for contingent benefits, the claim portion of lawsuits, and any experience rating refunds paid or received. Experience rating refunds exclude rebates based on an issuer's MLR, as required by § 158.140. If there are any group conversion charges for a health plan, the conversion charges should be subtracted from the incurred claims for the aggregation that includes the conversion policies, and this same amount should be added to incurred claims for the aggregation that provides coverage that is intended to be replaced by the conversion policies. Incurred claims must not include claims recovered as a result of fraud and abuse programs. Treatment of the amount expended to reduce fraudulent claims is discussed below in the section regarding quality improving activities. Additionally, if the issuer transfers portions of earned premium associated with group conversion privileges between group and individual lines of business in its Annual Statement accounting, these amounts should be added to or subtracted from incurred claims.

Unpaid claims reserves are included in incurred claims. Unpaid claim reserves are the reserves for claims that were incurred during the reporting period but that had not been paid by the date on which the report was prepared. To minimize reliance on estimates for the amount of the reserve, unpaid claim reserves shall be calculated based on claims that have been processed within three months after the end of the MLR reporting year. This claims collection period provides a better estimate of outstanding liability than the reserve established at the end of the MLR reporting year. Claims reserves are included in incurred claims in order for claims to be paid effectively and to allow for the insurance company to continue operating year after year.

The NAIC includes the change in contract reserves in reimbursement for clinical services, and HHS has followed this approach. The NAIC and this interim final regulation define contract reserves as reserves that are established which, due to the gross premium pricing structure at the time of issue, account for the value of the future benefits that at any time exceeds the value of any appropriate future valuation of net premiums at that time. In the early years of a new product being introduced, reserves are established to cover losses in the future, but as reserves are drawn down to cover current losses the amount collected from reserves will be deducted from claims. An issuer may establish contract reserves to reduce the need to increase premiums for a newly introduced product as the experience under that policy matures. As a policy matures, the reserves that were set aside in the beginning of the policy's existence are used to cover claims that are incurred in the future.

Contract reserves must not include premium deficiency reserves. Premium deficiency reserves are reserves that are established when premium is no longer adequate to cover losses. They are excluded because contract reserves would provide for these future losses over time to the extent that such losses were anticipated and factored into the premiums charged during the reporting period. Contract reserves shall not include reserves for expected MLR rebates.

Guidance is also provided as to types of expenses or revenue that are to be treated as adjustments to claims. The NAIC recommended that prescription drug costs should be included in incurred claims and prescription drug rebates should be deducted from incurred claims. Prescription drug rebates are rebates that pharmaceutical companies pay to issuers based upon the drug utilization of the issuer's enrollees at participating pharmacies. We agree with the NAIC that drug rebates should be accounted for, and under § 158.140(b)(1)(i) we treat such rebates as an adjustment to incurred claims.

The NAIC allows an adjustment to claims for State stop loss, market stabilization, and claims/census based assessments. HHS agrees that these types of expenses should be allowed as an adjustment to incurred claims. These assessments include:

(1) Any market stabilization payments or receipts by issuers that are directly tied to claims incurred and other claims based or census based assessments;

(2) State subsidies based on a stop-loss payment methodology; and

(3) unsubsidized State programs designed to address distribution of health risks across health issuers via charges to low risk issuers that are distributed to high risk issuers.

The NAIC also considered but rejected the inclusion of an adjustment to incurred claims for so-called "large claim pooling" as a means of reducing the need for and magnitude of credibility adjustments. NAIC rejected large claim pooling for two reasons. First, it would not have not addressed the needs of issuers that either are not part of a holding company or company group or that are operate in a single State. Second, it would require extensive and complex regulations and close oversight. We have accepted the NAIC's recommendations.

Incurred medical incentive pools and bonuses to incurred claims are also allowed as an adjustment to incurred claims, and this is reflected in § 158.140(b)(2)(iii) of the interim final regulation. Medical incentive pools are arrangements with providers and other risk sharing arrangements whereby the reporting entity agrees to either share savings or make incentive payments to providers. These payments may not be counted under quality improvement expenditures.

HHS received numerous comments from consumer groups, issuers, and regulators regarding whether, and to what extent, reserves should be included in incurred claims. A consumer advocacy group felt that only

paid claims should be used, arguing that the use of actual claims paid is reasonable because the review is historical; this would avoid the possibility of issuers gaming the system by manipulating reserves. However, several issuers and regulators support the inclusion of unpaid claims reserves in incurred claims. A State regulator indicates that the advantage of such inclusion is that it deals only with data for the one year in which claims are incurred, and avoids any distortion due to possible errors in the estimate of the unpaid claim reserve as of the beginning of the year. The disadvantage is that the result is unduly influenced by the unpaid claim reserve as of the end of the year.

HHS acknowledges the consumer group concern for the potential that reserves can be manipulated, and in particular overstated, and can thus produce a reported MLR for a given calendar year that is higher than the true MLR for that year. Nevertheless, over the long run such over-reserving for one year necessarily results in a reduction, or "releasing," of reserves in future years. HHS concurs with the NAIC that including contract reserves in claims is fair to consumers over the long run, and has adopted this approach.

6. Activities That Improve Health Care Quality (§§ 158.150 Through 158.151)

Section 2718(a)(2) of the PHS Act requires health insurance issuers to submit an annual report to the Secretary concerning the percent of total premium revenue that is spent on activities that improve health care quality. Section 2718(c) of the PHS Act directs the NAIC, subject to certification by the Secretary, to establish uniform definitions of activities that improve health care quality. In developing the definition of a quality improvement activity, the NAIC has relied upon section 2717 of the PHS Act. HHS concurs with the NAIC in this approach and has followed the recommendations of the NAIC.

Section 2717 provides for the development of "reporting requirements for use by a group health plan, and a health insurance issuer offering group or individual health insurance coverage, with respect to plan or coverage benefits and health care provider reimbursement structures that—

(A) improve health outcomes through the implementation of activities such as quality reporting, effective case management, care coordination, chronic disease management, and medication and care compliance initiatives, including through the use of the medical homes model as defined for purposes of section 3602 of the Patient Protection and Affordable Care Act, for treatment or services under the plan or coverage;

(B) implement activities to prevent hospital readmissions through a comprehensive program for hospital discharge that includes patient-centered education and counseling, comprehensive discharge planning, and post-discharge reinforcement by an appropriate health care professional;

(C) implement activities to improve patient safety and reduce medical errors through the appropriate use of best clinical practices, evidence-based medicine, and health information technology under the plan or coverage; and

(D) implement wellness and health promotion activities.

The NAIC model regulation contains definitions of activities that improve health care quality that track the categories set forth in section 2717. After considering the NAIC's definitions, and public comments thereon, HHS has decided to certify and adopt them. In addition, the NAIC provided examples to illustrate activities that qualify as quality improving activities and these are also certified and adopted in toto in this interim final regulation. Finally, the NAIC designated certain activities as not qualifying as quality improving, and we certify and adopt these exclusions as well.

As recommended by the NAIC, this interim final regulation allows a non-claims expense incurred by a health insurance issuer to be accounted for as a quality improvement activity only if the activity falls into one of the categories set forth in section 2717 and meets all of the following requirements:

(1) It must be designed to improve health quality;

(2) It must be designed to increase the likelihood of desired health outcomes in ways that are capable of being objectively measured and of producing verifiable results and achievements;

(3) It must be directed toward individual enrollees or incurred for the benefit of specified segments of enrollees or provide health improvements to the population beyond those enrolled in coverage as long as no additional costs are incurred due to the non-enrollees; and

(4) It must be grounded in evidence-based medicine, widely accepted best clinical practice, or criteria issued by recognized professional medical associations, accreditation bodies, government agencies or other nationally recognized health care quality organizations. These criteria are recommended by the NAIC in its model regulation.

In this interim final regulation HHS recognizes that some quality improvement activities may be what are sometimes referred to as "population-directed" and may not involve face-to-face interaction between an employee of the health insurance issuer (or a contractor of the issuer) and the enrollee. However, such activities must be directed to identified segments of the issuer's enrollees. The issuer must be able to measure the level of engagement with these enrollees in addition to tracking the effect(s) of these activities on health outcomes in this population through a process that is well defined, well developed, and utilized.

Any quality improvement activity that results in cost savings to an issuer should not, by itself, cause expenditures on that activity to be classified as non-quality improving expenditures, if they meet the criteria set forth in this interim final regulation. However, if the activity is designed primarily to control or contain costs, then expenditures for it may not be included as a quality improvement activity, as provided in § 158.150(d). This approach follows the NAIC's model regulation.

As many quality improvement activities are fluid in nature, they may properly be classified in more than one quality improvement activity category. However, following the recommendation of the NAIC, the interim final regulation does not permit issuers to count any occurrence of a quality improvement activity more than once, as explained in § 158.170(a). Moreover, shared expenses among related entities as well as expenses that are for or benefit lines of business or products other than those being reported, including self-funded plans, must be apportioned among the entities and among the lines of business or products. For example, a quality improvement program that is developed and implemented for self-funded plans and fully insured plans must be pro-rated among the lines of business, and the portion of expenditures for the program that are for the self-funded plans may not be included in quality improvement activities reported under section 2718(a) of the PHS Act.

The NAIC recommended, and HHS adopts in its entirety, the list of activities that are not to be reported as a quality improving activity. Section 158.150(c) sets forth types of activities that are not to be reported as a quality improvement activity. These include:

(1) Those activities which are designed primarily to control or contain costs;

(2) Concurrent and retrospective Utilization Review;

(3) Fraud Prevention activities (beyond the scope of those activities which recover incurred claims);

(4) Development, execution, and management of a provider network;
(5) Provider credentialing;
(6) Marketing expenses;
(7) Costs associated with calculating/administering individual enrollee or employee incentives;
(8) Clinical data collection without any subsequent data analysis;
(9) Establishment and/or maintenance of a claims adjudication system; and
(10) 24-hour customer service/or health care professional hotline addressing non-clinical member questions.

HHS requested public comments regarding the types of activities that would improve the quality of health care. Numerous consumer advocacy groups, issuers, State regulators, and other interested parties responded with various suggestions as to the type of activities that should be included in the definition of quality improving activities.

Many issuers and interest groups advocated for a broad definition for "quality improving activities" that allows for future innovations. However, numerous providers and consumer advocacy groups asserted that HHS should develop a definition for 'quality improving activities' that is not so broad that issuers may improperly classify administrative activities as improving quality. Several commenters also advocated for a definition that requires issuers to clearly articulate the activity's purpose and to provide detailed accounts of the underlying activity with measurable evidence as to the effects of the activity on the quality of care received by enrollees.

This interim final regulation provides a set of criteria in § 158.150 which issuers must comply with in order for the activity in question to be treated as improving quality. The definition, or foundational criteria, of a quality improvement activity should be specific enough so as to provide clear guidance without overly prescribing acceptable activities and possibly stifling future innovative quality improving activities; the NAIC's definition which we have adopted achieves these goals.

Numerous consumer groups advocated for a definition that includes only evidence-based quality improving initiatives, and excludes alleged quality-improving activities that have not been demonstrated to improve quality. Some consumers and providers want issuers to provide specific data illustrating the success of a proposed quality improving measure prior to HHS acknowledging the validity of such an activity. Issuers argue, however, that imposing a specific data requirement prior to engaging in a quality improvement activity will stifle development in future innovations, as data demonstrating the effectiveness of such activity may not yet be available.

The NAIC recommended and HHS agreed that, as provided in § 158.150, a quality improvement activity is "grounded in evidence-based medicine, widely accepted best clinical practice, or criteria issued by recognized medical associations, accreditation bodies, government agencies, or other nationally recognized health care quality organizations." This interim final regulation further requires any proposed quality improving activities to be designed to improve the quality of care received by an enrollee and capable of being objectively measured (taking into account the individual needs of the patient) and of producing verifiable results and achievements. While an issuer does not have to present initial evidence proving the effectiveness of a quality improvement activity, the issuer will have to show measurable results stemming from the executed quality improvement activity.

A consumer advocacy group called for issuers to be required to spend a specified percentage of premiums on preventive and health-lifestyle promotional activities. Several interested parties, including issuers, other interest groups and providers, asserted that capping or limiting quality improvement initiatives would deter issuers from engaging in such activities. Issuers further commented that although these types of activities "add value to the health care system," issuers would be deterred from engaging in such activities if HHS limited the amount an issuer could spend on quality improving activities.

The Affordable Care Act does not dictate the amount an issuer must expend on quality improving activities, nor did the NAIC make a recommendation in this regard, nor does this interim final regulation. Section 158.150 requires that a quality improvement activity be provided by an issuer or through a third party to whom it delegated such responsibilities by contract in connection with which the issuer remains ultimately responsible for the underlying insurance policy. In calculating its MLR, an issuer may allocate any percentage of its expenses to quality improvement activities, so long as the activities comply with the criteria established under § 158.150.

Some industry groups argued that network fees associated with third party provider networks should be classified as quality improving activities, because they increase enrollees' access to providers. Consumer groups argued that these fees are traditional administrative expenses which should not be classified as improving quality. While HHS agrees that administrative expenses such as network fees should not be counted as quality improving, some traditional administrative activities can qualify as quality improving if they meet the criteria set forth in § 158.150. For example, expenses for prospective utilization review and fraud recovery activities up to the amount of fraudulent claims recovered may be classified as expenses for quality improving activities. Prospective utilization review is considered a quality improving activity because it is rendered before care is given and can help ensure that the most appropriate medical treatment is given in the most appropriate setting. In contrast, the network fees associated with third party provider networks do not stem from a quality improving activity and therefore only count as an administrative expense.

Issuers pointed out that the recovery of fraudulently paid claims reduces their MLR. They argued, therefore, that costs of preventing and discovering fraud should be counted as a quality improving activity; otherwise, there would be a reduced incentive to incur these costs. We agree with this concern. The NAIC model regulation addresses this concern by allowing fraud recovery expenses as a quality improving activity expense up to the amount of fraudulent claims recovered. This treatment would help mitigate whatever disincentive might occur if fraud recovery expenses were treated solely as non-claims and non-quality improving expenses. We adopt the NAIC's approach.

HHS also adopts the NAIC's recommendation to exclude the conversion of International Classification of Disease code sets from ICD–9 to ICD–10 as a quality improvement activity with the following qualification. As a general matter, the development and maintenance of claims adjudication systems are not designed primarily to improve the quality of care received by an individual and, therefore, are not classified as a quality improvement activity. However, there is general recognition that the conversion to ICD–10 will enhance the provision of quality care through the collection of better and more refined data. The difficulty is in parsing expenses associated with ICD–10 conversions that may be solely "development and maintenance of claims adjudication systems" as opposed to those that are uniquely conversion costs. As with some other reporting categories defined in this regulation, little public data currently exist to guide decision making

regarding this distinction. Although the NAIC excluded these costs as a quality improving activity, the NAIC supplemental forms allow for the collection of data relating to the conversion for the calendar year 2010 that will be reported in 2011. HHS intends to examine the reported conversion costs along with other quality activity costs and other administrative costs in the NAIC supplemental form in 2011 to determine whether the policy in this regulation should be revisited. HHS solicits further comments on whether ICD–10 expenses should be included as a quality improving activity.

Health Information Technology (Section 158.151). Section 158.151 of this interim final regulation provides guidance on the use of Health Information Technology ("HIT") in conjunction with quality improving activities. Although HIT is not specifically addressed in section 2718(a) of the PHS Act, it is addressed in other provisions within the Affordable Care Act, and HHS has determined that it is important to address HIT's role in quality improvement activity. HHS recognizes HIT as its own separate category of quality improving activities, provided that the use of HIT meets certain requirements. In doing so, HHS has followed the approach of the NAIC.

HIT offers providers, issuers and patients the capability to share clinical information in a real-time setting. Any HIT expenditure that is attributable to improving health care, preventing hospital readmissions, improving patient safety and reducing errors, or promoting health activities and wellness to an individual or an identified segment of the population, is classified as a quality improvement activity. HIT resources that are designed to improve the quality of care received by an enrollee include the provision of electronic health records and patient portals, as well as the monitoring, measuring, and reporting of clinical effectiveness measures. As indicated in § 158.151, HIT expenses that are consistent with Medicare/Medicaid meaningful use requirements may be treated as an expenditure to improve health care quality. This treatment of HIT is also recommended by the NAIC.

7. Other Non-Claims Costs (§ 158.160)

The report required by section 2718(a) of the PHS Act must include information on expenditures for "all other non-claims costs, including an explanation of the nature of such costs, and excluding Federal and State taxes and licensing or regulatory fees." "Other non-claims costs" refers to expenditures that are not used to adjust premiums, incurred claims, or activities that improve quality care. HHS interprets this to mean that issuers must account for the use of all premium revenue, not just claims expenses and expenses to improve quality. The NAIC includes in these non-claims expenses sales expenses, agents' and brokers' fees and commissions, other taxes, community benefit expenditures, and general administrative expenses. HHS supports the NAIC approach to defining non-claims costs and has followed it in § 158.160 of this interim final regulation. For example, direct sales salaries and work force salaries and benefits should be allocated as non-claims costs unless a specific position can be directly correlated with an activity that improves health care quality, as defined in this regulation. The NAIC's inclusion of "other taxes" as non-claims expenses does not refer to taxes that section 2718(a) of the PHS Act excludes from "all other non-claims costs" and which section 2718(b) allows to be excluded from premium revenue. Rather, "other taxes" refers to taxes that may not be excluded from premium revenue, such as taxes of a foreign country and sales taxes (excluding State sales taxes) if an issuer does not exercise the option of including such taxes with the cost of goods and services produced. Another type of expense included in non-claims costs is cost containment expenses not included as an expenditure related to a quality improving activity under § 158.150.

Notably, in correspondence with HHS, the NAIC raised concerns regarding the potential impact of this regulation on agents' and brokers' fees and commissions. Some companies in some States may be particularly reliant on producers to distribute their products. Agents and brokers perform a range of functions on behalf of consumers and companies. In some cases, issuers may have entered into longer term compensation arrangements with agents and brokers which the MLR standard may stress. The NAIC considered, but declined to incorporate in the model regulation, special treatment for such expenses in the MLR calculations. The NAIC opted instead to establish a working group with HHS to address the impact of the Affordable Care Act on agents and brokers, especially during years leading up to 2014. As discussed below, the potential impact of the MLR standard on agents and brokers merits recognition, and in this regulation the impact of the MLR standard on agents and brokers will be a factor in considering whether a particular individual markets would be destabilized. HHS seeks comments on the approach taken in this regulation and on the issues related to agents and brokers during years leading up to 2014.

Loss adjustment expense is part of other non-claims costs that cannot be excluded from premium revenue and cannot be considered part of reimbursement for clinical services to enrollees or a quality improving activity. Loss adjustment expense is referred to as "claims adjustment expenses" in the forms the NAIC has developed for reporting by issuers. Claims adjustment expenses are not reported as an adjustment to premium revenue or as an adjustment to claims. Instead, they are expenses associated with claims and are reported as "other non-claims costs." One type of claims adjustment expenses is cost containment expenses. Such expenses reduce either the number of health services provided or the cost of such services. They may include: Post and concurrent claim case management activities associated with past or ongoing specific care; utilization review; detection and prevention of payment for fraudulent requests for reimbursement; expenses for internal and external appeals processes; and network access fees to preferred provider organizations and other network-based health plans (including prescription drug networks), and allocated internal salaries and related costs associated with network development and/or provider contracting.

Examples of other types of claims adjustment expenses include: Estimating the amounts of losses and disbursing loss payments; maintaining records, general clerical, and secretarial; office maintenance, occupancy costs, utilities, and computer maintenance; supervisory and executive duties; and supplies and postage. As previously explained, claims adjustment expenses are other non-claims costs.

8. Federal and State Taxes and Licensing and Regulatory Fees (§§ 158.161–158.162)

Section 2718 of the PHS Act requires that Federal and State taxes and licensing and regulatory fees be reported. Section 2718(a) lists these expenses as an exclusion from non-claims costs. Section 2718(b)(1)(A) requires that Federal and State taxes and licensing or regulatory fees be excluded from the total amount of premium revenue when calculating an issuer's MLR. Section 2718(b)(1)(B)(i)(II) also requires that such taxes and fees be excluded from the total amount of premium revenue when determining

any rebates. However, section 2718 does not specifically define what is included in Federal and State taxes.

The NAIC defines Federal taxes as all Federal taxes and assessments allocated to health insurance coverage reported under section 2718 of the PHS Act, excluding Federal income taxes on investment income and capital gains. This interim final regulation adopts the NAIC recommendation that Federal income taxes on investment income and capital gains are not taxes based on premium revenues, and thus should not be used to adjust premium revenues, as specified in § 158.162, while all other Federal taxes allocated to health insurance coverage should be excluded from non-claims costs for purposes of the report required by section 2718. Section 158.162 also makes clear that Federal taxes which are excluded from non-claims costs are to be excluded from premium revenue when calculating an issuer's MLR.

We have adopted the NAIC's recommended approach to reporting State taxes and assessments. State taxes and assessments that must be separately identified and reported to the Secretary include: Any industry-wide (or subset) assessments (other than surcharges on specific claims) paid to the State directly, or premium subsidies that are designed to cover the costs of providing indigent care or other access to health care throughout the State; assessments of State industrial boards or other boards for operating expenses or for benefits to sick unemployed persons in connection with disability benefit laws or similar taxes levied by States; advertising required by law, regulation or ruling, except advertising associated with investments; State income, excise, and business taxes other than premium taxes; State premium taxes plus State taxes based on policy reserves, if in lieu of premium taxes; State sales taxes, if the issuer does not exercise the option of including such taxes with the cost of goods and services purchased; and any portion of commissions or allowances on reinsurance assumed that represents specific reimbursement of premium taxes.

The NAIC has interpreted the language in section 2718(a)(3) that refers to "excluding Federal and State taxes and licensing or regulatory fees" from non-claims costs as encompassing the community benefit expenditures by not-for-profit health plans that they are required to make in lieu of State and Federal taxes. As discussed below, we adopt the NAIC's approach.

Under the NAIC's recommendation, "community benefit expenditures" are limited to expenditures that the non-profit issuer is required to make under State law in lieu of State taxes that would otherwise apply, or that the Federal government requires them to make in order to preserve their Federal tax exempt status, and that they report to the Federal government. The proceeds of such expenditures fund activities or programs that seek to achieve the objectives of improving access to health services, enhancing public health and relief of government burden.

Under the NAIC's interpretation, these mandated community benefit expenditures are essentially deemed to be the equivalent of State and Federal taxes for non-profit issuers for purposes of the exclusion in section 2718(a)(3). The NAIC recommended that non-profit issuers be permitted to report community benefit expenditures as a deduction from premium revenue, and further recommended that they be permitted to split such expenditures between Federal and State taxes as applicable, but not to report them more than once.

HHS believes that NAIC's interpretation avoids an inequity between for-profit and non-profit plans, and that it is reasonable to interpret community benefit expenditures by non-profits that they are required by the State or Federal government to make as the equivalent of taxes for purposes of the exclusion in section 2718(a)(3). Thus, in § 158.162(c) and (e), HHS has adopted the NAIC's approach and allows such mandatory community benefit expenditures by not-for-profit plans, made in lieu of income taxes, to be excluded from premium revenue to the same extent as State taxes. In order to implement the NAIC-recommended approach that community benefit expenditures may be split between Federal and State taxes as applicable, § 158.162(e) of this interim final regulation provides that the NAIC's approach applies equally to Federal and to State taxes, and that community benefit expenditures made in lieu of income taxes, whether Federal or State, may be reported as a deduction from premium revenue.

A commenter representing not-for-profit plans asserted that community benefit expenditures should be more broadly recognized in the MLR calculation, and not be limited to the amount required to be paid in lieu of taxes. This commenter pointed out that not all States impose a premium tax, that the amount of premium tax varies among States, and that the NAIC rule would discourage not-for-profits from making these contributions to the community.

Although the NAIC did not recognize community benefit expenditures beyond the amount of taxes that would have been paid, we share the concern that the MLR standard should not create a disincentive for not-for-profits to make community benefit expenditures beyond those required in lieu of taxes. Thus, we invite comments on the proper treatment of community benefit expenses.

The NAIC defines and specifies the licensing and regulatory fees that must be reported and whether they may be included as an adjustment to premium revenue. In § 158.161, we adopted the NAIC approach under which statutory assessments to defray operating expenses of any State or Federal department, and examination fees in lieu of premium taxes as specified by State law are included in the licensing and regulatory fees that may be used as an adjustment to premium revenue. HHS believes that, consistent with the Affordable Care Act, examination fees under State law should also be included as an adjustment to premium revenue, and § 158.161 of the interim final regulation has such a provision. Fines and penalties of regulatory authorities and fees for examinations by State and Federal departments other than referenced above must be separately reported, but may not be used as an adjustment to premium revenue.

9. Allocation of Expenses (§ 158.170)

Section 2718(a)(3) of the PHS Act requires health insurance issuers to submit an annual report to the Secretary concerning the percentage of total premium revenue spent "on all other non-claims costs, including an explanation of the nature of such costs, and excluding Federal and State taxes and licensing or regulatory fees." However, section 2718(a) does not provide a standardized method for allocating such expenditures. Section 2718(c) directs the NAIC to develop definitions and methodologies, which are subject to the certification of the Secretary, to assist issuers in reporting the information stipulated under section 2718(a). The NAIC's model regulation and this interim final regulation require issuers to report their expenses by State and by line of business. Section 158.170 of this interim final regulation addresses the allocation of claims and non-claim related expenses as well as expenses stemming from quality improving activities. Issuers operating within the individual market, small group market, and large group market who also offer products, such as Medicare supplemental insurance, or services, such as administration of group health

plans, must report and properly allocate all related expenses stemming from each individual line of business.

There are several different methods for allocating costs incurred by health issuers allowable under statutory accounting principles. The NAIC model regulation requires issuers to allocate costs consistent with these principles. HHS has therefore not prescribed a standardized method for allocating costs beyond the allocation method designated in § 158.170. All costs reported by issuers must be allocated according to generally accepted accounting methods that yield the most accurate results and are well documented. An issuer's allocation method must illustrate the costs associated with a specific activity and any resulting effect the activity has had on a particular line of business. Section 158.170(d) further provides that issuers must maintain records containing an explanation of all incurred expenditures allocated as non-claims costs and quality improving activities. If the expense is related to a specific activity, the allocation of such expenditure must be on a direct basis. If an expense is not easily attributable to a specific activity, then the expenses must be apportioned based on pertinent factors or ratios, such as studies of employment activities, salary ratios or similar analyses. Section 158.170(b) provides that any shared expenses between two or more affiliated entities must be "apportioned pro rata to the entities incurring the expense" even if the expense has been paid solely by one of the incurring entities.

Each expense that is allocated by an issuer for each State in which it is licensed to conduct an insurance business must be appropriately attributed using a generally accepted accounting method to each line of business in each State, as designated in § 158.170(b). However, all Federal taxes paid by a health insurance issuer must be attributed proportionately and appropriately to each State in which the issuer reports. While Federal taxes are not typically allocated to health insurance issuers on a State-by-State basis, for purposes of complying with the reporting requirements in § 158.110 all health insurance issuers are required to report some percentage of Federal taxes paid on their behalf.

HHS received a number of comments regarding allocation issues in response to the April **Federal Register** solicitation. Several State regulators and issuers noted that issuers currently have considerable flexibility in establishing and utilizing product and State-by-State allocation methods and that such flexibility should be maintained. Numerous regulators and issuers also advocated for allowing multiple methods of approved allocation, including the current financial reporting requirements provided by statutory accounting principles. A few State regulators, medical providers and other interested parties called for a standardized methodology for allocating administrative and quality improvement expenses among States and lines of business. In contrast, issuers stated that a revamped reporting methodology would be costly, administratively burdensome and less efficient in distinguishing a subcontractor's medical versus administrative expenses. A few industry groups also indicated that HHS should not develop an allocation methodology that is inflexible and inconsistent with current statutory accounting requirements and the accounting guidance provided under generally accepted accounting principles.

The NAIC did not mandate the use of a specific methodology for apportioning non-claims costs to health insurance issuers. Section 158.170 adopts this flexible approach and requires health insurance issuers to explain how premium revenue is used to pay for non-claims expenditures (as provided for in § 158.160). Health insurance issuers are required to allocate their non-claims and quality improving expenses on a State-by-State basis, and further allocate such expenses to each line of business within a State, as stated in § 158.170. If an expense is attributable to a specific activity, then an issuer should allocate the expense to that particular activity. However, if it is not feasible for an issuer to allocate such expenditure to a specific activity, then the issuer must apportion the costs using a generally accepted accounting method that yields the most accurate results. Each reporting health insurance issuer must identify in its required report under § 158.110 the specific basis used to allocate to each State its reported expenses, and within each State, to each line of business which the issuer operates. HHS believes that a clear allocation method for all expenses stemming from services provided by issuers includes allocation to each line of business as designated in § 158.170(c). This level of detailed expense reporting is crucial in order to verify that issuers are properly allocating and reporting such expenses.

D. Subpart B—Calculating and Providing the Rebate

1. Applicable MLR Standard and States With Higher MLR Standards (§§ 158.210–158.211)

Section 158.210 mirrors PHS Act section 2718(b)(1)(A)(i) and (ii) by stating the general requirement that issuers must provide their enrollees a rebate if their MLR is less than 85 percent in the large group market or less than 80 percent in the small group market and individual market. While explained in greater detail in subsequent sections of Subpart B of this interim final regulation, this means that issuers must spend at least 85 or 80 percent, respectively, of each premium dollar, as adjusted for taxes and regulatory and licensing fees, on reimbursement for clinical services provided to enrollees and activities that improve health care quality. Additionally, § 158.210 acknowledges that the Secretary may, in her discretion, adjust the MLR standard that applies in the individual market in a State if the Secretary determines, upon application by the State, that the application of the 80 percent MLR may destabilize the individual market in such State. The requirements related to that statutory provision are delineated in Subpart C of this interim final regulation.

Section 158.211 provides that in States that have established under State law a higher MLR standard than that prescribed by section 2718, such higher percentage applies to issuers in that State and should be substituted for the percentages set forth in § 158.210. In States that have established, under State law, a lower MLR standard than that of section 2718, the higher percentage set forth in section 2718 applies to issuers.

2. Calculating an Issuer's MLR (§§ 158.220 Through 158.221)

The NAIC model regulation addresses the calculation of an issuer's MLR, and HHS has certified and adopted the NAIC's uniform definitions and methodologies. The NAIC, in its model regulation, combines calculating the MLR with instructions related to how an issuer should aggregate data in certain instances, such as in connection with employer groups with blended rates, newer experience (deferring reporting of business with less than 12 months' experience), and other related issues such as a credibility, or statistical adjustment for smaller issuers. The requirements for reporting data and handling special circumstances, such as group policies with blended rates, mini-med plans, expatriate plans, and issuers

with newer experience, are set forth in Subpart A of this interim final regulation. These special circumstances are discussed in section II.B of the preamble.

Sections 158.220 and 158.221 of this interim final regulation contain the instructions for calculating an issuer's MLR for each MLR reporting year for purposes of determining whether any rebate is owed and, if so, in what amount. In the 2013 MLR reporting year, an issuer's MLR is calculated using the data for a three-year period, consisting of the MLR reporting year whose MLR is being calculated, and the data for the two prior MLR reporting years. Numerous commenters strongly support the use of a three year, rolling average MLR calculation in determining rebates, and some also support beginning it with the first MLR reporting year, or 2011. One commenter questioned whether the three year MLR was based on averaging three different one-year MLR values or based on accumulating experiences over the three-year period and calculating an MLR for that three-year period. The Department adopts the recommendation that the data should consist of the accumulated experience, rather than the average three MLRs.

For the 2011 and 2012 MLR reporting years, there will not be sufficient data reported to use a three-year average. The NAIC has addressed this in its model regulation, and in § 158.220(b), HHS has adopted the NAIC's approach. For the 2011 MLR reporting year, an issuer's MLR will be calculated using only the data reported for the 2011 MLR reporting year. For the 2012 MLR reporting year, the data that should be used in calculating an issuer's MLR depends in part upon whether the issuer's experience is credible. Credible experience refers to whether an issuer insures a sufficiently large number of lives to be statistically valid, and is defined and discussed later in this preamble. If an issuer's experience for the 2012 MLR reporting year is fully credible, then its MLR for that year is calculated using only the data reported for the 2012 MLR reporting year. If an issuer's experience for the 2012 MLR reporting year is partially credible or non-credible, then its MLR is calculated using the data reported for both the 2011 and 2012 MLR reporting years. To prevent double counting, an adjustment will be made to incurred claims when any rebate owed for the 2012 and 2013 MLR reporting years is calculated using data from 2011 or 2012, as provided in § 158.221(b)(1).

With respect to the issue of which portions of the data reported by an issuer are to be used to determine the numerator of the MLR and which portions of the data reported are to be used to determine the denominator of the MLR, the numerator equals the issuer's incurred claims and expenditures for activities that improve health care quality, and the reporting of data for these categories of expenses is detailed in §§ 158.140, 158.150 and 158.151. As discussed above, Section 158.221(b)(3) provides, for 2011 only, in the case of a mini-med plan reporting separately under § 158.120(d)(3) and an expatriate plan reporting separately under § 158.120(d)(4), that the numerator amount specified in § 158.221(b) shall be multiplied by a factor of two. The purpose of this adjustment is to recognize the "special circumstances" applicable to these plans by restating claims and quality improvement expense (if any) associated with these types of plans so that they are commensurate with the higher administrative expenses of these plans relative to premium. These types of plans are discussed at greater length under Subpart A.

The denominator of the MLR equals the issuer's premium revenue minus the issuer's Federal and State taxes and licensing and regulatory fees. The reporting of data for premium revenue is detailed in § 158.130 and the reporting of data regarding Federal and State taxes and licensing and regulatory fees is set forth in §§ 158.161 and 158.162. Section 2718(b)(1)(A) also provides that the total amount of premium revenue used for the denominator of the MLR shall take into account payments or receipts for risk adjustment, risk corridors, and reinsurance. However, in the reporting requirements related to premium revenue in § 158.130, the Department has provided that the premium revenue reported be adjusted for these types of payments or expenses. Because these issues have been addressed in the cited earlier sections of this interim final regulation, there is no need to address them again in § 158.221 regarding the calculation of an issuer's MLR.

This interim final regulation also provides that an issuer's MLR must be rounded to the nearest one-tenth of one percentage point, after dividing the numerator by the denominator when calculating the MLR. HHS has adopted the NAIC's approach in this regard.

3. Credibility Adjustment (§§ 158.230–158.232)

Section 2718(c) of the PHS Act charges the NAIC with developing uniform methodologies for calculating measures of the expenditures that make up the MLR calculation, and provides that "such methodologies shall be designed to take into account the special circumstances of smaller plans, different types of plans, and newer plans." To address the special circumstances of smaller plans, the NAIC model regulation allows smaller plans to adjust their MLRs by applying a so-called "credibility adjustment." HHS adopts this method of "credibility adjustment" in § 158.230.

A credibility adjustment is a method to address the impact of claims variability on the experience of smaller plans. All issuers experience some random claims variability, where actual claims experience deviates from expected claims experience. In a health plan with a large customer base the impact of such random deviations is less than in plans with fewer insureds. One source of variability is the impact of large claims, which are infrequent, but have greater impact on financial experience than average or typical claims. Large claims have a disproportionate impact on small plans because the higher claim cost is spread across a smaller premium base. These random variations in the claims experience for enrollees in a smaller plan may cause an issuer's reported MLR to be below or above the statutory standard in any particular year, even though the issuer estimated in good faith that the combination of the premium it projected it would collect and the claims it projected would produce an MLR that meets the statutory standard.

The credibility adjustment is a method to address the problem associated with this random variation. A credibility adjustment serves to modify the reported MLR of an issuer by adding to the reported percentage additional percentage points in recognition of the statistical unreliability of the reported number. A number of stakeholders in the NAIC proceedings have supported credibility adjustments in concept, including the American Academy of Actuaries and a number of the consumer representatives to the NAIC.

In evaluating the desirability of including a credibility adjustment, it is important to emphasize that health insurance rates are the product of assumptions, estimates, and projections, and not of calculations based entirely on hard data. When an actuary projects that the rate it has calculated will produce an 80 percent MLR, whether in fact it will produce an 80 percent MLR depends on whether the assumptions the actuary has made—such as those concerning the mix of business it will attract, the intensity and frequency with

which its insureds will use health care services, and unit costs—turn out to be correct. All things being equal, it is more likely that those assumptions will turn out to be correct when an issuer insures a large number of risks rather than a small number.

Credibility adjustments have advantages and disadvantages. Issuers benefit from credibility adjustments because such adjustments—and thus the ability to report a higher MLR than what the issuer's MLR would be using the methodology that applies to other plans—make it less likely that an issuer will be required to pay a rebate. For consumers, on the other hand, credibility adjustments eliminate some rebates that would otherwise have been paid.

In general, the smaller the size of the insured population whose experience is used to calculate the MLR, the more variable the reported MLR will be. Statistical analysis conducted for the NAIC by an independent actuarial consulting firm based on historical data for companies offering coverage in the group and individual markets examined the statistical variation that would be expected in reported MLR. The consultants concluded that if a company estimates that its premium will produce an MLR of 80 percent, random variation would cause the company to pay a rebate of:

- 0.9 percent or more in 1 out of every 4 years if it insures 75,000 lives,
- 2.6 percent or more in 1 out of every 4 years if it insures 10,000 lives, and
- 8.8 percent or more in 1 out of every 4 years if it insures only 1,000 lives.

After extensive analysis and public discussion, the NAIC adopted a credibility adjustment table designed to result in an issuer that charges premiums intended to produce an 80 percent MLR to pay a rebate less than 25 percent of the time. Toward the conclusion of its public proceedings on these issues, the NAIC gave some consideration to setting the base credibility factors so that such an issuer would be required to pay a rebate less than ten percent of the time. The credibility factors in that case would have been roughly twice as large as the factors the NAIC adopted. The argument made in favor of making this change is that it would reduce the likelihood of requiring a plan to pay a rebate simply because of chance variation in claims experience. However, it would also have increased the likelihood that a plan setting premiums to achieve an MLR that is less than the applicable MLR standard would avoid paying a rebate, and it would have reduced the size of the rebates that plans pricing below the MLR standard would have to pay. The NAIC concluded, and HHS agrees, that the credibility factors it adopted more equitably balance the consumers' interest in requiring plans that should pay rebates to pay rebates against the issuers' interest in minimizing the risk of paying rebates as a result of chance variations.

HHS adopts the NAIC credibility adjustment methodology in § 158.230. The NAIC recommends that the credibility factors be evaluated and updated as the Affordable Care Act reforms are implemented over the next several years. HHS concurs with this recommendation and notes its intention both to monitor the effects of the credibility adjustment and, as appropriate, to update the credibility adjustment method.

This interim final regulation adopts the approach taken by the NAIC by, in § 158.230(c)(3), designating as "non-credible" any reported MLR that is based on experience from fewer than 1,000 life-years. Thus, § 158.240(a)(1) provides that issuers with non-credible experience do not owe rebates because there is no valid data to determine that the issuer has failed to meet the MLR standard.

This interim final regulation also adopts the NAIC's assumption that variations of less than approximately one percent are reasonably to be expected based on ordinary variation in claims experience of very large plans. The experience of such plans is "fully credible," and such a plan therefore should be required to pay a rebate based on its reported MLR. The model regulation designates as "fully credible" any reported MLR that is based on experience from 75,000 or more life-years, and this definition is adopted, as provided in § 158.230(b)(1) of this interim final regulation.

The NAIC model regulation provides that a reported MLR that is based on experience from 1,000 to 75,000 life-years is "partially credible" and entitled to a credibility adjustment, as stated in § 158.230(b)(2) of the interim final regulation. The magnitude of the "credibility adjustment" for "partially credible" aggregations is intended to represent the amount by which an issuer's reported MLR would be expected to vary as a result of random variation in claims experience. Under the credibility provisions of the NAIC model regulation, which HHS adopts in § 158.232 of the interim final regulation, the "credibility adjustment" for a specific issuer is the product of two components: A "base credibility factor," determined by the number of life-years of experience used to calculate the issuer's reported MLR; and a "deductible factor," determined by the average deductible of the policies whose experience went into the reported MLR. The credibility adjustment will be added to the reported MLR, as provided in § 158.221(a), before calculating rebates. As stated above, the credibility adjustment applies to partially credible issuers.

The base credibility factor recommended by the NAIC is based on an actuarial analysis of anticipated claims experience. The results of this analysis are summarized in Table 1, below.

Table 1: Base Credibility Factors

Life-Years	Base Credibility Factor
<1,000	Not credible
1,000	8.3%
2,500	5.2%
5,000	3.7%
10,000	2.6%
25,000	1.6%
50,000	1.2%
75,000	0.0%

The deductible factor recommended by the NAIC is also based on the independent actuarial consulting firm's analysis. It is intended to recognize that the variability of claims experience is greater under health insurance policies with higher deductibles than under policies with lower deductibles. Few people incur claims above $10,000, which means that high cost claims represent a much larger portion of the total claims experience in a higher deductible policy than in a lower deductible policy. As a result, issuers who write a small number of high deductible policies are more likely to report a low MLR than an issuer who covers the same number of lives under a low deductible policy, even if the premium they establish is set to achieve the MLR required by section 2718. Therefore, the deductible factor takes into account greater variability among high deductible plans. The deductible factors recommended by the NAIC are shown in Table 2.

Table 2. Deductible Factors

Deductible	Deductible Factor
$0	1.000
$2,500	1.164
$5,000	1.402
$10,000	1.736

Under the NAIC model regulation, an issuer would use the deductible factors from Table 2 to determine a deductible factor for the average deductible of the coverage whose experience was used to calculate the reported MLR. The factors included in Table 2 were developed by the actuarial consultants to the NAIC using methods consistent with standards of professional actuarial practice.

NAIC methodology uses "linear interpolation" to determine life year factors for experience between the life year categories in table 1. HHS adopts this methodology in § 158.230. When the number of life-years reported by an issuer falls between two numbers on Table 1, the base credibility factor is calculated by first determining where, by percentage of the difference between those two numbers, the reported number of lives falls. Thus if Issuer X reports 4,000 life-years, its number of life-years falls 60 percent of the way between 2,500 and 5,000. To calculate the interpolated adjustment factor it is necessary to determine the base credibility factor for the number of lives 60 percent of the way between 2,500 and 5,000. Therefore, this percentage is multiplied by the difference between the base credibility factor corresponding to the number of life-years on Table 1; $0.60 \times (.052 - .037) = .009$. To find the base credibility factor, this amount is then subtracted from the factor corresponding to the lower number of lives on Table 1. Thus, $0.052 - .09$ is equal to .043, which is the base credibility factor for an issuer covering 4,000 lives.

The deductible factor is based on the average deductible of all policies whose experience is included in the reported MLR. When the average deductible is greater than $2,500 and is between two of the deductible categories shown in Table 2, the NAIC model regulation calls for the deductible adjustment to be calculated by linear interpolation. In § 158.232 of this interim final regulation, HHS adopts the methodology using linear interpolation.

The NAIC specifies that the number of life-years used to calculate the base credibility factor matches the number of life-years that comprise an issuer's experience as reported under subpart A. HHS adopts this approach in § 158.231. An issuer's credibility adjustment for the 2011 MLR reporting year is based on the life-years and weighted-average deductible for the 2011 MLR reporting year. An issuer's 2012 MLR reporting year credibility adjustment is based on experience from the 2012 MLR reporting year, unless issuer experience for 2012 is less than 75,000 life-years. In that circumstance, the 2012 MLR reporting year experience is combined with 2011 MLR reporting year experience to calculate the 2012 credibility adjustment.

An issuer's credibility adjustment for 2013 is based on three years' experience, comprised of the current MLR reporting year and the two previous MLR reporting years. In 2013, an issuer is not eligible for a credibility adjustment if (1) the MLR (prior to any

credibility adjustment) in each of the three MLR reporting years was below the MLR standard for each year, and (2) each of the three MLR reporting years included 1,000 life-years or more. This exception prevents issuers from receiving a credibility adjustment when the issuer consistently sets its prices to produce an MLR below the statutory 80 percent MLR standard.

In responding to HHS's request for comments, many issuers, industry associations, and State departments of insurance emphasize that to avoid requiring issuers to pay rebates due to statistical variations, rather than due to their underlying pricing and benefits structure, it is important to assess MLRs on sufficient numbers of lives for statistical credibility. Commenters also argue that requiring issuers to pay rebates when statistical variations lead to surpluses (low MLRs) but requiring issuers to absorb losses when statistical variations lead to losses (high MLRs) will lead to product volatility, market exit, and inadequate levels of surplus to ensure solvency. HHS agrees that rebates should be based on the underlying premium pricing, rather than chance variation in claims experience. But as noted above, any credibility adjustment can also serve to deprive insureds of rebates to which they would otherwise be entitled under the Affordable Care Act. HHS has concluded that the NAIC credibility adjustment methodology provides an acceptable balance between the interests issuers have in not paying rebates when a low MLR is the result of ordinary variation in claims experience, and the interests consumers have in receiving rebates when issuers provide coverage and establish prices that do not result in MLRs, and therefore the value, required by the Affordable Care Act.

4. Rebating Premium if MLR Standard Not Met (§ 158.240)

Section 158.240, subsections (a), (b) and (c), delineates the general requirement regarding rebates, the calculation of the rebate amount, and the time frame for payment of any rebate that may be due. Section 158.240(a) simply provides that if an issuer does not meet the applicable MLR standard set forth in § 158.210 and, if applicable, § 158.211, then the issuer must provide a rebate to each enrollee unless the issuer has too little experience to calculate a reliable MLR. As discussed above, because an issuer that has fewer than 1,000 covered lives does not have sufficiently credible data to determine that the MLR standard has not been met, a non-credible issuer is not required to pay any rebates.

Section 158.240 explains the amount of the rebate due to enrollees. The Affordable Care Act provides a rebate that is the amount by which the applicable MLR standard exceeds the issuer's actual MLR multiplied by "the total amount of premium revenue (excluding Federal and State taxes and licensing or regulatory fees and after accounting for payments or receipts for risk adjustment, risk corridors, and reinsurance * * *)." This language describing premium revenue as the premium paid minus taxes and other adjustments is the same as statutory language describing the denominator of the MLR. The NAIC model regulation matches the statutory methodology, and HHS adopts this methodology. Therefore, the rebate paid to each enrollee is based on the earned premium paid by or on behalf of the enrollee minus taxes and other permissible adjustments.

The Affordable Care Act requires the issuer to "provide an annual rebate to each enrollee under such coverage, on a pro rata basis." The NAIC determined, and the Department concurs, that this requirement is most simply met by requiring the rebate returned to the enrollee to be proportional to the amount of premium paid by or on behalf of the enrollee. As noted above, the total rebate owed by the issuer is required, by statute, to be a percentage of the issuer's total earned premium. An individual who was covered by an issuer for only three months would have paid substantially less than an individual who was covered by the issuer for the entire MLR reporting year. It would be unfair to pay both individuals the same dollar rebate. Similarly, an individual or group that purchases coverage from the issuer that has a higher deductible but lower premium should not receive the same dollar rebate as an individual or group that paid a higher premium for a product with a lower deductible. The rebate paid to a policyholder or enrollee would be based upon the amount of premium paid minus taxes and other permissible adjustments, multiplied by the amount by which the issuer MLR is below the applicable MLR standard; the result is the actual rebate.

For example, take an issuer who owes a five percent rebate to its enrollees in the individual market. An enrollee may have paid $2,000 in premiums for the MLR reporting year. If the Federal and State taxes and licensing and regulatory fees that may be excluded from premium revenue as provided in §§ 158.161(a), 158.162(a)(1) and 158.162(b)(1) are $150 for a premium of $2,000, then the issuer would subtract $150 from premium revenue, for a base of $1,850 in premium. The enrollee would be entitled to a rebate of five percent of $1,850, or $92.50.

Section 158.240(d) requires issuers to provide any rebates that are due no later than August 1 following the end of the MLR reporting year. Since the report is due by June 1 of the year following the MLR reporting year, this allows issuers two full months (a) to provide any rebate that may be due, (b) for the group market, to notify their employer clients to arrange for the distribution of the rebates, if applicable, and (c) to prepare and send the notice of rebate that is required by § 158.250.

5. Form of Rebate (§ 158.241)

While the NAIC model regulation does not specifically address some of the administrative details of section 2718(b)(1)(A) of the PHS Act, which requires an issuer offering group or individual health insurance coverage to provide an annual rebate to each enrollee if the issuer's MLR is less than the statutory minimum, the NAIC advisory group's proposals in this regard have been adopted. The statute does not specify the particular form of rebate that is to be provided to enrollees. For example, must the rebate be provided in the form of cash or check, or may it be provided through a credit to premium? Does the requirement differ based on whether the enrollee to whom a rebate is owed is a current or former enrollee? Section 158.241 of this interim final regulation addresses the method by which an issuer must provide any rebate owing to enrollees and the issuer has the choice as to form of the rebate for then-current enrollees but not for former enrollees, who must receive an actual payment.

Several commenters addressed the administrative expenses involved in distributing rebates. Although the NAIC model regulation does not specifically address the form in which an issuer must disburse rebates, an NAIC advisory group suggested that an issuer should be able to choose whether to disburse rebate payments to current enrollees as a premium credit or a cash lump sum. The NAIC advisory group also proposed that an issuer should have to disburse rebate checks to former enrollees. HHS considered the comments it received and has concluded that the proposals made by the NAIC advisory group may reduce the administrative burden felt by an issuer in providing rebates to its enrollees.

Section 158.241(a) of this interim final regulation thus states that an issuer may choose to provide current enrollees with a rebate in the form of a premium credit (i.e., reduction in a premium

owed), lump-sum check, or, if an enrollee paid by credit card or debit card, by lump-sum reimbursement to the same account that the enrollee used to pay the premium. We believe that this ensures that enrollees receive any rebate owing while giving issuers the ability to provide the rebate in a way that has the least administrative burden. If an issuer chooses to provide a premium credit to a recipient, the issuer must apply the full amount of the rebate owing to the first premium due on or after August 1. If the rebate exceeds the amount of the first premium due on or after August 1, the issuer must apply any overage to succeeding premium payments until the entire rebate has been credited. With respect to rebates owing to former enrollees, § 158.241(b) requires the rebate to be made in a lump-sum, but allows an issuer the flexibility to provide it by check or using the same method that was used for payment of the premium, such as credit card or debit card. Regardless of the method used to pay rebates, all enrollees eligible for rebates must be notified as required by § 158.250.

6. Recipients of Rebates (§ 158.242)

Section 2718(b) requires an issuer to provide a rebate to each enrollee on a pro rata basis if the issuer has not met the applicable MLR standard. However, it does not prescribe how rebates must be distributed. This interim final regulation establishes methods for distributing rebates that are efficient and cost-effective, and that ensure that enrollees receive any rebate to which they may be entitled.

The NAIC, in an Issue Resolution Document on which it did not vote, discussed that the rebates should be provided to the group policyholder and that the group policyholder should be advised that enrollees may have a claim to some or all of the rebate to the extent that they have contributed to the premium. Numerous commenters also suggested that any rebate should go to the company or person who actually paid the premium, and not to the enrollee. They point out that under a group policy the employer often pays a portion, or even all, of the premium. In addition, when an employee pays a portion of the premium, it is generally the employee and not every enrollee in the employee's family who makes payment. This concept applies in the individual market as well; it is often one family member who pays the premium on behalf of all enrollees in the family. The Department agrees with the NAIC's and the commenters' concerns. A technical reading of section 2718(b)(1)(A) requires that the rebate shall be provided "to each enrollee under such coverage, on a pro rata basis." However, the purpose of the section 2718 is to ensure that value is achieved for the premium paid. It would frustrate the purpose of the section to deprive those who actually paid premiums of the rebate, and to instead provide a windfall to those who did not pay premiums with the "value" that was returned by the issuer. Consistent with the NAIC discussion, HHS therefore interprets this provision as requiring any rebate be provided on a pro rata basis to the person or entity that paid the premium on behalf of the enrollee. This requirement is addressed in § 158.242.

Several comments HHS received in response to its April request for information pertaining to this regulation also pointed out that group policyholders may be in a better position to determine the rebate amount each individual enrollee should receive. They suggested that issuers be permitted to pay rebates to group policyholders for distribution to enrollees. The Department agrees that group policyholders and subscribers are in a better position than issuers to fairly distribute rebates to individual enrollees given that it is the group policyholders and subscribers, and not the issuers, who know the extent to which the enrollees made the original premium payments. However, the statute provides that it is the issuer's obligation to provide the rebate, if any.

HHS has adopted an approach which satisfies both the statutory requirement that an issuer provide any rebates and the practical reality that group policyholders and subscribers are in a better position to distribute any rebates. Section 158.242 of this interim final regulation allows an issuer to enter into an agreement with a group policyholder to distribute the rebates on behalf of the issuer. HHS invites public comment on to whom rebates should be paid.

The regulation specifies that, regardless of whether an issuer provides rebates to enrollees directly or indirectly through a group policyholder, an issuer must take steps to ensure that each enrollee receives a rebate that is proportional to the amount of premium paid by that enrollee and that the group policyholder does not retain more of the rebate than is proportional to the amount of premium it paid.

Therefore, this interim final regulation allows an issuer to delegate its rebate distribution functions to a group policyholder, but provides that the issuer remains liable for complying with all of its obligations under the statute and maintains records received from the group policyholder demonstrating that rebates were accurately distributed.

7. *De Minimis* Rebates (§ 158.243)

Although the NAIC model regulation does not specifically address de minimis rebate payments because the distribution of rebates was outside the scope of the NAIC's statutory mandate, an NAIC actuarial subgroup suggested that issuers should not be required to provide rebates in minimal amounts that are largely of symbolic value. It argued that setting the minimum threshold somewhere in the range of $1 to $20 should be sufficient to avoid requiring largely symbolic rebates to enrollees. HHS agrees with this approach.

Section 2718(b) is also silent on the subject of whether there is a *de minimis* amount below which issuers need not pay a rebate to an enrollee. Without a minimum threshold, each enrollee would receive the rebate owed to him or her, but the cost of processing and distributing the rebate might be greater than the amount of the rebate.

The Department received several comments from issuers and others who recommended that HHS set a minimum threshold for issuer payment of rebates because of this potential for relatively high administrative expenses associated with the provision of very small rebates.

We agree that it does not make sense for issuers to provide rebates when the administrative cost of providing them exceeds their value to enrollees. Thus, § 158.243 provides that an issuer need not provide rebates when the combined dollar amount of a rebate owed to the policyholder and subscribers under a group policy, or to the subscriber in the individual market, is less than five dollars per subscriber covered by the policy. Five dollars is an amount that is commonly used by States when setting *de minimis* levels for issuer refunds.

Although each *de minimis* rebate may seem insignificant, the aggregate amount of such rebates by market type may be quite substantial. Thus, consistent with the rebate requirements of the Affordable Care Act, issuers should not be allowed to retain these unpaid rebate funds, which belong to enrollees. Furthermore, if issuers retained the unpaid rebate funds, it would in essence lower their MLR. Instead, issuers must aggregate the *de minimis* rebates and distribute them in equal amounts to all then-current enrollees who receive a premium credit.

8. Unclaimed Rebates (§ 158.244)

The Affordable Care Act does not specifically address the situation of rebates being unclaimed. This situation

is likely to occur either because an issuer has not been able to locate certain enrollees, or enrollees have not redeemed their rebate payments.

Some consumer representatives recommended that an issuer be required to make all reasonable efforts to provide a rebate to an enrollee and that an issuer be prohibited from keeping any unclaimed funds. At least one consumer group recommended that such funds be directed to a State consumer assistance program that has been approved by the Department, or if such a program is unavailable, to the Department itself. Another group recommended that rebates for any individuals who cannot be located should be applied toward reduction of premiums for all policyholders in the subsequent plan year.

We agree that an issuer should be required to make a good faith effort to locate enrollees and to distribute to them any rebate that is owed. This requirement is reflected in § 158.244. We also believe that an issuer should be prohibited from retaining unclaimed rebates. However, unclaimed rebates will be subject to relevant State law provisions.

9. Notice of Rebates to Enrollees (§ 158.250)

The Affordable Care Act and the NAIC model regulation provide that an issuer must provide enrollees with rebates if its MLR falls below the statutory standard, but neither specifies what information should accompany a rebate. Section 158.250 of this interim final regulation requires issuers to provide enrollees with a rebate notification along with any rebate check or premium credit.

There are several reasons for this notification. Enrollees may not understand why they are receiving a rebate and may not be familiar with the significance of the MLR and the rebate requirement in the Affordable Care Act. Without the information provided by this notification, enrollees have no explanation as to how rebates are calculated. In addition, MLR transparency is a way to educate consumers and promote informed decision-making in the purchasing of health insurance.

The rebate notification must accompany the rebate check or be sent at the same time as the premium credit is applied. The rebate notification must include a brief explanation of what an MLR is, why the Affordable Care Act created the policy (for example, increased transparency, incentive to lower premiums), and why the enrollee is receiving a rebate. It must also include the aggregate amount of premium revenue reported by the issuer during the MLR reporting year, the issuer's MLR (taking into account any adjustment allowed by the regulation), the required MLR threshold, the percentage of premium being rebated, and the total amount being paid or credited to enrollees, including the amount paid or credited to an employer based on its having paid all or a portion of the premium. In addition, the notification to enrollees must explain that rebates to current enrollees are being provided in the form of premium credit, and that rebates to former enrollees are being provided either by check or in the same form as the premium was paid. For example, an issuer has the option of reimbursing enrollees who paid the premium by credit card or debit card by applying the rebate amount back to the credit or debit card. The form of the rebate notification will be established by the Secretary and published in guidance.

HHS is not requiring issuers who do not have to provide a rebate to provide notification to enrollees about the MLR and the fact that no rebate is owed. However, issuers who do meet the MLR standard may choose to provide such notice to their enrollees.

10. Reporting Rebates to the Secretary (§ 158.260)

Section 2718(b) of the PHS Act is meant to ensure that consumers receive value for their premium payments, and does so by requiring an issuer that does not meet a specified MLR to rebate a portion of the premium to enrollees. In order to provide for appropriate oversight and enforcement for which regulations are specifically authorized by section 2718(b)(3), HHS needs the ability to validate an issuer's calculation and distribution of rebates. Accordingly, the interim final regulation prescribes certain data retention, data access, and reporting requirements.

Subpart A of this interim final regulation requires an issuer to report to the Secretary data concerning premium revenue, how premium revenue is spent, and the various categories of expenses that go into determining the issuer's MLR. In Subpart B, the Department implements the statutory requirement for rebates to enrollees, and as part of this implementation, requires issuers to report to the Secretary certain information regarding rebates.

The interim final regulation requires issuers to report, for each MLR reporting year, information regarding the rebates it makes to enrollees. Consistent with the reporting requirements in Subpart A, § 158.260(b) requires that the information reported regarding rebates be aggregated by State, and by the large group, small group, and individual markets within a State. The information required includes:

(1) the number and percent of enrollees who receive a rebate;

(2) the amount of rebates provided to enrollees, including a breakdown of how much of the rebates were paid to policyholders and how much of the rebates were paid to subscribers;

(3) the amount of de minimis rebates that were aggregated and a breakdown of how they were disbursed to enrollees; and

(4) the amount of unclaimed rebates, a description of the good faith efforts that were made to locate the applicable enrollees, and a description of how the unclaimed rebates were disbursed.

HHS considered several options for the timing of reporting the information required by § 158.260. In doing so, HHS has tried to balance the need for timely information and the desire to minimize the administrative burden on issuers. Almost all of the information required by § 158.260 should be available to issuers at the time they submit the report required under § 158.110 for each MLR reporting year. Thus, for that set of information, the Department is requiring that it be submitted with the report required under § 158.110. The amount of unclaimed rebates would be the only information that would not be available to the issuer at the time it reports its data for the MLR reporting year, since the issuer needs time to make a good faith effort to locate former enrollees and to know if certain enrollees fail to cash their rebate checks. HHS is requiring that this information be submitted with the report required under § 158.110 for the subsequent MLR reporting year.

11. Effect of Rebate Payments on Solvency (§ 158.270)

Section 158.270 addresses concerns expressed in some comments that the obligation to pay rebates might cause an issuer's surplus to decline to levels threatening its solvency. The NAIC also raised concerns about issuer solvency in its October 13, 2010 letter to the Secretary. Issuer solvency is, of course, an important consideration and is a major focus of State insurance regulators. Consistent with the NAIC's concern, this interim final regulation provides, therefore, that the Secretary may permit the payment of rebates by an issuer to be deferred if the insurance commissioner in its State of domicile informs the Secretary that the timely payment of rebates would cause the issuer's risk based capital (RBC) level to

fall to a level that causes concern about its solvency.

Section 158.270 provides that a State's insurance commissioner, superintendent, or other responsible official must notify the Secretary if the payment of rebates by a domestic issuer will cause the issuer's RBC level to fall below specific regulatory thresholds. The State must provide the Secretary with the domestic issuer's RBC reports for the current year and the prior two years, along with a calculation of the amount of rebates that would be owed by the issuer.

Section 158.270 provides that the Secretary will review this information, along with any other information requested from the issuer, and will determine whether the timely payment of rebates would cause the issuer's RBC level to fall below the specified regulatory action level. When the Secretary makes this determination, the Secretary will provide that the issuer must pay these rebates, with interest, in a future year in which payment of the rebates would not cause the issuer's RBC level to fall below the specified regulatory action level.

E. Subpart C—Potential Adjustment to the Medical Loss Ratio for a State's Individual Market

1. Introduction

Section 2718(b)(1)(A) of the PHS Act establishes MLR standards for insurance coverage sold in the individual market, the small group market, and the large group market. For the small group and individual markets, the MLR standard is 80 percent. For the large group market, the MLR standard is 85 percent. However, if a State sets a higher MLR within its State, that higher MLR must be met.

Section 2718(b)(1)(A)(ii) also provides that "the Secretary may adjust" the 80 percent level with respect to the individual market of a State "if the Secretary determines that the application of such 80 percent may destabilize the individual market in such State." The PHS Act does not, however, define "destabilize the individual market" or provide the process or criteria for making a determination regarding potential destabilization of that market. In addition, the section does not specify the kind or amount of adjustment the Secretary may make.

Subpart C of this interim final regulation implements this provision of section 2718(b)(1)(A)(ii) by addressing these important considerations, and adopts the recommendations of the NAIC on this issue. It sets forth the process by which the Secretary may exercise the authority provided under section 2718(b)(1)(A)(ii). It also establishes the criteria the Secretary will apply in determining whether to lower the MLR standard applicable to the individual market in a State.

2. Subpart C's Approach and Framework

HHS has received comments from many interested parties regarding the application of MLR standards in the individual market and the process for granting requests to adjust the required standard.

Notably, in an October 13, 2010 letter to the Secretary, the NAIC observed that the MLR standard "may enhance the value of plans for consumers and improve carrier accountability for spending and pricing decisions," but also that improper application of it "could threaten the solvency of insurers or significantly reduce competition in some insurance markets." The NAIC further stated that "the threshold consumer protection is ensuring a health insurance company is solvent." HHS agrees with the NAIC on the importance of maintaining issuer solvency. If an insurance company does not have enough money to pay claims, then any MLR standard becomes irrelevant.

Further, while the focal point of any market destabilization analysis must be the manner in which any requested MLR adjustment may affect consumers, as the NAIC points out, consumers have numerous interests that extend beyond whether they will receive rebates, including an interest in multiple health insurance options. To that end, this interim final regulation adopts the recommendation the NAIC Consumer Representatives made in an October 25, 2010 letter to the Secretary, that the Secretary "establish a formal process that provides ample opportunity for consumers and consumer advocate input and involvement in determining whether and to what extent adjustments should be made in any State." The Department believes the recommendation by the Consumer Representatives should apply to all stakeholders, including issuers, agents and brokers, health care providers, as well as consumers, and has therefore established a process by which all stakeholders may provide information and input.

This interim final regulation does not require the Secretary to find that adherence to the 80 percent MLR standard is certain to result in market destabilization in order to grant an adjustment from it. Nor does it allow the Secretary to grant an adjustment in the case where market destabilization is a remote possibility. Rather, this interim final regulation both allows and requires an adjustment to a State's MLR to be granted when there is a reasonable likelihood that market destabilization, and thus harm to consumers, will occur.

Subpart C establishes the procedure and criteria the Secretary will use to assess requests to adjust the MLR standard that applies in the individual market in a State. We note that the law allows adjustments of the MLR for the individual market in a State and does not apply to the small group market or to the large group market.

Section 158.301 states the criteria the Secretary will apply in considering requests to adjust the minimum individual market MLR standard applicable to a State. Subpart C then proceeds to address the four major issues that HHS believes are relevant to any potential requests for adjustments to the statutory MLR standard. The first is who may submit a request and the duration of such a request. The second is the information the submitter of such a request will be required to supply. The third is the criteria the Secretary will use in making her decision regarding the request. The fourth is the process by which the Secretary will receive information and make her determination. Each of those issues is discussed separately below.

Finally, in its October 13, 2010 letter, the NAIC did not recommend a national transition, but instead wrote that "while some states seek national relief from the 2011 MLR, all states recognize that transitional relief may be appropriate for *some* state insurance markets." (Emphasis added.) Commenters in the industry have also advocated for a "national" transition or "national" relief from the MLR standards. As indicated above, the Affordable Care Act does not contemplate or provide for such relief in the context of § 158.301 which, as required by section 2718(b)(1)(A)(ii), provides for State-specific relief.

However, it is clear that other sections of this regulation do in fact provide for national rather than State-specific relief from the immediate application of the MLR standards, and not just in the individual market. The credibility adjustments provided for in §§ 158.230–158.231 are national in scope and apply without regard to State-specific market conditions. First, the credibility adjustments result in many issuers being presumed to meet the MLR standards altogether because of their small size. Second, the adjustments add up to 8.3 percent to an issuer's reported MLR for smaller plans that are not

presumed to meet the MLR standard already. Third, issuers with policies that have large deductibles may receive an additional adjustment of up to 6.1 percent on top of the 8.3 percent. Other components of the MLR formula, such as treatment of expenses for quality improving activities and treatment of Federal and State taxes, also better enable issuers to meet the MLR standard. In addition, the process set out in Subpart C provides further opportunity to modify MLR standards in the individual market to address state-specific circumstances. The rationale for a national transition—which is to provide accommodation for issuers to meet the MLR standards—we believe is satisfied by these many adjustments.

3. Who May Request Adjustment to the MLR and Duration of Request (§§ 158.310–158.311)

Section 158.310 provides that a request for an adjustment to the MLR standard for a State must be submitted by that State's insurance commissioner or other applicable State official. State insurance commissioners have valuable local knowledge of their State's insurance market and share a responsibility to protect consumers, which makes them best qualified to attest to the impact of the MLR standard on consumers within their State. State insurance regulators also often have considerable power to compel or influence issuers to take steps that may reduce the risk of market destabilization.

It is appropriate for three reasons that requests for an adjustment to the MLR standard come from State insurance commissioners on behalf of the State individual insurance market as a whole. First, the statute allows such an adjustment only for all issuers in the individual market in a State; it does not allow an adjustment for specific issuers. Second, only the State commissioner has knowledge of all issuers' experience and market conduct in the State and as to any action the State might deem appropriate to address any potential for market destabilization. Third, State insurance commissioners have responsibility for protecting the interests of the general public, policyholders, and enrollees within their respective States.

Section 158.311 provides that a request for an adjustment to the MLR standard may be for one, two, or three MLR reporting years. This permits a State to request an adjustment for up to three years, as deemed appropriate by the State, based on the condition of its individual health insurance market. Allowing for multi-year adjustments, when necessary, will provide certainty to issuers within the State regarding the applicable MLR standard, which in turn enhances stability of the market.

4. Required Information (§§ 158.320–158.323)

Subpart C requires the applicable State official to provide the Secretary with information on the applicant State and the market that is the subject of the request. Section 158.323 requests contact information for the person submitting the State's request. This information is needed because the Secretary anticipates working closely with individual States regarding their requests.

The remaining information requested by Subpart C falls into two general categories. The first is information about how the individual health insurance market is organized and functions in the State. Section 158.321 requests the following structural and operational information about the submitting State's individual health insurance market:

- The State's current MLR standard for the individual market, if any. Such an MLR is relevant to determining the effect the statute's 80 percent MLR may have in the State.
- Any requirements that an issuer seeking to withdraw from the State's individual health insurance market must meet before doing so.
- Any limitations imposed by the State on issuers regarding rating based on health status.
- Mechanisms available in the State to provide consumers with options in the event an issuer in the individual market withdraws from the State, such as a guaranteed-issue or issuer-of-last-resort requirement or a State-operated high-risk pool.
- Operational and financial information about the issuers operating in the State's individual market, including the capacity of incumbent issuers to write additional business, the premiums such issuers charge and the benefits they offer, and the amount they pay to agents and brokers.

Notably, in its October 13, 2010 letter to the Secretary, the NAIC stated that among the factors State regulators would consider in making their own determinations as to whether application of the statutory 80 percent MLR standard would destabilize the individual market are the "potential impact on premiums paid by current policyholders," the "potential impact on benefits and cost-sharing of existing products," and "the potential impact on consumer access to agents and brokers." This information will assist the Secretary in understanding the insurance market in the State submitting a request and will enable her to better address the criteria for assessing the request set forth in this subpart.

The second general category of information a State must provide is its own assessment of how best to address any risk of destabilization through an adjustment to the MLR standard. In its October 13 letter, the NAIC stated that "when recommending to HHS that a transitional exception should be applied to a state or insurance market, the regulator shall also propose a solution to the factors on which the recommendation is based." The NAIC also suggested that HHS give deference to its analysis and recommendations. HHS agrees with the NAIC that, just as a State commissioner is best qualified to request an adjustment to the MLR standard, a State commissioner seeking an MLR adjustment is also best qualified to suggest an appropriate alternative MLR standard for each of the reporting years for which the State is requesting an adjustment. Thus, § 158.322 further requires any request for an MLR adjustment to estimate the rebates that would be paid under the 80 percent individual market MLR standard and under the alternate proposal a State official submits for each year for which the State is requesting an adjustment.

Section 158.320 also provides some flexibility in the event certain data are unavailable or collection of certain data is unduly burdensome. In such situations, a State may provide notice of this to the Secretary and the Secretary may request alternative supporting data or move forward with her determination on the State's request without the data the State is unable to provide.

5. Assessment Criteria (§ 158.330)

Section 158.330 sets forth the criteria the Secretary will use in determining the risk of destabilization. It does not set forth a single test for determining that risk, but rather states that the Secretary may consider five main criteria in assessing such risk.

The first criterion the Secretary will consider, as set forth in § 158.330(a), is the number of issuers reasonably likely to exit the individual market or cease offering specific products in a State absent an adjustment to the 80 percent MLR and the resulting impact on competition in the State. In making this determination, the Secretary may consider (1) each issuer's MLR relative to an 80 percent MLR, (2) each issuer's profitability and risk-based capital level, (3) the requirements and limitations within the State with respect to market withdrawals, and (4) the number of

issuers that may not be required to pay rebates pursuant to § 158.240.

Second, the Secretary may consider the number of individual market enrollees covered by issuers that are reasonably likely to exit the State absent the adjustment. All other things being equal, the greater the number of policyholders in a market who are enrollees of issuers reasonably likely to exit the market, the greater the likelihood of market destabilization.

Third, the Secretary will consider whether, absent an adjustment to the MLR standard, consumers may be unable to access insurance agents or brokers. Access could be restricted if, in order to comply with MLR standards, issuers reduced compensation to agents or brokers to the point where agents or brokers were not available to assist consumers in finding coverage and other options for consumers were limited. In its October 13th letter, the NAIC noted the important role that agents and brokers will play in the next four years as markets transition to Exchanges, and encouraged HHS to "recognize the essential role served by producers and accommodate producer compensation arrangements in any MLR regulation promulgated." This criterion recognizes that role.

Fourth, the Secretary will consider the alternate coverage options available within the State for enrollees of issuers that are reasonably likely to exit the market—or as the NAIC puts it in its October 13 letter, she will consider "the ability of consumers to find easily affordable products in the State should their carrier leave the State market." Section 158.330(d) provides that, in assessing alternative coverage options, the Secretary will take into account (1) any requirement that issuers who exit the State's individual market must have their block(s) of business assumed by another issuer, (2) which issuers may remain in the State if the adjustment request were denied, and the breadth and price of the products offered by such issuers, (3) the capacity of incumbent issuers to write additional business, (4) the mechanisms, such as guaranteed-issue products, an issuer of last resort, or a State high risk pool, available to the State to provide coverage to consumers to the extent, if any, that issuers withdraw from the market, and (5) any authority the insurance commissioner might have that would help stabilize the State's individual insurance market.

Fifth, the Secretary will consider the impact on premiums charged, the benefits offered, and the cost-sharing provided to consumers by issuers remaining in the market in the event one or more issuers were to withdraw from the market. For example, premiums may rise if the loss of one or more issuers reduced competition to an extent that allowed remaining issuers to increase premiums beyond what competitive conditions would have allowed.

Section 158.330 also states that the Secretary will consider any other relevant information submitted by the State's insurance commissioner, superintendent, or comparable official in the State's request.

6. Process (§§ 158.340 Through 158.350)

Section 158.340 provides that the request for adjustment must be submitted in electronic format, and § 158.340(a) provides that all the information that Subpart C requires in support of a request must be submitted electronically. HHS has determined that these requirements are necessary if, as the PHS Act envisions and the public interest demands, State requests for MLR adjustments are to be handled as expeditiously as possible. Section 158.340(b) permits a State, solely at its option and only if it wishes, also to submit to the Secretary a copy of its request by regular or express mail.

Section 158.341 provides that the State's request will be promptly posted on the Secretary's healthcare.gov website. In addition, § 158.342 states that the Secretary will invite public comment upon the request when it is posted, and will, when assessing the request, consider any comments filed by the public within 10 days of that posting. Section 158.343 provides that any State that submits a request may, at its option, hold a public hearing and create an evidentiary record with respect to its request. If the State does so, the Secretary will consider the evidentiary record of the hearing in making her determination as to the State's request for an adjustment. Section 158.344 provides that the Secretary may also hold a public hearing with respect to a State's request, at the Secretary's discretion. HHS believes that a transparent yet expeditious process will allow all interested parties to provide input while satisfying the need to come to a prompt determination.

Once the Secretary determines that the request has sufficiently satisfied the information required by the interim final regulation and the public comment period has expired, the Secretary will make a determination within 30 days as to whether to grant a State's request for an adjustment to the MLR standard. Section 158.345 also allows the Secretary to extend that 30-day period up to an additional 30 days at her discretion. The Secretary believes that it is in the interests of both issuers and consumers in a State to have certainty about the applicable MLR for the individual market in the State at the earliest practicable date.

Section 158.350 provides that a State submitting a subsequent request for an adjustment shall "submit information as to what steps the State has taken since its initial and other prior requests, if any, to increase the likelihood that enrollees who have health coverage through issuers that are considered likely to exit the State's individual market will receive coverage at a comparable price and with comparable benefits if the issuer does exit the market."

A State that disagrees with the Secretary's initial decision regarding its request for an adjustment to the statutory 80 percent MLR standard may request reconsideration of a denial if it does so in writing within 10 days of the initial decision. Section 158.345(b) provides that the Secretary will issue her determination on the request for reconsideration within 20 days of receiving the request. Section 158.345(a) makes clear that a State may include any additional information it wishes in support of its reconsideration request.

The process established in Subpart C seeks to give States and interested parties full opportunity to present all information necessary and helpful to a determination of requests for adjustments to the statutory 80 percent MLR standard while ensuring that States and issuers will know as early as possible the standard that issuers in the State will be required to meet.

7. Public Comments

In creating this framework for considering a State's request for an adjustment of the MLR for the individual market, HHS reviewed and took into consideration the public comments submitted in response to its Notice. Only a relatively few of the comments received mentioned the authority granted to the Secretary regarding potential destabilization in a State's individual market and offered suggestions with respect to the process and criteria for determining destabilization.

Commenters specifically suggested that markets may become destabilized if issuers choose to withdraw from the market or terminate or materially change existing policies. Commenters also suggested that markets may become destabilized if customers losing coverage have insufficient product choice or are unable to find new

coverage that covers pre-existing conditions. The determination whether to adjust the MLR standard should, commenters suggested, take into account guaranteed issue options, issuers of last resort, requirements that issuers offer individual coverage, and eligibility flexibility under State high risk pools. HHS agrees that these are important considerations, and has incorporated into this Subpart consideration of both the potential causes of destabilization and the systems in place that mitigate destabilization risks.

Other commenters suggested potential warning signals of market destabilization. These included volatility in premium rates, decreases in issuers' reported capital levels, increases in assumption reinsurance, changes in marketing, increases in complaints from brokers or consumers, declines in insurance coverage, increases in applications to State high risk pools, and significant changes in benefit design. State insurance commissioners may wish to further comment on these factors and other local trends in their requests for an adjustment.

One insurance issuer's comment letter suggested that whether at least 10 percent of enrollees are impacted by exiting issuers or at least 10 percent of products are withdrawn from the marketplace may be valid criteria for determining market destabilization. While HHS agrees that market destabilization could not occur absent a significant impact on consumer welfare, HHS believes it is difficult to generalize and create a single numeric test given the different characteristics of State insurance markets, different State laws, and different types of issuers.

As the NAIC Consumer Representatives noted in their letter, the NAIC addressed market destabilization in an "issue resolution document." That document suggested the Secretary consider existing State laws and historic MLRs in each State. The Secretary seeks information regarding existing State laws and issuers' MLRs in order to consider them in connection with a State's request for an adjustment of the MLR standard in the individual market. HHS notes that although State MLR standards are, in general, lower than the 80 percent MLR standard, many issuers are currently above both the 80 percent MLR standard and the applicable State regulatory standard. HHS also received comments suggesting that the MLR standard in all States be adjusted to historic MLR levels and increased to 80 percent over a three year period until 2014. The NAIC did not recommend a national transition. Instead, while noting in its October 13th letter that "*some* states seek national relief from the 2011 MLR, all states recognize that transitional relief may be appropriate for *some* State insurance markets." (Emphasis added.)

Finally, an NAIC advisory subgroup suggested that the Secretary may consider State laws and regulations regarding cancellation and non-renewal of health insurance and the cost to issuers of withdrawing from the individual health insurance market. HHS agrees that in making a determination regarding market destabilization, alternatives available to a State and to an issuer should be considered, and has provided that these are factors to be considered in assessing whether to grant an adjustment to the 80 percent MLR for a State's individual market.

F. Subparts D–F—HHS Enforcement, Additional Requirements on Issuers, and Federal Civil Penalties

Section 2718 of the PHS Act created two requirements for health insurance issuers. Under section 2718(a) of the PHS Act, all health insurance issuers in the group and individual markets are required to report to the Secretary certain data concerning the amount of premium revenue as well as the amounts spent on clinical care, quality improvement activities, and adjusted non-claims expenses. Section 2718(b) requires the calculation of MLR and payments of rebates to enrollees if the MLR standard is not met.

The data that must be reported to the Secretary under section 2718(a) of the PHS Act are addressed in Subpart A of this interim final regulation. The calculation of rebates is addressed in Subpart B. Subparts D through F of this interim final regulation implement enforcement authority in section 2718(b)(3) and provide for enforcement of the reporting obligations set forth in section 2718(a) and rebate requirements in section 2718(b).

Section 2718(b)(3) of the PHS Act [as added by the Affordable Care Act] specifically requires the Secretary to promulgate regulations to enforce the provisions of section 2718. It makes HHS responsible for direct enforcement of the reporting and rebate provisions of section 2718. This interim final regulation implements this statutory mandate.

Section 2718(a) requires issuers to report the data specified directly to the Secretary, rather than to the States. HHS is thus best situated, consistent with the mandate in section 2718(b)(3), to directly enforce the requirement that data be reported to it. This does not mean, however, that the States should play no role in enforcement of these provisions.

States are currently responsible for solvency and, in many States, rate oversight as well. In performing these functions, many states collect and review data and conduct audits of issuer information related to MLRs. In addition, some twenty-nine States already have experience in regulating MLRs either prospectively through rate filing or retrospectively through rebate requirements. States already receive detailed financial reporting from issuers for solvency purposes. Finally, section 2718 of the PHS Act gives States the discretion to impose a higher MLR standard than that prescribed in section 2718. Taking all of these factors into consideration, together with the historical role that States have had in regulating insurance, it is appropriate for the States to have an oversight role with respect to the reporting provisions of section 2718(a), even though the statute gives HHS direct enforcement authority.

Under the regulation, while HHS is responsible for enforcing the reporting provisions and for conducting audits to test the validity and accuracy of the data reported (§ 158.401), HHS may also, in its discretion, accept the findings of audits conducted by State regulators, so long as certain specified conditions are met (§ 158.403). In particular, HHS may accept the findings of audits from a State which report on:

(1) The validity of data on expenses and premiums reported to the Secretary, including the appropriateness of the allocations of expenses, taxes, and revenues used in such reporting;

(2) Whether the activities associated with the issuer's reported expenditures for quality improving activities meet the definition of such activities; and

(3) The accuracy of rebate calculations and the timeliness and accuracy of rebate payments.

In addition, in order to accept the findings of audits from a State, the State's laws must permit the public release of the audit findings of health insurance issuers and the State must submit its audit findings to HHS within 30 days of finalization and submit all preliminary or draft reports within six months of the completion of audit field work unless the audit findings have already been finalized and reported to HHS.

While this interim final regulation provides that HHS may accept audit findings from a State, it makes clear that pursuant to the statutory requirement in section 2718(b)(3), HHS is responsible

for direct enforcement of the MLR reporting and rebate provisions, and retains the discretion to conduct its own audits of issuers, including in States that have acceptable audit programs as defined in the regulation. This approach recognizes that although States have traditionally conducted financial examinations for the purpose of determining solvency, the type of audit needed to assess whether the data reported pursuant to section 2718 is accurate and valid is quite different. As HHS and the States develop greater experience and expertise in conducting these audits, it is likely that the States' role will increase.

This interim final regulation sets forth the procedure to be followed by HHS when it conducts an audit of an issuer to determine whether the reports it has submitted pursuant to this regulation are accurate and valid. The procedure set forth is comparable to the procedures used by HHS when conducting audits of Medicare Advantage plans pursuant to 42 CFR Part 422.

This interim final regulation contains provisions requiring issuers to retain documentation relating to the data reported, and requiring issuers to provide access to that data to HHS or its outside auditors. These provisions are intended to make it possible for HHS or the relevant State to have access to the information needed to determine whether the reports submitted are accurate and valid.

Finally, this interim final regulation provides for the imposition of civil monetary penalties in the event an issuer fails to comply with the reporting and rebate requirements set forth in the regulation. It provides criteria and a process for determining whether and in what amount such penalties should be imposed. While HHS's intent is not to be punitive to issuers, given the importance of receiving timely and accurate reporting and making appropriate rebates, and given the desire to bring down the cost of health care for consumers as soon as practicable following the effective date of the Affordable Care Act, this regulation strikes a balance between penalties that are severe enough so as to encourage compliance with the requirements of the regulations but not so severe as to be punitive. The civil monetary penalties provided for are identical to those for violations of title XXVII that are set forth in the current regulations on enforcement, 45 CFR 150.301 *et seq.* They provide for a penalty for each violation of $100 per entity, per day, per individual affected by the violation. HHS is interested in public comments as to the proper amount or range of penalties for violations of various provisions of this interim final rule. This interim final regulation also adopts the provisions in the existing enforcement regulation regarding factors in aggravation and mitigation that HHS will take into account in determining whether to impose civil monetary penalties and if so, in what amount.

The interim final regulation also provides that if a State has assessed a penalty against an issuer, then HHS will take that into account in considering whether it should assess any penalty for violation of the requirements of this Part.

III. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

IV. Waiver of Proposed Rulemaking and Delay of Effective Date

Section 2792 of the PHS Act authorizes the Secretary to promulgate any interim final rules determined to be appropriate to carry out the provisions of Part A of title XXVII of the PHS Act. The provisions of these interim final regulation requirements in section 2718, and the foregoing interim final rule authority applies to this interim final regulation.

In addition, under section 553(b) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) a general notice of proposed rulemaking is not required when an agency, for good cause, finds that notice and public comment thereon are impracticable, unnecessary, or contrary to the public interest. Although the provisions of the APA that ordinarily require a notice of proposed rulemaking do not apply here because of the specific authority granted by section 2792 of the PHS Act, even if the APA were applicable, the Secretary has determined that it would be impracticable and contrary to the public interest to delay putting the provisions of this interim final regulation in place until a public notice and comment process was completed.

Prior notice and comment in this situation is impracticable because section 2718 of the PHS Act directs the NAIC, not later than December 31, 2010, and subject to certification by the Secretary, to establish uniform definitions of the activities reported as reimbursement for clinical services, activities that improve health care quality, and non-claims costs. However, the reporting required by section 2718 of the PHS Act applies to plan years beginning not later than January 1, 2011. The NAIC transmitted its recommendations to the Secretary on October 27, 2010, in the form of a model regulation. The regulation implementing the reporting requirements must be in effect on or before January 1, 2011, so that issuers, regulators, and consumers know what information must be reported and how to aggregate it prior to the time period which they must report. There are fewer than 60 days between when HHS would be able to review the NAIC's recommendations, certify them, and issue an implementing regulation.

Therefore, we find good cause to waive the notice of proposed rulemaking and to issue this final rule on an interim basis. We are providing a 60-day public comment period.

In addition, the Congressional Review Act, at 5 U.S.C. 801(a)(3), ordinarily requires that the effective date of a "major rule" such as this interim final rule be at least 60 days after publication. However, under 5 U.S.C. 808(2), this delay of effective date may be modified when an agency "for good cause finds (and incorporates the finding and a brief statement of reasons therefore in the rule issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." Specifically, where "good cause" is found to waive prior notice and comment, the rule may "take effect at such time as the Federal agency promulgating the rule determines." 5 U.S.C. 808. Given the exigencies discussed above, and the fact that the provisions of this rule apply, by statute, on January 1, 2011, we find good cause under section 808 to make this interim final rule effective on that date.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.

• The accuracy of our estimate of the information collection burden.

• The quality, utility, and clarity of the information to be collected.

• Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

A. ICRs Regarding MLR and Rebate Reporting Requirement (§ 158.101 Through § 158.170)

This interim final regulation describes the information that will be reported by health insurance issuers on an annual basis to the Secretary starting in 2012, and quarterly in 2011 only for certain plans. Issuers' submissions will include information regarding reimbursement for clinical services, expenditures for activities that improve health care quality, other non-claim costs, earned premiums, and Federal and State taxes and regulatory fees, among other data elements. Issuers will be required to calculate MLRs and rebates as part of their submission to the Secretary.

Generally, the data and methodologies that the regulation instructs issuers to use follow the NAIC 2010 blank, approved August 17, 2010 and the NAIC MLR model regulation, which was finalized on October 27, 2010. Most issuers file information with the NAIC on a regular basis, in accordance with State laws; it is expected that issuers who typically file information with the NAIC will file the supplemental exhibit and the rebate reporting documents that the NAIC created in fulfilling its mandate in section 2718. We expect the NAIC to collect MLR and rebate information beginning for plan year 2010 and to continue collecting such data for the foreseeable future.

HHS's data collection requirements described in this interim final regulation are very similar to the NAIC's. One exception is that we are requiring health insurance issuers who sell expatriate plans or mini-med plans to disaggregate that business from the rest of their business in that market segment and report the MLR data separately. As discussed above in the impact analysis section, HHS estimates that approximately 442 entities will submit reports for each of the States and markets in which they operate; further, we estimate that approximately 25 health insurance issuers will report data for expatriate plans and 50 health insurance issuers will report data for mini-med plans.

At this time, HHS has not developed the MLR and rebate forms that health insurance issuers will have to complete on an annual basis beginning for plan years starting January 1, 2011. In addition, as described above, we are requiring issuers who opt to separately report the experience for expatriate plans and mini-med plans to submit quarterly reports in 2011, so that we can better understand these products. We will revisit the special filing circumstances for expatriate plans and mini-med plans after reviewing the quarterly filings. We plan to publish the instructions and forms that issuers must file for all plans in future guidance. At that time we will solicit public comments on both the forms the estimated burden imposed on health insurance issuers for complying with the provisions of this interim final regulation. The information collection requirements associated with §§ 158.101–158.170 will become effective upon OMB approval. HHS will publish a notice in the **Federal Register** notifying the public of OMB approval at the appropriate time.

B. ICRs Regarding Notice of Rebates to Enrollees (§ 158.250)

Within Subpart B of this interim final regulation, we describe the obligation of health insurance issuers to calculate and pay rebates to consumers in years when the issuer's MLR does not meet the applicable minimum MLR threshold. In addition, the interim final regulation requires issuers to provide information to consumers about the rebate they are receiving. At this time, HHS has not developed the model disclosure language for the rebate notice to enrollees that issuers will be required to send beginning August 1, 2012, based upon plan years starting January 1, 2011. In the near future, HHS will publish the model disclosure language and will solicit public comment. At that time, and per the requirements outlined in the Paperwork Reduction Act, we will estimate the burden on health insurance issuers of complying with this provision of this interim final regulation. The information collection requirements associated with § 158.250 will become effective upon OMB approval. HHS will publish a notice in the **Federal Register** notifying the public of OMB approval at the appropriate time.

C. ICRs Regarding Retention of Records (§§ 158.501–158.502)

Subpart E of the interim final regulations establishes the Secretary's enforcement authority regarding the reporting requirements under section 2718. Issuers must maintain all documents and other evidence necessary to enable HHS to verify that the data required to be submitted comply with the definitions and criteria set forth in this interim final regulation, and that the MLR is calculated and any rebates owing are calculated and provided in accordance with this interim final regulation. The interim final regulation requires issuers to maintain all of the documents and other evidence for the current year and six prior years, unless a longer period is required under § 158.501.

We expect all issuers will have to retain data relating to the calculation of MLRs; we expect only some issuers will have to retain information regarding the payment of rebates and the notice to enrollees. We believe that the burdens associated with our record retention requirements do not exceed standard record retention practices in that issuers are already required to retain the records and information required by this interim final regulation in order to comply with the legal requirements of their States' departments of insurance. For that reason, we are assigning a minimal burden to these requirements. We estimate that 442 issuers must comply with the aforementioned requirements. We further estimate that it will take each issuer a total of one hour to file and maintain both the data for MLR calculations and the information regarding payment of rebates and notices to enrollees. The total estimated annual burden associated with the requirements in §§ 158.501 through 158.502 is 442 hours at a cost of $10,045.

However, we welcome comments regarding the burden associated with maintaining the information described in subpart E of this interim final regulation.

D. ICRs Regarding State Request for MLR Adjustment (§§ 158.301–158.350)

Subpart C of this interim final regulation implements the provisions of section 2718(b)(1)(A)(ii). The interim final regulation describes the data and narratives which States must submit that are seeking an adjustment to the applicable MLR in the individual market for their State. There is no standardized application form associated with a State's request. As discussed in §§ 158.321, 158.322, and158.323, the data elements that a requesting State must provide include:

• The applicable State minimum required MLR, if any;

• State individual market withdrawal requirements, if any;

• Any mechanisms to provide options to consumers in case of issuer withdrawal;

• Information on issuers in the State's individual market;

• The State's proposed adjustment to the minimum MLR for the State's individual market; and

• The contact information for the State representative.

In addition, a State whose request for adjustment to the MLR standard has been denied by the Secretary may request reconsideration of that determination. A request for reconsideration must be submitted in writing to the Secretary within 10 days of her decision to deny the State's request for an adjustment, and may include any additional information in support of its request.

Based on preliminary data analysis and indications by a few States that they may apply for an adjustment, the Department estimates that approximately 20 States will submit applications and that it will take approximately ten working days for a State to complete the application. An exact time burden estimate is uncertain because some States may have better access to the required application information elements than others; some States may have to seek some of the required information from health insurance issuers in their States, which could increase their burden. Some States may, if providing the requested information is an undue burden, have the Secretary consider their application without some of the information elements.

The Department estimates that it will take a State 94 hours to complete an application including gathering data, developing data analyses, synthesizing information, and developing the adjusted MLR threshold. For the purposes of this estimate, the Department assumes that this application will take various professional staff approximately 75 hours (at an average rate of $125 an hour), an associate general counsel 10 hours (at $175 an hour), a senior general counsel 5 hours (at $350 an hour), and the Commissioner 4 hours (at $450 an hour) to assemble and review the various components of the application.[1] The Department estimates that the total cost burden associated with the submission of a MLR adjustment application to be approximately $14,675 per response for a total estimated burden of $293,500.

The Department is soliciting public comments for 60 days concerning the process described in subpart C of the preamble whereby a State may request an adjustment of the minimum MLR applicable in the individual market. The Department has submitted a copy of these interim final regulations to OMB in accordance with 44 U.S.C. 3507(d) for review of the information collections. If you comment on this information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, *Attention:* CMS Desk Office, 9998–IFC. *Fax:* (202) 395–6974; or *E-mail: OIRA_submission@omb.eop.gov.*

VI. Regulatory Impact Analysis

A. Summary

As stated earlier in this preamble, this interim final regulation implements sections 2718(a) through (c) of the PHS Act, which set forth requirements for reporting of certain medical loss ratio (MLR)-related data to the Secretary on an annual basis by issuers offering coverage in the individual and group markets, and calculating and providing rebates to policyholders in the event that an issuer's MLR fails to meet the minimum statutory requirements. This interim final rule also establishes uniform definitions and standardized methodologies for calculating MLR-related data; provides a process and criteria for the Secretary to determine whether application of the 80 percent minimum MLR threshold may destabilize the individual market in a given State; and addresses enforcement of the reporting and rebate requirements. These provisions are generally effective for plan years beginning January 1, 2011.

The Department is publishing this interim final regulation to implement the protections intended by Congress in the most economically efficient manner possible. We have examined the effects of this rule as required by Executive Order 12866 (58 FR 51735, September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), Executive Order 13132 on Federalism, and the Congressional Review Act (5 U.S.C. 804(2). In accordance with OMB Circular A–4, the Department has quantified the benefits, costs and transfers where possible, and has also provided a qualitative discussion of some of the benefits, costs and transfers that may stem from this interim final regulation.

B. Executive Order 12866

Executive Order 12866 (58 FR 51735) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity).

Section 3(f) of the Executive Order defines a "significant regulatory action" as an action that is likely to result in a rule (1) having an annual effect on the economy of $100 million or more in any one year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities (also referred to as "economically significant"); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year); and a "significant" regulatory action is subject to review by the Office of Management and Budget (OMB). As discussed below, we have concluded that this rule is likely to have economic impacts of $100 million or more in any one year, and therefore meets the definition of "significant rule" under Executive Order 12866. Therefore, the Department has provided an assessment of the potential costs, benefits, and transfers associated with this interim final regulation. Accordingly, OMB has reviewed this interim final regulation pursuant to the Executive Order.

1. Need for Regulatory Action

Consistent with the provisions in Section 2718 of the PHS Act, this interim final rule requires health insurance issuers offering coverage in

[1] Estimates were developed by interviewing two former insurance commissioners, a former insurance department actuary, and a former health plan employee familiar with the burden of submitting financial data to health insurance departments.

the individual and group markets to provide a rebate to consumers if they do not spend a specified portion of premium income on reimbursement for clinical services (i.e., incurred claims) and activities that improve quality. Section 2718(a) of the PHS Act (captioned "clear accounting of costs") requires health insurance issuers to "submit to the Secretary a report concerning the ratio of the incurred loss (or incurred claims) plus the loss adjustment expense (or change in contract reserves) to earned premiums." Section 2718(b) of the PHS Act (captioned "ensuring that consumers receive value for their premium payments") requires issuers to provide an annual rebate to each enrollee if the ratio of the amount of premium revenue expended on reimbursement for clinical services and activities that improve quality is less than the applicable minimum standards, specifies how the rebate is to be calculated, and allows the Secretary to adjust the 80 percent minimum MLR threshold if the Secretary determines that applying this standard may destabilize the individual market in a given State. Section 2718(c) of the PHS Act directs the NAIC to establish uniform definitions and calculation methodologies subject to certification by the Secretary. As discussed elsewhere in this preamble, after considering the NAIC's recommendations, HHS in this interim final regulation certifies and adopts them in full. Consistent with Section 2718(b)(3) of the PHS Act, which requires the Secretary to promulgate regulations, this interim final regulation sets forth the provisions in Sections 2718(a) through (c) and is needed for their implementation to provide rules that issuers can use to implement effective processes for reporting the required data and calculating and paying applicable rebates.

2. Summary of Impacts

In accordance with OMB Circular A–4, Table VI.1 below depicts an accounting statement summarizing the Department's assessment of the benefits, costs, and transfers associated with this regulatory action. The Department limited the period covered by the regulatory impact analysis (RIA) to 2011–2013 Estimates are not provided for subsequent years both because there will be significant changes in the marketplace in 2014 related to the offering of new individual and small group plans through the exchanges, and because there will be statutorily required adjustments to the MLR formula to account for payments or receipts for risk adjustment, risk corridors, and reinsurance under sections 1341, 1342, and 1343 of the Affordable Care Act that are not effective until 2014. Those provisions require additional regulations that have not yet been promulgated.

The Department anticipates that the transparency and standardization of MLR reporting in this interim final regulation will help consumers to ensure that they receive good value for their premium dollars. Additionally, the inclusion of activities that improve quality in calculating the MLR could help to increase the level of investment in and implementation of effective quality improving activities, which could result in improved quality outcomes and lead to a healthier population. The Department estimates that issuers' total one-time administrative costs related to the MLR reporting, record retention, and rebate payment and notification requirements represent less than 0.02 percent of their total premiums for accident and health coverage, and their total annual ongoing administrative costs related to these requirements represent less than 0.01 percent of their total premiums for accident and health coverage. Executive Order 12866 also requires consideration of the "distributive impacts" and "equity" of a regulation. As described in this RIA, this regulatory action will help ensure that issuers spend at least a specified portion of premium income on reimbursement for clinical services and quality improving activities and will result in a decrease in the proportion of health insurance premiums spent on administration and profit. It will require issuers to pay rebates to consumers if this standard is not met. As the table shows, although we are unable to quantify benefits, the transfers (rebates from issuers to consumers) could be substantial—estimated monetized rebates of $0.6 billion to $1.4 billion annually. As noted, Executive Order 12866 requires consideration of "distributive impacts" and "equity." The rebates will help insure that issuers spend at least a specified portion of premium income on reimbursement for clinical services and quality improvement, resulting in less disparate MLRs and value to consumers across issuers and States. In accordance with Executive Order 12866, the Department believes that the benefits of this regulatory action justify the costs.

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Table VI.1 - Accounting Table

Benefits:						
Qualitative: * increased transparency relating to portion of premium spent on benefits and quality could help policyholders to select higher value coverage * increased quality of medical care as a result of increased spending on quality-improving activities by issuers * improved health as a result of increased spending on medical care by issuers						
Costs:	Low Estimate	Mid-range Estimate	High Estimate	Year dollar	Discount rate percent	Period covered
Annualized Monetized ($millions/year)	24.8	37.4	57.0	2010	7	2011-2013
	23.0	34.7	52.8	2010	3	2011-2013
One-time costs to develop methods for capturing data, and annual costs related to reporting data to the Secretary and providing rebate notifications and payments.						
Qualitative: * increased spending on quality-improving activities by issuers * increased spending on medical care by issuers * potential market disruption if some issuers limit plan offerings as a result of the MLR requirements (offset, as with all benefits, costs, and transfers, to the extent that States obtain adjustments to the MLR due to such potential disruptions)						
Transfer:						
Annualized Monetized ($millions/year)	633.1	930.8	1,541.8	2010	7	2011-2013
	587.4	863.5	1,430.4	2010	3	2011-2013
Annual transfer from shareholders or nonprofit stakeholders to enrollees of rebates paid by issuers for coverage in the individual, small group, and large group markets that do not meet the minimum MLR standards (approximately 2.8 million to 9.6 million enrollees could receive rebates each year)						
Qualitative: * savings for consumers and reduced profit for issuers						

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3. Qualitative Discussion of Anticipated Benefits, Costs and Transfers

The medical loss ratio (MLR) is an accounting statistic that, stated simply, measures the percentage of total premiums that insurance companies spend on health care and quality initiatives, versus what they spend on administration, marketing and profit. In the following sections, we discuss some of the anticipated benefits, costs and transfers associated with the Affordable Care Act MLR requirements.

a. Benefits

In developing this interim final regulation, the Department carefully considered its potential effects including both costs and benefits. Because of data limitations, the Department did not attempt to quantify the benefits of this regulation. Nonetheless, the Department was able to identify several potential benefits which are discussed below.

Health insurance markets in the United States are often not highly competitive. The share of the US population living in areas where markets are least competitive has been increasing.[2] Even in markets with multiple competing plans, lack of transparency in pricing may prevent adequate competition based on the value of product, since it is difficult to ascertain if a low premium is due to high efficiency, low coverage of medical claims, or a healthy underlying population of enrollees. As a result, insurers can provide an inefficient, low-value product without consumers being fully aware of what they are purchasing. A potential benefit to this regulation is greater market transparency and improved ability of consumers to make informed insurance choices. The uniform reporting required under this regulation, along with other programs required by Affordable Care Act such as *http://www.HealthCare.gov*, a Web site with plan-level information, will mean that consumers will have better data to inform their choices, enabling the market to operate more efficiently.

In addition, issuers that would not otherwise meet the MLR minimum defined by this regulation may increase spending on quality-promoting activities. These programs, which include case management, care coordination, chronic disease management and medication compliance, have the potential to create a societal benefit by improving outcomes and population health.

Issuers that would not otherwise meet the MLR minimum may also expand covered benefits or reduce cost sharing. To the extent that these changes result in increased consumption of effective health services, the regulation could result in improved health outcomes, thereby creating a societal benefit.

b. Costs

The Department has identified the primary sources of costs associated with this regulation as the costs associated with reporting, recordkeeping, rebate notifications and payments, and other costs.

The Department estimates that issuers will incur approximately $33 million to $67 million in one-time administrative costs, and $11 million to $29 million in annual ongoing administrative costs related to complying with the requirements of this interim final regulation from 2011 through 2013. Additional details relating to these costs are discussed later in this regulatory impact analysis.

Other Costs—There are two other potential types of costs associated with this regulation: Costs of potential increases in medical care use, the cost of additional quality-improving activities, and costs to consumers if some issuers decide to limit offered products as a result of this interim final regulation.

As discussed under benefits, there may be increases in quality-improving activities or in consumption of medical care due to this regulation. Both of these very likely have some benefit to enrollees but they also represent an additional cost to issuers and society.

It is also possible that some issuers in particular areas or markets will not be able to operate profitably when required to comply with the requirements of this regulation. They may respond by changing or reducing the number of products they offer. The Department anticipates that issuers' decisions regarding whether to limit offered products will not be governed solely by short-term profitability. Issuers are likely to consider whether they expect to be successful competitors in Exchanges in 2014 and beyond.[3] Some low MLR plans may decide to leave a given market entirely or be acquired by a larger company, while other low MLR plans (particularly those that are subsidiaries of larger organizations) may find ways to achieve higher MLRs through increased efficiencies.

To the extent that issuers do decide to limit product offerings, group purchasers or individual enrollees in these plans may bear some costs associated with searching for and enrolling in a new insurance plan. For employers, particularly small employers, these costs may include increased administrative expenses. For consumers, this may lead to reduced choice, the inability to purchase similar coverage, and higher search costs related to finding affordable insurance coverage. States may apply for an adjustment of the MLR threshold in the individual market if the Secretary concurs that the adjustment is necessary to prevent market destabilization. This could mitigate the potential costs.

c. Transfers

To the extent that insurers' MLR experience falls short of the minimum thresholds, they must provide rebates to enrollees. These rebates would reflect transfers of income from the insurers or their shareholders to the policy holders. Based on the methods described above, we have estimated ranges for the rebates that may occur during 2011–2013. These estimates are discussed later in this regulatory impact analysis (see Tables VI.7, VI.8, and VI.9).

4. Overview of Data Sources, Methods, and Limitations

The most complete source of data on the number of licensed entities offering fully insured, private comprehensive major medical coverage in the individual and group markets is the National Association of Insurance Commissioners (NAIC) Annual Financial Statements and Policy Experience Exhibits database. These data contain multiple years of information on issuers' revenues, expenses, and enrollment collected on various NAIC financial exhibits called "Blanks" that issuers submit to the NAIC through State insurance regulators. The NAIC has four different Blanks for different types of insurers: Health, Life, Property & Casualty, and Fraternal issuers.[4] A Technical Appendix for this analysis, available at *http://www.hhs.gov/ociio/regulations/index.html*, provides more detail on the

[2] Dafny, Leemore S.. 2010. "Are Health Insurance Markets Competitive?" American Economic Review, 100(4): 1399–1431.

[3] Bernstein, Jill, "Recognizing Destabilization in the Individual Health Insurance Market," Changes in Health Care Financing and Organization (HCFO) Issue Brief, July 2010, accessed at *http://www.hcfo.org/files/hcfo/HCFO%20Policy%20Brief%20July%202010.pdf*.

[4] If a company's premiums and reserve ratios for its health insurance products equals 95 percent or more of their total business for both the current and prior reporting years, a company files its annual statement using the Health Blank. Otherwise, a company files the annual statement associated with the type of license held in its domiciliary State, i.e. it files either the Life, Property& Casualty, or Fraternal Blank.

precise NAIC data sources used for this analysis.

A total of 618 insurers offering comprehensive major medical coverage filed annual financial statements in 2009, with the Health and Life Blank filers accounting for approximately 99 percent of all comprehensive major medical premiums earned. It is for this reason that we have restricted our analysis to Health and Life Blank companies. Comprehensive major medical coverage[5]—including both coverage offered in the individual and group markets that is subject to this interim final regulation—accounted for approximately 47.8 percent of all Accident and Health (A&H) premiums in 2009.

Although the NAIC data represent the best available data source with which to estimate impacts of the MLR regulation, the data contain certain limitations that should be noted. For example, the NAIC data do not include issuers regulated by California's Department of Managed Health Care (DMHC) as well as small, single-State insurers that are not required by State regulators to submit NAIC annual financial statements. When we compare the NAIC enrollment data to InterStudy data, we estimate that these limitations cause the NAIC data to exclude approximately 9 percent of the total fully insured, private comprehensive major medical market.[6] Additionally, the NAIC data do not break out small and large group coverage at the State level, and administrative expenses such as taxes are reported at the national level for all A&H lines of business. We developed imputation methods to account for these limitations. Finally, we made several edits to the data that led us to exclude from the analysis 176 of the companies that the NAIC data identify as reporting comprehensive major medical coverage.[7] However, these excluded companies represent a small portion of the overall comprehensive major medical market (3 percent of life years and 2 percent of earned premiums). The Technical Appendix (available at *http://www.hhs.gov/ociio/regulations/index.html*) contains a detailed description of the limitations of the NAIC data, and the data edits that were made by the Department. We use the remaining 442 companies to estimate the regulatory impacts discussed below.

5. Estimated Number of Affected Entities Subject to the MLR Provisions

Section 2718(a) of the PHS Act specifies that the MLR provisions apply to health insurance issuers offering group or individual health insurance coverage, including grandfathered health plans. As discussed earlier in this preamble, in this context, the term "issuer" has the same meaning provided in 45 CFR 144.103, which states that an issuer is "an insurance company, insurance service, or insurance organization (including an HMO) that is required to be licensed to engage in the business of insurance in a State and that is subject to State law that regulates insurance (within the meaning of section 514(b)(2) of ERISA)." As discussed elsewhere in this preamble, and consistent with the NAIC recommendations, the MLR provisions in this interim final rule apply to issuers that offer comprehensive major medical coverage, and these issuers will be required to report these data and determine if rebates are owed at the company, State, and market level (*e.g.*, individual, small group, and large group).[8] The following sections summarize the Department's estimates of the number of entities that will be affected by the requirements of this interim final regulation.

a. Estimated Number of Affected Entities

The MLR provisions will apply to all health insurance issuers offering comprehensive major medical coverage in the individual and group markets. For purposes of the regulatory impact analysis, we have estimated the total number of issuers that will be affected by the requirements of this interim final regulation at the company level because this is the level at which issuers currently submit their annual financial reports to the NAIC (including both company- and State-level exhibits where appropriate). However, because issuers will be required to report MLRs and calculate any rebates that are owed at the company/State level for each market in which they offer coverage (for example, individual, small group, large group), we have estimated rebates by "licensed entity" (company/State combination) for each market.

Table VI.2 shows the estimated distribution of issuers offering coverage in the individual, small group and large group markets for the analytic sample used in this RIA.[9] Approximately 70 percent (311) of these issuers offer coverage in the individual market, 77 percent (342) offer coverage in the small group market, and 77 percent (338) offer coverage in the large group market. Approximately half (224) of these issuers offer coverage in all three markets that are subject to the MLR requirements, while the other half offer coverage in one or two of the markets that are subject to the requirements (118 and 100, respectively).

Additionally, the Department estimates that there are 74.8 million enrollees in the analytic sample in coverage that is subject to the requirements in this interim final rule, including approximately 10.6 million enrollees in individual market coverage (estimated based on "life years" for 2009 NAIC Health and Life Blank filers, which as discussed earlier excludes data for companies that are not required to file annual statements with the NAIC), 24.2 million enrollees in small group coverage, and 40.0 million enrollees in large group coverage (excluding enrollees in companies that did not file annual financial statements on the NAIC's Health or Life Blanks in 2009).[10]

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[5] Comprehensive major medical coverage sold to associations and trusts has been included in individual comprehensive major medical coverage for purposes of the RIA. The Department's estimates exclude Medigap, which is reported separately in the NAIC data from comprehensive major medical coverage offered in the individual and group markets. The NAIC data do not allow us to identify mini-med plans or expatriate plans.

[6] This estimate is based on a comparison of 2008 NAIC and InterStudy data. Interstudy data report 79.7 million enrollees for comprehensive major medical coverage in 2008 whereas NAIC data report approximately 72.9 million enrollees. The NAIC enrollment number represents 91 percent of the Interstudy total enrollment figure.

[7] These exclusions reflect the restriction to Health and Life Blank companies, which drops 22 Fraternal and Property and Casualty companies from the analysis.

[8] This includes some issuers that offer mini-med plans which, as discussed elsewhere in the preamble, often cover the same types of medical services as comprehensive medical plans, but have low annual benefit limits and typically have lower premiums than plans providing higher ceilings on benefits. Data for mini-med plans are not broken out separately from other data that issuers reported to NAIC in 2009. Therefore, the regulatory impact analysis does not include separate estimates relating to mini-med plans.

[9] As noted above, the analytic sample excludes companies that are regulated by the Department of Managed Health Care in California, as well as small, single-State insurers that are not required by State regulators to submit NAIC annual financial statements.

[10] The estimate provided here of the size of the individual market differs from estimates provided in previous rulemaking for a number of reasons. First, as discussed in this regulatory impact assessment, issuers that are regulated by the Department of Managed Health Care in California do not file with the NAIC. Second, and more importantly, the estimate provided here is of enrollment at an average point in time, while previous estimates included people who were enrolled at some point during the year. Third, the Current Population Survey, which was the source of previous estimates, is thought by some analysts to overestimate the number of people purchasing individual coverage.

Table VI.2
Estimated Number of Issuers and Licensed Entities Subject to the Medical Loss Ratio Reporting Requirements By Market

Description	Issuers (1) Offering Comprehensive Major Medical Coverage		Licensed Entities (2) Offering Comprehensive Major Medical Coverage		Enrollees in Comprehensive Major Medical Coverage (3)	
	Number	% of Total	Number	% of Total	Number (thousands)	% of Total
Total Issuers (4)	442	100.0%	2,002	100.0%	74,830	100.0%
By Market:						
Individual Market	311	70.4%	1,429	71.4%	10,603	14.2%
Small Group Market (5)	342	77.4%	976	48.8%	24,189	32.3%
Large Group Market	338	76.5%	912	45.6%	40,039	53.5%
By Number of Markets:						
Single Market Only	118	26.7%	1,159	57.9%	3,722	5.0%
Individual Market Only	66	14.9%	792	39.6%	2,317	3.1%
Small Group Market Only	27	6.1%	187	9.3%	845	1.1%
Large Group Market Only	25	5.7%	180	9.0%	560	0.7%
Two Markets	100	22.6%	371	18.5%	9,934	13.3%
All Three Markets	224	50.7%	472	23.6%	61,173	81.7%

Notes: (1) Issuers represents companies (e.g., NAIC company codes). (2) Licensed Entities represents company / State combinations. (3) Enrollment represents "life years" (total member months divided by 12). (4) Total issuers represents 2009 NAIC Health and Life Blank filers with valid data. Excludes data for companies that are regulated by the California Department of Managed Health Care and other non-Health and Life Blank filers. (5) Small group is defined based on the current definition in the PHS Act.
Sources: 2009 NAIC Health and Life Annual Statements and A&H Policy Experience Exhibit data.

b. Characteristics of the Affected Entities

Table VI.3 provides additional information about the characteristics of the issuers that are subject to the MLR requirements. Most (80 percent) of these companies are subsidiaries of larger carriers, and more than two thirds (315) only offer coverage in a single State. A third (143) of the issuers that are subject to the MLR requirements collected less than $50 million in earned premiums for individual and group comprehensive major medical coverage in 2009, 21 percent (92) collected $50 to $149 million, 31 percent (138) collected $150 to $999 million, and 16 percent (69) collected $1 billion or more in earned premiums that year. Meanwhile, 80 percent of the affected issuers also offer other types of accident and health coverage that is not subject to the requirements of this interim final regulation.

Table VI.3
Selected Characteristics of Issuers Subject to the Medical Loss Ratio (MLR) Reporting Requirements

Description		Number of Issuers (1)	Percent of Total
Estimated Total Number of Issuers Subject to the MLR Requirements (2)		442	100.0%
By Corporate Structure			
	Independent Company	87	19.7%
	Subsidiary of a Larger Carrier (3)	355	80.3%
By Number of States in Which Coverage is Offered			
	1 State	315	71.3%
	2 to 5 States	74	16.7%
	5 to 19 States	22	5.0%
	20 or More States	31	7.0%
By Total Earned Premiums for Individual and Group Comprehensive Major Medical Coverage			
	Less Than $10 Million	72	16.3%
	$10 million to $49 million	71	16.1%
	$50 million to $149 million	92	20.8%
	$150 million to $999 million	138	31.2%
	$1 billion or more	69	15.6%
By Scope of Coverage Offered			
	Only Offers Individual and Group Comprehensive Major Medical Coverage	82	18.6%
	Also Offers Other Types of Accident and Health Coverage	360	81.4%

Notes: (1) All data are based on the issuers' 2009 NAIC annual financial statements. (2) Total issuers represents 2009 NAIC Health and Life Blank filers with valid data. Excludes data for companies that are regulated by the California Department of Managed Health Care and other non-Health and Life Blank filers. (3) The Department estimates that in addition to the 87 independent companies, approximately 109 multi-company carriers offer coverage that is subject to the requirements of this interim final rule.
Sources: 2009 NAIC Health and Life annual statements and A&H Policy Experience Exhibit data.

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While all 442 of these issuers will be subject to the requirements of this interim final regulation, the Department estimates only a subset of these companies will be required to pay MLR-related rebates to policyholders during any given year. The following section contains estimates of the number of entities whose coverage will not meet the applicable minimum MLR thresholds, the estimated MLR rebate payments, and the estimated number of enrollees that would receive the MLR rebates.

6. Estimated MLR Rebate Payments

To date, there have been few published studies that document MLRs for comprehensive major medical coverage offered in the individual, small group and large group markets at the State and company levels nationwide.[11] Additionally, as discussed earlier, there are a number of challenges related to using the 2009 NAIC data. Despite these limitations, the Department believes that the 2009 NAIC data provide a reasonable basis for developing a model to be used for estimating the universe of entities that are likely to be affected by the MLR requirements, and estimating a potential range of other impacts including rebate amounts.[12] Specifically, the Department believes that a reasonable range of assumptions can be applied to the 2009 NAIC data making it the best available source for estimating the potential impacts of this interim final regulation. Therefore, using data from NAIC annual financial statements, the Department summarized data on traditional or unadjusted MLR values prior to the enactment of Affordable Care Act and estimated the impact of the Affordable Care Act's MLR provisions on the market.

In considering how to model the MLR impacts, the Department examined State experience with various types of related policies. Some States have traditionally used MLR standards for reviewing rate filings, others have set minimum standards, a few States require rebates to be made if minimum standards are not met, and many States have no requirements. The Department estimates that prior to the enactment of the Affordable Care Act, approximately 32 States (including the District of Columbia) had enacted requirements relating to minimum MLR standards or administrative expense limits for coverage in at least some segments of the individual and group markets,[13] primarily in the context of submitting historical and anticipated loss ratios as part of their rate filings; approximately 19 States did not have any minimum MLR requirements for individual or group coverage prior to the enactment of the Affordable Care Act. State-level MLR requirements, where they existed, often varied by the type of coverage being offered, were sometimes optional, and lacked standardization in the way that the MLRs were to be calculated. In addition, States' minimum MLR requirements were often quite low—approximately 10 States had loss ratio requirements that were as low as 55 percent for at least some segments of the market, and another 13 States had minimum MLR thresholds between 60 and 75 percent for at least some segments of the market. The Department estimates that nine States have enacted minimum MLR thresholds or administrative expense limits requiring that at least 80 percent of premiums be spent on clinical services in at least some segments of the individual and group markets.

For several reasons, the State experience with MLR requirements was not useful for modeling the effects of imposing an 80 percent MLR requirement nationwide for the individual and small group markets, and an 85 percent MLR requirement nationwide for the large group market. First, as described above, the States varied considerably in terms of MLR definitions and policy implementation. The experience of the nine States that have enacted 80 percent or higher MLR thresholds for at least a portion of the affected market may have been relevant, but there was not sufficient data available to estimate the impact of their policies and generalize to the national level. For example, in five of these States, the 80 percent or higher thresholds only apply to a portion of the market.[14] Additionally, there is limited data available for several of these States; for example, there is limited availability of California HMO data because they do not file with the NAIC; New Jersey first imposed its 80 percent requirement for the individual and small group markets in 2009 (prior to that, the State had a 75 percent minimum MLR standard for individual and small group coverage);[15] and New Mexico's 80 percent and 85 percent standards for the small group and large group markets, respectively, were just enacted on March 3, 2010 (prior to that, the State had a 55 percent minimum MLR standard for small group coverage, and no minimum MLR standard for the large group market). Additionally, in New York and New Jersey, the market for individual unsubsidized insurance is extremely small, largely as a result of rating rules. Finally, Ohio's provision limiting the administrative expenses that an insurer can spend to no more than 20 percent applies to the insurance company as a whole (*e.g.*, the State does not have separate requirements for coverage offered in the individual, small group and large group markets, as required by the Affordable Care Act).[16] The State's regulators estimate that carriers will be close to the Affordable Care Act's minimum MLR thresholds for small group and large group coverage, but that some carriers will have to "raise the bar" in order to meet the standards for the individual market.[17]

[11] For example, the Senate Commerce Committee used NAIC data to report on nationwide MLRs for selected companies, but did not analyze MLRs at the State level (see "Implementing Health Insurance Reform: New Medical Loss Ratio Information for Policymakers and Consumers: Staff Report For Chairman Rockefeller," U. S. Senate, Committee on Commerce, Science and Transportation, April 15, 2010, accessed at *http://commerce.senate.gov/public/index.cfm?p=Reports*). It is also important to note that MLRs calculated for other purposes may not provide an accurate picture of MLRs under the Affordable Care Act, which includes adjustments for administrative expenses related to quality improving activities and small plans.

[12] The NAIC has developed a "Supplemental Blank" that will be used to collect 2010 comprehensive major medical data by company, State and market that are consistent with the uniform definitions and standardized calculation methodologies that NAIC was required to develop under Section 2718(c) of the PHS Act (subject to certification by the Secretary). However, this information will not be available until the Spring of 2011.

[13] This is consistent with America's Health Insurance Plans (AHIP) data, which suggest that there are 32 States that have established MLR guidelines or imposed limitations on administrative expenses for comprehensive major medical insurance (excluding States that require filing of loss ratios, but have not established minimum standards), see "State Mandatory Medical Loss Ratio (MLR) Requirements for Comprehensive, Major Medical Coverage: Summary of State Laws and Regulations, as of April 15, 2010", AHIP, accessed at *http://www.naic.org/documents/committees_lhatf_ahwg_100426_AHIP_MLR_Chart.pdf*.

[14] The 80 percent or higher minimum MLR requirements apply only to HMOs in California, only to HMO point of service plans in Arkansas, only to small group special health care plans in Connecticut, only to small group plans assessed 3 percent or more of the total annual amount assessed by the State's high risk pool in Minnesota, and only for nonprofit medical and dental indemnity or health and hospital service corporation individual direct payment contracts in New York.

[15] Carriers in New Jersey are required to pay rebates if they have a loss ratio below the minimum standard. In 2008, total standard and non-standard market refunds paid by carriers in the State were approximately $850,000. New Jersey Department of Banking and Insurance, "SEH Loss Ratio and Refund Reports for 2008," April 19, 2010, accessed at *http://www.pdcbank.state.nj.us/dobi/division_insurance/ihcseh/sehrpts/seh08lossratiorpt.pdf*.

[16] Ohio Revised Code § 3923.022, accessed at *http://codes.ohio.gov/orc/3923*.

[17] Adamczak, Rick, "New Regs Unlikely to Have Much Impact on Ohio Insurers," Dayton Legal News, November 1, 2010, accessed at *https://www.dailycourt.com/articles/index/id/7284*.

It is difficult to draw general lessons from the experience in these nine States about the likely results of imposing an 80 percent MLR requirement for the individual and small group market nationwide—relevant data are not available in many of the States, the level of aggregation is not consistent in one of the States, and rating rules in two of the States are so different than in most of the rest of the country that results are not likely to be generalizable. Most importantly, in all nine States data were not available over a sufficient time period to establish causality between State policies and observed MLRs.

a. Data Limitations and Modeling Assumptions

As discussed earlier in section VI.B.4 of this regulatory impact analysis, and in a Technical Appendix that is available at *http://www.hhs.gov/ociio/regulations/index.html*, the available data are less than perfect for the task at hand. Among the larger imperfections: The data do not measure quality improving activities as defined by this interim final regulation; the data for some issuers and States are clearly in error; and the data capture administrative expenses at the national level, but do not allocate them to States or to markets (individual, small group, and large group).

The Department expects that as a result of this interim final regulation that issuer behavior may well change, and even if the data could precisely measure MLRs in 2009, MLRs in 2011 may well be different as a result of issuer behavioral change. However, for purposes of this analysis we do not explicitly model these behavioral changes in our estimates. Potential behavioral changes as a result of this regulation and impact on our estimates are discussed below, including:

- Insurer Pricing Policy—Companies will likely consider a number of responses in pricing 2011 policies (e.g., reducing premium increases or increase health care expenditures) that would minimize or avoid rebates. As a result of these anticipated responses, estimates based on the 2009 data would result in upwardly biased estimates of potential rebates;
- Allocation of Expenses Across States and Markets and Affiliates—Issuers were not previously required to allocate company-level expenses by State and by line of business in their annual financial report submissions to the NAIC. However, companies are likely to focus more attention on the methodologies that they use for allocating administrative expenses now that this information will be used in determining if they owe rebates for a given company/State/market. The choices issuers make in determining allocation methods could have a material impact on MLR rebates;
- Activities That Improve Quality—Issuers may increase their quality-improving activities given the financial incentive to do so, or newly describe existing activities as such, and spending on these activities may vary significantly by State or company;
- Other Changes in Categorization—Companies are expected to carefully scrutinize all of their expenditures to determine whether some could legitimately be categorized as expenditures for clinical services or quality improvement based on the definitions implemented by this regulation;
- Other Behavioral Changes—It is unclear to what extent companies may make other behavioral changes that could affect MLR rebates (*e.g.*, expanding coverage to increase medical claims, limiting premium increases, consolidation, etc.); and
- Potential Impact of Destabilization Policy—It is unknown to what extent State Commissioners of Insurance will request adjustments of the 80 percent individual market minimum MLR threshold under the destabilization policy, and unknown whether the justifications provided with these requests will be sufficient to allow the Secretary to grant the adjustments. Thus, it is unknown how these potential adjustments will affect the size of MLR rebates.

b. Methods for Estimating MLR Rebates

The analysis includes estimates that are based on both unadjusted and adjusted MLRs. Information on unadjusted MLRs, which are simply incurred claims divided by earned premiums, is included to assess the impact of the adjustments allowed by the regulation on companies' State-level MLRs.[18]

The adjusted MLRs include three sets of adjustments for: (1) Taxes and fees; (2) credibility adjustments; and (3) quality improvements. First, the adjustments include deductions for Federal and State taxes and licensing and regulatory fees from premiums. These adjustments follow the policy described in the regulation.

Second, they apply estimates of the credibility adjustments for licensed entities that have partially credible experience, that is, issuers with life years that are greater than or equal to 1,000 life years but less than 75,000 life years, based on the 2009 NAIC data.[19] Section D of the preamble describes the rationale and method for calculating credibility adjustments. As stated in this section, there are two components to the credibility adjustment: A base factor that depends on the number of life years a company has in a particular market and State and a factor that depends on average per person deductible for the experience reported in the MLR for a particular market and State. The total credibility adjustment to the MLR equals the base factor times the deductible factor. We used linear interpolation to calculate the base credibility adjustment factor for life years that fall between the values in Table 1 of the preamble.

Third, the adjusted MLRs reported in this analysis also incorporate assumptions about the size of expenses for quality improvement activities, as well as assumptions about other actions that insurers might take to increase their reported MLR. Because the definitions of quality improving activities are new to this rule, the NAIC data collected in 2009 cannot be used to directly estimate how much insurers spent on quality improving activities in 2009 or how much they are expected to spend on these activities in 2011. The closest category in the NAIC data is "cost containment expenses", which averaged approximately 1 percent of premiums in 2009, but the definition of quality improving activities includes many activities that were not included in cost containment expenses. Discussions with industry experts suggest that quality improving activities are likely to account for an average of approximately 3 percent of premium, but there is substantial uncertainty concerning this estimate. Few observers think that quality improving activities will be greater than 5 percent of premium, and few expect that they will be less than 1 percent of premium. In the mid-range estimate, the Department assumes that quality improving activities will account for 3 percent of premium, and uses the 1 percent and 5 percent estimates as the range in a sensitivity analysis.

In addition to uncertainty about the magnitude of quality improving activities, as discussed above, there are many other sources of uncertainty about how insurers will respond to this

[18] As discussed earlier, data for mini-med plans are not broken out separately from other data that issuers reported to NAIC in 2009. Therefore, this regulatory impact analysis does not include separate estimates relating to mini-med plans.

[19] For purposes of this analysis, the Department has not made any assumptions relating to the potential for annual fluctuations in the estimated number of issuers with non-credible and partially credible experience.

interim final regulation, and the effects of these responses on MLRs and rebate amounts.

Given the combination of data imperfections and behavioral uncertainties, the Department has chosen to provide a range of estimates, based on a range of assumptions. A reasonable range of assumptions is that, in the mid-range estimate, MLRs will increase by 1 percentage point relative to the data reported in 2009, with a reasonable bound for this assumption being on one end, no change from the 2009 data, and, on the other end, an assumption that MLRs will increase by 2 percentage points relative to the 2009 data.

Combined with the low-rebate assumption that quality improving activities will increase MLRs by 5 percentage points, the assumption that other behavioral changes may increase MLRs by an additional 2 percentage points will result in estimated MLRs in the low-rebate scenario being 7 percentage points higher than they would be with no allowance for either quality improving activities or other behavioral changes. Consultation with industry experts suggests that this is a reasonable upper bound for the low-rebate assumption as an average for the industry. It is possible that some issuers may invest greater than 5 percent of premium in quality improving activities, or change their behavior in ways that result in a greater than 2 percentage point increase in MLR, but the Department thinks it is unlikely that the changes across the industry for quality improving activities and behavioral changes will be greater than 7 percentage points.

The Department further assumes that issuers with an MLR that is already above the minimum threshold (80 percent in the individual and small group markets, 85 percent in the large group market) will have less incentive to change their behavior in an attempt to increase their MLR than will issuers with lower MLRs that would require them to pay rebates. In the mid-range and low-rebate scenarios, the Department assumes that issuers whose adjusted MLR is above the minimum threshold after an assumed 3 percent increase for quality improving activities will not further increase the MLR with additional quality improving activities or other behavioral changes.

Table VI.4 summarizes the values that are added to the base MLR to adjust for quality improving expenses and other behavioral uncertainties.

Table VI.4
Assumptions used to estimate MLRs under a range of scenarios

Category	Low estimate for rebates *(in percentage points)*	Medium estimate for rebates *(in percentage points)*	High estimate for rebates *(in percentage points)*
Quality improvement activities	+5	+3	+1
Behavioral uncertainties	+2	+1	+0
Total impact on MLRs	+7	+4	+1

NOTE: In the low-range and mid-range scenarios, for issuers whose MLR is above the minimum threshold after 3 percentage points are added for quality improving activities, additional adjustments are not made.

These three sets of adjustments are combined to produce the following formula for estimating companies' adjusted MLRs for the individual, small group, and large group markets by State, rounded to the nearest thousandth decimal place as dictated in the regulation: [20]

Adjusted MLR = (c)/(p − t − f) + (b * d) + u,

p = earned premiums
t = Federal and State taxes
f = licensing and regulatory fees
b = base credibility adjustment factor
d = deductible credibility adjustment factor
u = low, medium, or high assumptions to account for quality improving activities, unknown behavioral changes and data measurement error

We then calculate rebates for a company whose adjusted MLR value in a State falls below the minimum MLR standard in a given market using the following formulas:

Rebates = [(m − a) * (p − t − f)]

where m = minimum MLR standard for a particular market
a = adjusted State MLR for that market

Finally, to estimate impacts for each year covered by the regulation, we assume that the number of issuers, enrollment, and experience are stable over time. This interim final regulation requires that experience be combined across multiple years for issuers that are not fully credible based on a single year of data. Given the assumption that enrollment is stable over time, the Department estimates that issuers which are not fully credible in 2011 will have twice as much enrollment in the combined experience for 2011 and 2012, and three times as much enrollment in the combined 2011 through 2013 data. As a result, the magnitude of the credibility adjustment in 2012 will be smaller than in 2011, and smaller again in 2013. The Department is unable to model the impact of losing the MLR

[20] The text states that in the mid-range assumption, quality improving activities will account for 3 percent of premium. In the formula above, quality improving (and other behavioral change assumptions) are expressed as percentage point increases in the MLR amount. That is, in the mid-range assumption, we assume that quality improvement expenses will add 3 percentage points to the MLR. As a practical matter, because Federal and State taxes and licensing and regulatory fees are quite small, there is virtually no difference between assuming that quality improvement expenses account for 3 percent of premium or assuming that they will add 3 percentage points to the MLR.

credibility adjustment beginning in 2013 if licensed entities report partially credible experience for the current year and the two previous years and have MLRs below the minimum standard in all three years. Rebates are estimated in 2011 through 2013 by applying the projected growth rate in private health insurance premiums from the National Health Expenditures Accounts to the 2009 NAIC adjusted premiums. However, the analysis does simulate the impact of doubling life years in 2012 or tripling life years in 2013 for licensed entities that have non-credible or partially credible experience using a single year of data to estimate how this affects the portion of insurers that are deemed to have credible experience as well as their associated MLR values in those years. Additionally, rebates are estimated in 2011 through 2013 by applying the projected growth rate in private health insurance premiums from the National Health Expenditures Accounts (per privately insured) to the 2009 NAIC adjusted premiums.

c. Estimated Number of Issuers and Individuals Affected By the MLR Rebate Requirements

As shown in Table VI.5, the Department estimates that 68 percent of the licensed entities (State/company combinations) nationwide selling comprehensive major medical insurance in the individual market in 2011 will have fewer than 1,000 enrollees in at least one State, and will be designated as "non-credible" according to the standards of this interim final regulation, 30 percent of licensed entities will be partially credible, and 2 percent will be fully credible.[21] As discussed elsewhere in this preamble, issuers with non-credible experience in a given State, for a given market, during a given MLR reporting year are not required to provide any rebate to enrollees in that State/market because the issuer does not insure a sufficiently large number of lives to yield a statistically valid MLR.

Although the Department estimates that more than two-thirds of licensed entities (State-company combinations) have non-credible 2011 experience for the individual market, and will not be required to provide rebates to their enrollees, there are relatively few enrollees in licensed entities that are non-credible—the non-credible licensed entities account for 68 percent of all entities, but only 1 percent of enrollees and 2 percent of earned premiums in the individual market. Fully credible licensed entities, accounting for only 2 percent of licensed entities, account for 50 percent of enrollees and 49 percent of premiums.

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[21] As described above, insurers with non-credible experience are those with less than 1,000 life years in a particular State market and they are not subject to the rebate requirements. Insurers with partially credible experience are those with 1,000 or more life years but fewer than 75,000 life years. These insurers receive a credibility adjustment to their adjusted MLRs to account for statistical variability that is inherent in smaller blocks of business. Finally, insurers with fully credible experience are those with 75,000 life years or more. Reported MLR values for fully credible insurers are used without a credibility adjustment in a given reporting year to determine their rebate obligation.

Table VI.5. Percent distribution of credible experience, by market and year (2011-2013)

Year	Measure	Individual Market			Small Group Market			Large Group Market		
		Licensed entities	Life years (Millions)	Premiums earned (Millions)	Licensed entities	Life years (Millions)	Premiums earned (Millions)	Licensed entities	Life years (Millions)	Premiums earned (Millions)
2011	Non-credible coverage(%)	68%	1%	2%	40%	0%	0%	32%	0%	0%
	Partially credible coverage(%)	30%	49%	50%	52%	30%	31%	54%	24%	22%
	Fully credible coverage(%)	2%	50%	49%	7%	70%	68%	15%	76%	78%
	Total	1,429	11	$28,540	976	24	$92,142	912	40	$164,337
2012	Non-credible coverage(%)	60%	1%	1%	33%	0%	0%	28%	0%	0%
	Partially credible coverage(%)	36%	34%	34%	54%	17%	18%	48%	12%	11%
	Fully credible coverage(%)	4%	65%	65%	13%	82%	82%	24%	88%	89%
	Total	1,429	11	$29,513	976	24	$95,283	912	40	$169,938
2013	Non-credible coverage(%)	56%	0%	1%	30%	0%	0%	26%	0%	0%
	Partially credible coverage(%)	38%	26%	26%	53%	13%	13%	44%	8%	8%
	Fully credible coverage(%)	7%	73%	73%	17%	87%	87%	30%	92%	92%
	Total	1,429	11	$30,146	976	24	$97,326	912	40	$173,583

Source: 2009 NAIC Health and Life annual statements and A&H Policy Experience Exhibit data.

Notes: The analysis assumes that number of licensed entities, life years, and experience are stable over time. Excludes data for companies that are regulated by non-Health and Life Blank filers.

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Non-credible entities account for a smaller share of total entities, and a smaller share of enrollees and premiums in the small group market than in the individual market, and an even smaller share in the large group market than in the small group market. Conversely, fully credible entities are a larger share of the market in both the small group and large group markets than in the individual market.

As described above, the Department assumes that MLRs and enrollment are constant in 2012 and 2013. As a result of this assumption, the number of non-credible entities declines somewhat in 2012 and again in 2013, because experience is combined across multiple years.

d. Impact of Adjustments on MLRs

As shown in Table VI.6, the estimated average unadjusted MLR among all fully or partially credible entities in the individual market in 2011 is expected to be 79.5 percent—very close, on average, to the 80 percent minimum threshold required under the Affordable Care Act. When adjustments are made for taxes, licensing and regulatory fees, quality improving activities, and assumed behavioral changes, the Department's mid-range estimate is that the average MLR in the individual market in 2011 will be 86.5 percent, with a low-range estimate (where low-range refers to low-range for the rebate estimate) of 87.2 percent, and a high-range rebate estimate of 84.2 percent. The mid-range estimate is approximately 7 percentage points above the unadjusted estimate. Of this difference, 3.5 percentage points results from the assumption made about quality improving and other behavior assumptions (3 percentage points for quality improving activities and 0.5 percentage points for other behavioral assumptions), and 3.6 of the percentage point difference comes from the other adjustments, primarily the exclusion of Federal and State taxes and licensing and regulatory fees from the denominator, as well as the credibility adjustment.

The average adjusted MLR in the small group market in 2011 is estimated to be 90.8 percent for the mid-range estimate, and is estimated at 94.2 percent for the mid-range estimate in the large group market.

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Table VI.6. Average unadjusted and adjusted MLRs all credible filers, by market and year (2011)

Year	Individual Market					Small Group Market					Large Group Market				
	Number of licensed entities	Average Unadjusted MLRs	Average adjusted MLRs			Number of licensed entities	Average Unadjusted MLRs	Average adjusted MLRs			Number of licensed entities	Average Unadjusted MLRs	Average adjusted MLRs		
			Low rebate estimate	Medium rebate estimate	High rebate estimate			Low rebate estimate	Medium rebate estimate	High rebate estimate			Low rebate estimate	Medium rebate estimate	High rebate estimate
2011	461	79.5%	87.2%	86.5%	84.2%	584	85.1%	90.8%	90.8%	88.7%	624	88.6%	94.2%	94.2%	92.2%

Source: 2009 NAIC Health and Life annual statements and A&H Policy Experience Exhibit data.

Notes: Average MLRs are weighted by premiums in the market. Estimates are for insurers that are subject to rebate requirements in a given year. The analysis assumes that number of licensed entities, life years, and experience are stable over time. The variation in the average MLRs across the years is due to doubling life years in 2013 and tripling life years in 2013 for licensed entities that have non-credible or partially credible experience using a single year of data. This simulation affects the pool of insurers that are subject to the rebate requirements in any given year and the credibility adjustment factors they receive for their adjusted MLRs. The low, medium, and high estimates reflect assumptions for the adjusted MLRs that will give a low to high range of rebate etimates. Consequently, the low rebate estimate will have the highest average MLRs and the high rebate estimate will have the lowest average MLRs. Excludes data for companies that are regulated by the California Department of Managed Health Care and other non-Health and Life Blank filers.

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e. Estimated Range of MLR Rebates

As shown in Table VI.7, in the mid-range estimate in the individual market, rebates in 2011 are estimated to be $521 million. The $521 million accounts for approximately 7 percent of premium revenue at companies required to pay a rebate—that is, the average rebate at companies required to pay a rebate in the individual market is estimated to be 7 percent of premium. The $521 million accounts for approximately 2 percent of all premiums written in the individual market. Approximately 3.2 million people, accounting for approximately 30 percent of enrollees in the individual market are estimated to receive a rebate, and the average rebate per person receiving a rebate is estimated as $164.

Over the 2011–2013 period, the Department's mid-range estimate is that rebates will total $1.8 billion in the individual market, $770 million in the small group market, and $440 million in the large group market. Additionally, the Department estimates that 9.9 million enrollees in the individual market, 2.3 million enrollees in the small group market, and 2.7 million enrollees in the large group market will receive rebates over the 2011–2013 period under the mid-range estimate. Summing across all three markets, the mid-range estimate is a total of $3.0 billion in rebates over the 2011–2013 period. The low rebate estimate across all three markets for 2011–2013 is $2.0 billion, and the high rebate estimate is $4.9 billion.

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Table VI.7. Individual Market - Percent of market below minimum MLR threshold and total rebate amounts using unadjusted and adjusted MLR values, by year (2011-2013)

Year	Measure		Adjusted MLRs		
			Low rebate estimate	Medium rebate estimate	High rebate estimate
2011	Licensed entities	N	151	179	218
		% of total	11%	13%	15%
	Life years	N (Millions)	2.2	3.2	5.3
		% of total	21%	30%	50%
	Premiums	$ (Millions)	$5,364	$7,931	$13,329
		% of total	19%	28%	47%
	Rebates	$ (Millions)	$337	$521	$839
		% of total premiums	1%	2%	3%
		% of premiums below	6%	7%	6%
		Rebates per life year below	$150	$164	$157
2012	Licensed entities	N	204	233	277
		% of total	14%	16%	19%
	Life years	N (Millions)	2.4	3.3	5.4
		% of total	22%	31%	51%
	Premiums	$ (Millions)	$5,827	$8,564	$13,938
		% of total	20%	29%	47%
	Rebates	$ (Millions)	$392	$590	$935
		% of total premiums	1%	2%	3%
		% of premiums below	7%	7%	7%
		Rebates per life year below	$167	$177	$172
2013	Licensed entities	N	235	270	310
		% of total	16%	19%	22%
	Life years	N (Millions)	2.4	3.4	5.4
		% of total	23%	32%	51%
	Premiums	$ (Millions)	$6,250	$9,076	$14,563
		% of total	21%	31%	49%
	Rebates	$ (Millions)	$435	$646	$1,009
		% of total premiums	1%	2%	3%
		% of premiums below	7%	7%	7%
		Rebates per life year below	$179	$190	$185

Source: 2009 NAIC Health and Life annual statements and A&H Policy Experience Exhibit data.

Notes: Level estimates are for insurers that are subject to rebate requirements in a given year. "Percent of total" figures, however, reflect the percent of the entire market that is below the minimum MLR threshold for that market. The low, medium, and high estimates reflect assumptions for the adjusted MLRs that will give a low to high range of rebate esitmates. Additionally, premium and rebate totals estimated using 2009 data were inflated to 2011-2013 levels by applying the projected growth in private health insurance premiums from the National Health Expenditure Accounts. Excludes data for companies that are regulated by the California Department of Managed Health Care and other non-Health and Life Blank filers. Dollar values represent projected amounts for each year.

Table VI.8. Small Group Market - Percent of market below minimum MLR threshold and total rebate amounts using unadjusted and adjusted MLR values, by market and year (2011-2013)

Year	Measure		Adjusted MLRs		
			Low rebate estimate	Medium rebate estimate	High rebate estimate
2011	Licensed entities	N	32	54	91
		% of total	3%	6%	9%
	Life years	N (Millions)	0.3	0.7	1.7
		% of total	1%	3%	7%
	Premiums	$ (Millions)	$891	$2,876	$6,526
		% of total	1%	3%	7%
	Rebates	$ (Millions)	$166	$226	$359
		% of total premiums	0%	0%	0%
		% of premiums below	19%	8%	5%
		Rebates per life year below	$587	$312	$216
2012	Licensed entities	N	55	80	129
		% of total	6%	8%	13%
	Life years	N (Millions)	0.3	0.8	1.8
		% of total	1%	3%	7%
	Premiums	$ (Millions)	$1,043	$3,221	$7,112
		% of total	1%	3%	7%
	Rebates	$ (Millions)	$188	$260	$411
		% of total premiums	0%	0%	0%
		% of premiums below	18%	8%	6%
		Rebates per life year below	$595	$333	$232
2013	Licensed entities	N	70	95	147
		% of total	7%	10%	15%
	Life years	N (Millions)	0.3	0.8	1.9
		% of total	1%	3%	8%
	Premiums	$ (Millions)	$1,236	$3,597	$7,799
		% of total	1%	4%	8%
	Rebates	$ (Millions)	$201	$281	$444
		% of total premiums	0%	0%	0%
		% of premiums below	16%	8%	6%
		Rebates per life year below	$580	$335	$236

Source: 2009 NAIC Health and Life annual statements and A&H Policy Experience Exhibit data.

Notes: Level estimates are for issuers that are subject to rebate requirements in a given year. "Percent of total" figures, however, reflect the percent of the entire market that is below the minimum MLR threshold for that market. The low, medium, and high estimates reflect assumptions for the adjusted MLRs that will give a low to high range of rebate esitmates. Additionally, premium and rebate totals estimated using 2009 data were inflated to 2011-2013 levels by applying the projected growth in private health insurance premiums from the National Health Expenditure Accounts. Excludes data for companies that are regulated by the California Department of Managed Health Care and other non-Health and Life Blank filers. Dollar values represent projected amounts for each year.

Table VI.9. Large Group Market - Percent of market below minimum MLR threshold and total rebate amounts using unadjusted and adjusted MLR values, by market and year (2011-2013)

Year	Measure		Adjusted MLRs		
			Low rebate estimate	Medium rebate estimate	High rebate estimate
2011	Licensed entities	N	31	48	94
		% of total	3%	5%	10%
	Life years	N (Millions)	0.3	0.7	2.0
		% of total	1%	2%	5%
	Premiums	$ (Millions)	$831	$2,274	$6,765
		% of total	1%	1%	4%
	Rebates	$ (Millions)	$84	$121	$258
		% of total premiums	0%	0%	0%
		% of premiums below	10%	5%	4%
		Rebates per life year below	$312	$166	$127
2012	Licensed entities	N	41	72	116
		% of total	4%	8%	13%
	Life years	N (Millions)	0.3	1.0	2.2
		% of total	1%	2%	5%
	Premiums	$ (Millions)	$1,005	$3,176	$7,593
		% of total	1%	2%	4%
	Rebates	$ (Millions)	$100	$150	$309
		% of total premiums	0%	0%	0%
		% of premiums below	10%	5%	4%
		Rebates per life year below	$302	$156	$141
2013	Licensed entities	N	50	82	131
		% of total	5%	9%	14%
	Life years	N (Millions)	0.3	1.0	2.3
		% of total	1%	3%	6%
	Premiums	$ (Millions)	$1,096	$3,599	$8,257
		% of total	1%	2%	5%
	Rebates	$ (Millions)	$110	$165	$337
		% of total premiums	0%	0%	0%
		% of premiums below	10%	5%	4%
		Rebates per life year below	$321	$160	$148

Source: 2009 NAIC Health and Life annual statements and A&H Policy Experience Exhibit data.

Notes: Level estimates are for insurers that are subject to rebate requirements in a given year. "Percent of total" figures, however, reflect the percent of the entire market that is below the minimum MLR threshold for that market. The low, medium, and high estimates reflect assumptions for the adjusted MLRs that will give a low to high range of rebate esitmates. Additionally, premium and rebate totals estimated using 2009 data were inflated to 2011-2013 levels by applying the projected growth in private health insurance premiums from the National Health Expenditure Accounts. Excludes data for companies that are regulated by the California Department of Managed Health Care and other non-Health and Life Blank filers. Dollar values represent projected amounts for each year.

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In the low-rebate estimate, total rebates in the individual market are estimated at $337 million, with 21 percent of enrollees in the individual market estimated to receive a rebate, and in the high-rebate scenario, $839 million, with 50 percent of enrollees.[22]

Estimated rebates in the small group market range from $166 million to $359 million, with a mid-range estimate of $226 million (Table VI.8), and from $84 million to $258 million in the large group market, with a mid-range estimate of $121 million. In both the small group and large group (Table VI.9) markets a small fraction of enrollees are estimated to receive rebates—in the mid-range scenario, 3 percent in the small group market and 2 percent in large group.

f. Potential Impact of State Destabilization Adjustment Requests on MLR Rebates

Section 2718(b)(1)(A)(ii) provides that the Secretary may adjust the 80 percent level with respect to the individual market of a State "if the Secretary determines that the application of such 80 percent may destabilize the individual market in such State." Subpart C of this interim final regulation implements this provision by setting forth who may apply, how to apply, the criteria used in assessing an application, and how the adjustment would be made. It proposes that States apply for a specific adjustment to the individual market threshold that would be approved only if, according to information provided to the Secretary and assessed by the proposed criteria, there is a reasonable likelihood that market destabilization would occur in the absence of such an adjustment.

Prior to the publication of this interim final regulation, several States have indicated their interest in an adjustment to the MLR threshold for their individual markets. However, this interest was expressed before the NAIC recommendations and proposed rules that may lessen the need for such an adjustment. For example, the credibility adjustments, newer plan adjustments, and treatment of Federal taxes may lessen what they had projected would be the impact of the MLR rules. In addition, as described earlier, the behavioral response of issuers to the proposed rules is uncertain. As such, the Department has not produced quantitative estimates of the potential impact of this authority.

However, if this authority is exercised, by definition, there would be fewer issuers and enrollees to whom rebates in the individual market apply. There would also be fewer benefits as well as costs than previously described. While the benefit of transparency would persist regardless of whether a rebate is made, issuers may have less of an incentive to improve quality or benefits if the MLR threshold were lower than 80 percent. At the same time, the goal of the adjustment is prevent disruption, so individuals in States whose MLR threshold has been adjusted would have more health insurance options than they otherwise would.

7. Estimated Administrative Costs Related to MLR Provisions

As stated earlier in this preamble, this interim final regulation implements the reporting requirements of section 2718(a), describing the type of information that is to be included in the report to the Secretary and made available to consumers, as well as the rebate calculation, payment and enforcement provisions of section 2718(b). The Department has quantified the primary sources of start-up costs that issuers in the individual and group markets will incur to bring themselves into compliance with this interim final regulation, as well as the ongoing annual costs that they will incur related to these requirements. These costs and the methodology used to estimate them are discussed below and in the Technical Appendix available at *http://www.hhs.gov/ociio/regulations/index.html.* Additional detail on these estimates can be found in the Paperwork Reduction Act section of this preamble and we welcome comment on them.

a. Methodology and Assumptions for Estimating Administrative Costs

The Affordable Care Act MLR reporting requirements will affect health insurance issuers offering coverage in the individual and group markets, including both the small group and large group markets. As discussed earlier, most of the affected issuers currently report similar data to the NAIC as part of their annual financial statements. However, this interim final regulation includes requirements related to calculating some additional data elements, and allocating data by company, State and market.

As discussed earlier in this impact analysis, in order to assess the potential administrative burden relating to the requirements in this interim final regulation, the Department consulted with the NAIC and an industry expert to gain insight into the tasks and level of effort required. Based on these discussions, the Department estimates that issuers will incur one-time start-up costs associated with developing teams to review the requirements in this interim final regulation, and developing processes for capturing the necessary data (*e.g.*, automating systems; writing new policies for tracking expenses in the general ledger; developing methodologies for allocating expenses by State, company and market; etc.). The Department estimates that issuers will also incur ongoing annual costs relating to data collection, populating the MLR reporting forms, conducting a final internal review, submitting the reports to the Secretary, internal audit, record retention, and preparing and mailing rebate notifications/payments (where appropriate).

The Department anticipates that the level of effort relating to these activities will vary depending on the scope of an issuer's operations. Each issuer's estimated reporting burden is likely to be affected by a variety of factors that will affect the level of complexity of its filing—including the number of markets in which it operates (*e.g.*, individual, small group, large group), the number of States and licensed entities through which it offers coverage, the degree to which it currently captures relevant data at the State/company/market level, firm size (*e.g.*, claims, premiums, covered lives), whether it offers other types of A&H coverage, whether it is a Health Blank or Life Blank filer, and whether it is a subsidiary of a larger carrier. The assumptions used by the Department to estimate the administrative burden of reporting data needed to calculate MLRs, and information about the uncertainties associated with these assumptions is provided in the Technical Appendix, available at *http://www.hhs.gov/ociio/regulations/index.html.*

b. Estimated Costs Related to MLR Reporting

For each MLR reporting year (defined as a calendar year for purposes of this interim final regulation), issuers offering coverage in the individual and group markets must submit a report to the Secretary by June 1 of the following year that complies with the requirements of this interim final rule on a form and in the manner prescribed by the Secretary. For purposes of these impact estimates, the Department assumes that there will be a single MLR data submission for purposes of both the NAIC annual report and reporting to the Secretary, and that this report would include data

[22] The average rebate per person receiving a rebate is slightly lower in the high rebate scenario than in the mid-range scenario because in the high rebate scenario there are a larger number of issuers and enrollees with MLRs that are close to the 80 percent threshold, and average rebates for these enrollees are relatively low.

relating to both the amounts expended on reimbursement for clinical services, activities that improve quality and other non-clinical costs, as well as information relating to rebates.

The estimated total number of MLR data reports that issuers subject to the MLR reporting requirements will be required to submit to the Secretary under the provisions of this interim final regulation is 3,317. This is an upper-bound estimate, assuming that all issuers offering coverage in both the individual and small group markets will be submitting separate reports to the Secretary for this coverage. However, as discussed elsewhere in this preamble, the provisions of this interim final regulation allow issuers offering coverage in States requiring that the individual and small group markets be combined to submit consolidated reports for these two markets.

Table VI.10 shows that the Department estimates that issuers will incur one-time costs relating to the MLR reporting requirements in this interim final rule of approximately $75,018 to $151,507 per issuer on average, and annual ongoing costs of about $17,261 to $32,259 per issuer annually thereafter.

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Table VI.10
Estimated Administrative Costs Related to Medical Loss Ratio (MLR) Reporting Requirements

Description	Total Number of Issuers	Total Number of Reports	Estimated Total Hours	Estimated Average Cost Per Hour	Estimated Total Cost	Estimated Average Cost Per Issuer	Estimated Average Cost Per Report
LOW RANGE ASSUMPTIONS							
One-Time Costs	442	3,317	501,640	$66.10	$33,157,861	$75,018	$9,996
Ongoing Costs	442	3,317	150,817	$50.59	$7,629,237	$17,261	$2,300
Total Year One Costs	442	3,317	652,457	$62.51	$40,787,097	$92,279	$12,296
MID RANGE ASSUMPTIONS							
One-Time Costs	442	3,317	725,497	$66.31	$48,109,870	$108,846	$14,504
Ongoing Costs	442	3,317	211,214	$50.59	$10,684,490	$24,173	$3,221
Total Year One Costs	442	3,317	936,711	$62.77	$58,794,360	$133,019	$17,725
HIGH RANGE ASSUMPTIONS							
One-Time Costs	442	3,317	1,007,078	$66.50	$66,965,900	$151,507	$20,189
Ongoing Costs	442	3,317	281,863	$50.59	$14,258,342	$32,259	$4,299
Total Year One Costs	442	3,317	1,288,940	$63.02	$81,224,242	$183,765	$24,487

Notes: Issuers represents companies (e.g., NAIC company codes). Total number of reports represents the estimated total number of MLR reports that will be submitted to the Secretary (e.g., company / State / market combinations). Total issuers represents 2009 NAIC Health and Life Blank filers with valid data. Excludes data for companies that are regulated by the California Department of Managed Health Care and other non-Health and Life Blank filers. Total administrative cost includes estimated costs relating to the MLR reporting, record retention, and rebate payment requirements. Estimated costs are stated in 2010 dollars.
Sources: 2009 NAIC Health and Life Annual Statements and A&H Policy Experience Exhibit data.

c. Estimated Costs Related to MLR Record Retention Requirements

Consistent with the assumptions discussed above, MLR record retention costs are assumed to be relatively negligible, since issuers already retain similar data for State audits. Table VI.11 shows that the Department estimates that issuers will incur annual ongoing costs relating to the MLR reporting requirements in this interim final rule of approximately $17 to $29 per issuer on average.

Table VI.11
Estimated Administrative Costs Related to Medical Loss Ratio (MLR) Record Retention Requirements

Description	Total Number of Issuers	Total Number of Reports	Estimated Total Hours	Estimated Average Cost Per Hour	Estimated Total Cost	Estimated Average Cost Per Issuer	Estimated Average Cost Per Report
LOW RANGE ASSUMPTIONS							
Ongoing Costs	442	3,317	200	$38.34	$7,668	$17	$2
MID RANGE ASSUMPTIONS							
Ongoing Costs	442	3,317	200	$50.22	$10,045	$23	$3
HIGH RANGE ASSUMPTIONS							
Ongoing Costs	442	3,317	300	$42.45	$12,734	$29	$4

Notes: Issuers represents companies (e.g., NAIC company codes). Total number of reports represents the estimated total number of MLR reports that will be submitted to the Secretary (e.g., company / State / market combinations). Total issuers represents 2009 NAIC Health and Life Blank filers with valid data. Excludes data for companies that are regulated by the California Department of Managed Health Care and other non-Health and Life Blank filers. Total administrative cost includes estimated costs relating to the MLR reporting, record retention, and rebate payment requirements. Estimated costs are stated in 2010 dollars.
Sources: 2009 NAIC Health and Life Annual Statements and A&H Policy Experience Exhibit data.

d. Estimated Costs Related to MLR Rebate Notifications and Payments

Consistent with the assumptions discussed above, rebate notification and payment costs are expected to be relatively negligible on a per-notification and per-check basis, in particular because issuers have the option of paying rebates through premium withholds. However, the estimated total costs relating to rebate notifications and payments reflect the relatively large numbers of enrollees that could potentially receive rebates during any given year, and will be sensitive to annual fluctuations in the number of licensed entities that owe rebates for a given State and market.

Table VI.12 shows that the Department estimates that in 2011, approximately 60 to 119 issuers (companies) will pay rebates for at least one licensed entity/State/market combination, and that annual ongoing costs relating to the MLR rebate payment and notification requirements in this interim final rule will be approximately $58,010 to $122,891 per affected issuer during that year on average. This number will be sensitive to annual fluctuations in the number of licensed entities that owe rebates for a given State and market.

Table VI.12
Estimated Administrative Costs Related to Medical Loss Ratio (MLR) Rebate Notification and Payment Requirements

Description	Estimated Total Number of Affected Issuers	Estimated Total Number of Notifi-cations or Checks	Estimated Total Hours	Estimated Average Labor Cost Per Hour	Estimated Mailing and Supplies Cost Per Notifi-cation or Check	Estimated Total Cost	Estimated Average Cost Per Affected Issuer	Estimated Average Cost Per Notifi-cation or Check
LOW RANGE ASSUMPTIONS								
Notifi-cations	60	2,796,623	46,610	$28.30	$0.49	$2,689,296	$44,822	$1
Checks	18	838,987	20,975	$35.73	$0.05	$791,311	$43,962	$1
Total Ongoing Costs	60	2,796,623	67,585	$30.60	$0.51	$3,480,606	$58,010	$1
MID RANGE ASSUMPTIONS								
Notifi-cations	92	4,634,379	77,240	$28.30	$0.49	$4,456,523	$48,440	$1
Checks	46	2,317,189	57,930	$35.73	$0.05	$2,185,512	$47,511	$1
Total Ongoing Costs	92	4,634,379	135,169	$31.48	$0.51	$6,642,035	$72,196	$1
HIGH RANGE ASSUMPTIONS								
Notifi-cations	119	9,016,911	150,282	$28.30	$0.49	$8,670,865	$72,864	$1
Checks	83	6,311,838	157,796	$35.73	$0.05	$5,953,160	$71,467	$1
Total Ongoing Costs	119	9,016,911	308,078	$32.10	$0.53	$14,624,026	$122,891	$2

Notes: Affected issuers = the estimated total number of companies (e.g., NAIC company codes) paying rebates or mailing rebate checks for at least one licensed entity / State / market in 2011. Total issuers represents 2009 NAIC Health and Life Blank filers with valid data. Excludes data for companies that are regulated by the California Department of Managed Health Care and other non-Health and Life Blank filers. Estimated costs are stated in 2010 dollars.
Sources: 2009 NAIC Health and Life Annual Statements and A&H Policy Experience Exhibit data.

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C. Regulatory Alternatives

Under the Executive Order, the Department is required to consider alternatives to issuing regulations and alternative regulatory approaches. The Department considers a variety of regulatory alternative below.

1. Credibility Adjustment

Section 2718(c) requires the NAIC to develop uniform definitions and calculation methodologies subject to certification by the Secretary. This section directs the NAIC to take into account the special circumstances of smaller plans. In response to this direction, the NAIC recommended a credibility adjustment for smaller plans. After considering the NAIC's recommendation on credibility adjustments, HHS has decided to certify and adopt it in full.

One alternative to the credibility adjustment in this interim final regulation would be to not make any adjustment for credibility, and to require smaller plans to make rebate payments on the same terms as larger plans. If the Department had not adopted a credibility adjustment, the estimated mid-range rebate in the individual market in 2011 would be approximately $682 million, or approximately $161 million larger than the estimate shown in Table VI.7 including the credibility adjustment. The mid-range estimated rebate in the small group market would be $292 million, $66 million larger than the estimate in Table VI.8, and the mid-range estimate for the large group market would be $178 million, $57 million larger than the estimate in Table VI.9. As described elsewhere in this preamble, the Department has concluded that the credibility adjustment as proposed will best balance the goals of providing value to consumers assuring that issuers with relatively few subscribers will be able to function effectively.

2. Federal Taxes

As described elsewhere in this preamble, after considering the NAIC's recommendation on treatment of Federal taxes in the denominator of the MLR calculation, HHS has decided to certify and adopt it in full. An alternative would have been to adopt a narrower definition of the Federal taxes to be excluded. If the Department had decided that payroll and Social Security taxes should be included in the denominator, rather than excluded from the denominator as provided in this interim final regulation, the estimated rebate in the mid-range scenario in the individual market would have been $552 million, or $31 million higher than in the estimate shown in Table VI.7. Similarly, the effect of this regulatory alternative in the small group and large group markets would have been to increase the estimated rebate by $9 million in each of these two markets. As described elsewhere in this preamble, the Department has concluded that excluding payroll taxes and Social Security taxes from the denominator balances the legitimate needs of insurers with the needs of consumers.

3. Quality Improving Activities

Section 2718(a)(2) of the PHS Act requires health insurance issuers to submit an annual report to the Secretary concerning the percent of total premium revenue that is spent on activities that improve health care quality, and Section 2718(c) of the PHS Act directs the NAIC, subject to certification by the Secretary, to establish uniform definitions of activities that improve health care quality.

As discussed elsewhere in this preamble, the NAIC recommended definitions of quality improving activities that are consistent with the categories set forth in Section 2717 of the PHS Act. After considering the NAIC's recommendation on the definition of quality improving activities, HHS has decided to certify and adopt it in full. As discussed elsewhere in this preamble, potential alternatives would have been to adopt narrower or broader definitions of quality improving activities. These distinctions can be made based on the criteria for selecting quality improving activities and/or the specific types of activities included in the definition.

This interim final regulation defines quality-improving activities as being grounded in evidence-based medicine, designed to improve the quality of care received by an enrollee, and capable of being objectively measured and producing verifiable results and achievements. A narrower definition might include only evidence-based quality improving initiatives, while excluding activities that have not been demonstrated to improve quality. Similarly, a narrower definition would not allow for inclusion of future innovations before data are available demonstrating their effectiveness.

Conversely, a broader definition might allow additional types of administrative expenses to be counted as activities that improve quality—such as network fees associated with third party provider networks or costs associated with converting International Classification of Disease (ICD) code sets from ICD–9 to ICD–10. As discussed elsewhere in this preamble, while the Department agrees that certain administrative expenses should not be counted as quality improving, some traditional administrative activities can qualify as quality improving if they meet the criteria set forth in this interim final regulation.

The Department does not have data available to estimate the effects of alternative definitions of quality improving activities on MLRs, although it should be clear that if a broader definition of quality improving activities had been adopted that estimated rebates would be smaller, and if a narrowed definition had been adopted, estimated rebates would be larger.

4. Level of Aggregation

As discussed elsewhere in this preamble, the NAIC could have recommended that MLRs be aggregated to the national level for multi-State companies, rather than be calculated separately in each State. If MLRs were calculated at the national level for multi-State companies, estimated rebates in the individual market in the mid-range scenario would have been $461 in 2011, or $60 million less than the estimates provided in Table VI.7. The estimated effects of national-level aggregation on the small group and large group markets are proportionally larger: in the small group market, estimated rebates in the mid-range scenario fall from $226 million to $97 million in 2011, and in the large group market, from $121 to $42 million.

Requiring issuers to aggregate their individual, small group and large group experience at the national level, rather than by State could reduce the administrative burden associated with these requirements because nearly a third of the issuers that would be affected by the requirements of this interim final regulation offer coverage in multiple States. For example, under the Department's mid-range estimates, the estimated number of MLR reports to the Secretary would decrease by 29 percent (from 3,317 to 972), and the estimated one-time and annual ongoing costs associated with MLR reporting would decrease by approximately 49 percent compared with what is shown in Table VI.10.

Because insurance is regulated primarily at the State level, and because it is important for consumers in each State to receive value for their insurance premium, the Department has concluded that MLRs should be calculated at the issuer/market/State level, rather than aggregating results to

the national level. After considering the NAIC's recommendation on the level of aggregation for purposes of MLR reporting and rebate calculation, HHS has decided to certify and adopt it in full.

We welcome comments on the likely costs and benefits of this rule as presented, on alternatives that would improve the consumer and small business purchaser information to be provided, and on our quantitative estimates of burden.

D. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires agencies that issue a regulation to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. The RFA generally defines a "small entity" as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a nonprofit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000 (States and individuals are not included in the definition of "small entity"). HHS uses as its measure of significant economic impact on a substantial number of small entities a change in revenues of more than 3 to 5 percent.

The Regulatory Flexibility Act only requires an analysis to be conducted for those final rules for which a Notice of Proposed Rule Making was required. Accordingly, we have determined that a regulatory flexibility analysis is not required for this interim final rule. However, the Department has considered the likely impact of this interim final rule on small entities.

As discussed in the Web Portal interim final rule (75 FR 24481), HHS examined the health insurance industry in depth in the Regulatory Impact Analysis we prepared for the proposed rule on establishment of the Medicare Advantage program (69 FR 46866, August 3, 2004). In that analysis the Department determined that there were few if any insurance firms underwriting comprehensive health insurance policies (in contrast, for example, to travel insurance policies or dental discount policies) that fell below the size thresholds for "small" business established by the SBA (currently $7 million in annual receipts for health insurers).[23]

The Department has used the data set created from 2009 NAIC Health and Life Blank annual financial statement data to develop an updated estimate of the number of small entities that offer comprehensive major medical coverage in the individual and small group markets, and are therefore subject to the MLR reporting requirements. For purposes of this analysis, the Department is using total Accident and Health (A&H) earned premiums as a proxy for annual receipts. These estimates may overstate the actual number of small health insurance issuers that would be affected, since they do not include receipts from these companies' other lines of business.

The Department estimates that there are 28 small entities with less than $7 million in A&H earned premiums that offer individual or group comprehensive major medical coverage, and would therefore be subject to the requirements of this interim final regulation. These small entities account for 6 percent of the estimated 442 total issuers that the Department estimates will be affected by these requirements. The Department estimates that 86 percent of these small issuers are subsidiaries of larger carriers, 75 percent only offer coverage in a single State, 68 percent only offer individual or group comprehensive coverage in a single market, 46 percent also offer other types of A&H coverage, and 29 percent are Life Blank filers.

As discussed elsewhere in this preamble, Section 2718(c) of the PHS Act directed the NAIC to take the special circumstances of small plans into account in developing uniform definitions and calculation methodologies relating to the data being reported to the Secretary in Section 2718(a). This has been accomplished through the credibility adjustment, which provides that issuers with non-credible experience in a given market, based on definitions established by the NAIC, are not required to provide any rebate to enrollees in that State/market because the issuer does not insure a sufficiently large number of lives to yield a statistically valid MLR. Additionally, issuers with partially credible experience in a given State/market are allowed to make a credibility adjustment to their MLR during that year.

The Department estimates that the 28 small issuers that are subject to the requirements of this interim final regulation offer individual and group coverage through 73 licensed entities (company/State combinations). For example, the Department estimates that all of the total 85 company/State/market combinations offered by small entities will be either non-credible (92 percent) or partially credible (8 percent) in 2011.

The Department estimates that small entities will owe approximately $435,000 to $656,000 in rebates in 2011, accounting for 0.5 to 0.7 percent of their total A&H premiums during that year. By comparison, the Department estimates that small entities will owe approximately $1.8 to $3.0 million in rebates in 2013, accounting for 1.9 to 2.9 percent of their total A&H premiums during that year.

Additionally, the Department estimates that small entities will spend $44,656 to $62,518 per issuer in one-time costs (accounting for 1.3 to 1.9 percent of their total A&H premiums), and $10,240 to $14,031 per issuer in annual ongoing costs (accounting for 0.3 to 0.4 percent of their total A&H premiums) related to the MLR reporting, record retention, and rebate payment and notification requirements.

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[23] "Table of Size Standards Matched To North American Industry Classification System Codes," effective November 5, 2010, U.S. Small Business Administration, available at *http://www.sba.gov*.

Table VI.13
Estimated Administrative Costs Related to Medical Loss Ratio (MLR) Rebate Notification and Payment Requirements By Firm Size, 2011

Firm Size		Total Number of Issuers	Total Number of Licensed Entities	Total Number of Reports	Number of Issuers Paying Rebates	Estimated Average Total Administrative Cost Per Issuer	
						One-Time	Ongoing
LOW RANGE ASSUMPTIONS							
	Small Entities (<$7 million in A&H Premiums)	28	73	85	1	$44,656	$10,240
	All Other Issuers	414	1,929	3,232	59	$77,071	$30,910
	Estimated Total Number of Issuers Subject to the MLR Reporting Requirements	442	2,002	3,317	60	$75,018	$29,601
MID RANGE ASSUMPTIONS							
	Small Entities (<$7 million in A&H Premiums)	28	73	85	1	$53,145	$12,135
	All Other Issuers	100	1,929	3,232	91	$112,613	$41,055
	Estimated Total Number of Issuers Subject to the MLR Reporting Requirements	442	2,002	3,317	92	$108,846	$39,223
HIGH RANGE ASSUMPTIONS							
	Small Entities (<$7 million in A&H Premiums)	28	73	85	1	$62,518	$14,031
	All Other Issuers	100	1,929	3,232	118	$157,525	$52,828
	Estimated Total Number of Issuers Subject to the MLR Reporting Requirements	442	2,002	3,317	119	$151,507	$50,370

Notes: Issuers represents companies (e.g., NAIC company codes). Licensed Entities represents company / State combinations. Total issuers represents 2009 NAIC Health and Life Blank filers with valid data. Excludes data for companies that are regulated by the California Department of Managed Health Care and other non-Health and Life Blank filers. Total administrative cost includes estimated costs relating to the MLR reporting, record retention, and rebate payment requirements. Estimate costs are stated in 2010 dollars.

Sources: 2009 NAIC Health and Life Annual Statements and A&H Policy Experience Exhibit data.

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As discussed earlier, the Department believes that these estimates overstate the number of small entities that will be affected by the requirements in this interim final regulation, as well as the relative impact of these requirements on these entities because the Department has based its analysis on issuers' total A&H earned premiums (rather than their total annual receipts). Therefore, the Secretary certifies that these interim final regulations will not have significant impact on a substantial number of small entities. In addition, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a rule may have a significant economic impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. This interim final rule would not affect small rural hospitals. Therefore, the Secretary has determined that this rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

E. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits before issuing any rule that includes a Federal mandate that could result in expenditure in any one year by State, local or tribal governments, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. In 2010, that threshold level is approximately $135 million.

UMRA does not address the total cost of a rule. Rather, it focuses on certain categories of cost, mainly those "Federal mandate" costs resulting from: (1) Imposing enforceable duties on State, local, or tribal governments, or on the private sector; or (2) increasing the stringency of conditions in, or decreasing the funding of, State, local, or tribal governments under entitlement programs.

This interim final regulation is not subject to the Unfunded Mandates Reform Act, because it is being issued as an interim final regulation. However, consistent with policy embodied in UMRA, this interim final regulation has been designed to be the least burdensome alternative for State, local and tribal governments, and the private sector while achieving the objectives of the Affordable Care Act.

This interim final regulation contains MLR reporting, data retention and rebate notification and payment requirements for private sector firms (for example, health insurance issuers offering coverage in the individual and group markets), but these will not cost more than the approximately $32 million to $68 million in one-time administrative costs, and $11 million to $29 million in annual ongoing administrative costs related to complying with the requirements of this interim final regulation that we have estimated. This interim final rule also contains requirements related to rebates paid by issuers to enrollees for coverage offered in the individual, small group, and large group markets that does not meet the minimum MLR standards. The Department's estimates that approximately 2.8 million to 9.6 million enrollees could receive $0.6 to $1.8 billion in rebates during any individual year between 2011 and 2013. It includes no mandates on State, local, or tribal governments. Under Section 2718 of the Affordable Care Act, issuers are required to submit MLR data reports directly to the Secretary. States may voluntarily choose to review the MLR data that issuers submit through the NAIC supplemental blank; develop or modify their regulations relating to MLR definitions and calculation methodologies, reporting and rebates; request adjustments of the 80 percent individual market minimum MLR threshold under the destabilization policy; or modify their audit methodologies to include a more comprehensive review of MLR data reported under Section 2718. However, if they choose not to do so, the Secretary has direct enforcement authority relating to this provision. Thus, the law and this regulation do not impose an unfunded mandate on States.

F. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. In the Department's view, while this interim final rule does not impose substantial direct requirement costs on State and local governments, this interim final regulation has Federalism implications due to direct effects on the distribution of power and responsibilities among the State and Federal governments relating to determining and enforcing minimum MLR standards, reporting and rebate requirements relating to coverage that State-licensed health insurance issuers offer in the individual and group markets.

However, the Department anticipates that the Federalism implications (if any) are substantially mitigated because the Affordable Care Act does not provide any role for the States in terms of receiving or analyzing the data or enforcing the requirements of Section 2718 of the PHS Act. The enforcement provisions of this interim final rule state that the Secretary has enforcement authority and does not require the States to do anything. The States already require issuers to report the NAIC Annual Statement (Blanks) and audit those data. The regulation does contemplate that if a State includes MLR in its audit of issuers, the Secretary has the discretion to accept that audit. But, again, the regulation does not require the States to do anything and, in fact, it is not clear that we even have statutory authority to require them to do anything with respect to the MLR. It is HHS' responsibility to do the audits and enforce the statutory requirements.

States may continue to apply State law requirements except to the extent that such requirements prevent the application of the Affordable Care Act requirements that are the subject of this rulemaking. State insurance laws that are more stringent than the Federal requirements are unlikely to "prevent the application of" the Affordable Care Act, and be preempted. Additionally, States have an opportunity to request adjustments of the 80 percent individual market minimum MLR threshold under the destabilization policy, subject to the Secretary's approval. Accordingly, States have significant latitude to impose requirements on health with respect to health insurance issuers, insurance issuers that are more restrictive than the Federal law.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have Federalism implications or limit the policy making discretion of the States, the Department has engaged in efforts to consult with and work cooperatively with affected States, including participating in conference calls with and attending conferences of the National Association of Insurance Commissioners, and consulting with State insurance officials on an individual basis.

Throughout the process of developing this interim final regulation, to the extent feasible within the specific preemption provisions of HIPAA as it applies to the Affordable Care Act, the Department has attempted to balance the States' interests in regulating health insurance issuers, and Congress' intent to provide uniform minimum protections to consumers in every State.

By doing so, it is the Department's view that we have complied with the requirements of Executive Order 13132. Pursuant to the requirements set forth in section 8(a) of Executive Order 13132, and by the signatures affixed to this regulation, the Department certifies that the Office of Consumer Information and Insurance Oversight has complied with the requirements of Executive Order 13132 for the attached interim final regulation in a meaningful and timely manner.

G. Congressional Review Act

This interim final regulation is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and have been transmitted to Congress and the Comptroller General for review.

In accordance with the provisions of Executive Order 12866, this interim final rule was reviewed by the Office of Management and Budget.

List of Subjects in 45 CFR Part 158

Administrative practice and procedure, Claims, Health care, Health insurance, Health plans, Penalties, Reporting and recordkeeping requirements.

■ For the reasons stated in the preamble, the Department of Health and Human Services amends 45 CFR subtitle A, subchapter B, by adding a new part 158 to read as follows:

PART 158—ISSUER USE OF PREMIUM REVENUE: REPORTING AND REBATE REQUIREMENTS

Sec.
158.101 Basis and scope.
158.102 Applicability.
158.103 Definitions.

Subpart A—Disclosure and Reporting

158.110 Reporting requirements related to premiums and expenditures.
158.120 Aggregate reporting.
158.121 Newer experience.
158.130 Premium revenue.
158.140 Reimbursement for clinical services provided to enrollees.
158.150 Activities that improve health care quality.
158.151 Expenditures related to Health Information Technology and meaningful use requirements.
158.160 Other non-claims costs.
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Subpart B—Calculating and Providing the Rebate

158.210 Minimum medical loss ratio.
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158.220 Aggregation of data in calculating an issuer's medical loss ratio.
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158.241 Form of rebate.
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158.270 Effect of rebate payments on solvency.

Subpart C—Potential Adjustment to the MLR for a State's Individual Market

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158.330 Criteria for assessing request for adjustment to the medical loss ratio.
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158.345 Determination on a State's request for adjustment to the medical loss ratio.
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Subpart D—HHS Enforcement

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Subpart E—Additional Requirements on Issuers

158.501 Access to facilities and records.
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Subpart F—Federal Civil Penalties

158.601 General rule regarding the imposition of civil penalties.
158.602 Basis for imposing civil penalties.
158.603 Notice to responsible entities.
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158.606 Amount of penalty—general.
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158.608 Determining the amount of the penalty—mitigating circumstances.
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158.610 Determining the amount of the penalty—other matters as justice may require.
158.611 Settlement authority.
158.612 Limitations on penalties.
158.613 Notice of proposed penalty.
158.614 Appeal of proposed penalty.
158.615 Failure to request a hearing.

Authority: Section 2718 of the Public Health Service Act (42 U.S.C. 300gg–18, as amended.)

§ 158.101 Basis and scope.

(a) *Basis.* This Part implements section 2718 of the Public Health Service Act (PHS Act).

(b) *Scope.* Subpart A of this Part establishes the requirements for health insurance issuers ("issuers") offering group or individual health insurance coverage to report information concerning premium revenues and the use of such premium revenues for clinical services provided to enrollees, activities that improve health care quality, and all other non-claims costs. Subpart B describes how this information will be used to determine, with respect to each medical loss ratio (MLR) reporting year, whether the ratio of the amount of adjusted premium revenue expended by the issuer on permitted costs to the total amount of adjusted premium revenue (MLR) meets or exceeds the percentages established by section 2718(b)(1) of the PHS Act. Subpart B also addresses requirements for calculating any rebate amounts that may be due in the event an issuer does not meet the applicable MLR standard. Subpart C implements the provision of section 2718(b)(A)(ii) of the PHS Act allowing the Secretary to adjust the MLR standard for the individual market in a State if requiring issuers to meet that standard may destabilize the individual market. Subparts D through F provide for enforcement of this part, including requirements for issuers to maintain records and civil monetary penalties that may be assessed against issuers who violate the requirements of this Part.

§ 158.102 Applicability.

General requirements. The requirements of this Part apply to issuers offering group or individual health insurance coverage, including a grandfathered health plan as defined in § 147.140 of this subpart.

§ 158.103 Definitions.

For the purposes of this Part, the following definitions apply unless specified otherwise.

Contract reserves means reserves that are established by an issuer which, due

to the gross premium pricing structure at issue, account for the value of the future benefits that at any time exceeds the value of any appropriate future valuation of net premiums at that time. Contract reserves must not include premium deficiency reserves. Contract reserves must not include reserves for expected MLR rebates.

Direct paid claims means claim payments before ceded reinsurance and excluding assumed reinsurance except as otherwise provided in this Part.

Enrollee means an individual who is enrolled, within the meaning of § 144.103 of this title, in group health insurance coverage, or an individual who is covered by individual insurance coverage, at any time during an MLR reporting year.

Experience rating refund means the return of a portion of premiums pursuant to a retrospectively rated funding arrangement when the sum of incurred losses, retention and margin are less than earned premium.

Group conversion charges means the portion of earned premium allocated to providing the privilege for a certificate holder terminated from a group health plan to purchase individual health insurance without providing evidence of insurability.

Health Plan means health insurance coverage offered through either individual coverage or a group health plan.

Individual market has the meaning given the term in section 2791(e)(1) of the PHS Act and section 1304(a)(2) of the Affordable Care Act.

Large Employer has the meaning given the term in section 2791(e)(2) of the PHS Act and section 1304(b)(1) of the Affordable Care Act, except that as provided by section 1304(b)(3) of the Affordable Care Act, until 2016 a State may substitute "51" employees for "101" employees in the definition.

Large group market has the meaning given the term in section 2791(e)(3) of the PHS Act and section 1304(a)(3) of the Affordable Care Act.

MLR reporting year means a calendar year during which group or individual health insurance coverage is provided by an issuer.

Multi-State blended rate means a single rate charged for health insurance coverage provided to a single employer through two or more of an issuer's affiliated companies for employees in two or more States.

Policyholder means any entity that has entered into a contract with an issuer to receive health insurance coverage as defined in section 2791(b) of the PHS Act.

Situs of the contract means the jurisdiction in which the contract is issued or delivered as stated in the contract.

Small Employer has the meaning given the term in section 2791(e)(4) of the PHS Act and section 1304(b)(2) of the Affordable Care Act, except that as provided by section 1304(b)(3) of the Affordable Care Act, until 2016 a State may substitute "50" employees for "100" employees in the definition.

Small group market has the meaning in section 2791(e)(5) of the PHS Act and section 1304(a)(3) of the Affordable Care Act.

Subscriber refers to both the group market and the individual market. In the group market, subscriber means the individual, generally the employee, whose eligibility is the basis for the enrollment in the group health plan and who is responsible for the payment of premiums. In the individual market, subscriber means the individual who purchases an individual policy and who is responsible for the payment of premiums.

Unearned premium means that portion of the premium paid in the MLR reporting year that is intended to provide coverage during a period which extends beyond the MLR reporting year.

Unpaid Claim Reserves means reserves and liabilities established to account for claims that were incurred during the MLR reporting year but had not been paid within 3 months of the end of the MLR reporting year.

Subpart A—Disclosure and Reporting

§ 158.110 Reporting requirements related to premiums and expenditures.

(a) *General requirements.* For each MLR reporting year, an issuer must submit to the Secretary a report which complies with the requirements of this Part, concerning premium revenue and expenses related to the group and individual health insurance coverage that it issued.

(b) *Timing and form of report.* (1) Except as provided in paragraph (b)(2) of this section, the report for each MLR reporting year must be submitted to the Secretary by June 1 of the year following the end of an MLR reporting year, on a form and in the manner prescribed by the Secretary.

(2) An issuer that reports its experience separately under § 158.120(d)(3) or (4) of this subpart must submit a report for each quarter of the 2011 MLR reporting year, on the same form and in the same manner as described in paragraph (b)(1) of this section, as follows:

(i) By May 1 for the quarter ending March 31;

(ii) By August 1 for the quarter ending June 30; and

(ii) By November 1 for the quarter ending September 30.

(c) *Transfer of Business.* Issuers that purchase a line or block of business from another issuer during an MLR reporting year are responsible for submitting the information and reports required by this Part for the assumed business, including for that part of the MLR reporting year that was prior to the purchase.

§ 158.120 Aggregate reporting.

(a) *General requirements.* For purposes of submitting the report required in § 158.110 of this subpart, the issuer must submit a report for each State in which it is licensed to issue health insurance coverage that includes the experience of all policies issued in the State during the MLR reporting year covered by the report. The report must aggregate data for each entity licensed within a State, aggregated separately for the large group market, the small group market and the individual market. Experience with respect to each policy must be included on the report submitted with respect to the State where the contract was issued, except as specified in § 158.120(d) of this subpart.

(b) *Group Health Insurance Coverage in Multiple States.* Group coverage issued by a single issuer that covers employees in multiple States must be attributed to the applicable State based on the situs of the contract. Group coverage issued by multiple affiliated issuers that covers employees in multiple States must be attributed by each issuer to each State based on the situs of the contract.

(c) *Group Health Insurance Coverage With Dual Contracts.* Where a group health plan involves health insurance coverage obtained from two affiliated issuers, one providing in-network coverage only and the second providing out-of-network coverage only, solely for the purpose of providing a group health plan that offers both in-network and out-of-network benefits, experience may be treated as if it were all related to the contract provided by the in-network issuer. However, if the issuer chooses this method of aggregation, it must apply it for a minimum of 3 MLR reporting years.

(d) *Exceptions.* (1) For individual market business sold through an association, the experience of the issuer must be included in the State report for the State that has jurisdiction over the certificate of coverage.

(2) For employer business issued through a group trust or multiple employer welfare association, the

experience of the issuer must be included in the State report for the State where the employer or the association has its principal place of business.

(3) For the 2011 MLR reporting year, an issuer with policies that have a total annual limit of $250,000 or less must report the experience from such policies separately from other policies.

(4) For the 2011 MLR reporting year, an issuer with group policies that provide coverage for employees working outside their country of citizenship, employees working outside of their country of citizenship and outside the employer's country of domicile, and citizens working in their home country, must aggregate the experience from these policies but report the experience from such policies separately from other policies.

§ 158.121 Newer experience.

If, for any aggregation as defined in § 158.120, 50 percent or more of the total earned premium for an MLR reporting year is attributable to policies newly issued and with less than 12 months of experience in that MLR reporting year, then the experience of these policies may be excluded from the report required under § 158.110 of this subpart for that same MLR reporting year. If an issuer chooses to defer reporting of newer business as provided in this section, then the excluded experience must be added to the experience reported in the following MLR reporting year.

§ 158.130 Premium revenue.

(a) *General requirements.* An issuer must report to the Secretary earned premium for each MLR reporting year. Earned premium means all monies paid by a policyholder or subscriber as a condition of receiving coverage from the issuer, including any fees or other contributions associated with the health plan.

(1) Earned premium is to be reported on a direct basis except as provided in paragraph (b) of this section.

(2) All earned premium for policies issued by one issuer and later assumed by another issuer must be reported by the assuming issuer for the entire MLR reporting year during which the policies were assumed and no earned premium for that MLR reporting year must be reported by the ceding issuer.

(3) Reinsured earned premium for a block of business that was subject to indemnity reinsurance and administrative agreements effective prior to March 23, 2010, for which the assuming entity is responsible for 100 percent of the ceding entity's financial risk and takes on all of the administration of the block, must be reported by the assuming issuer and must not be reported by the ceding issuer.

(b) *Adjustments.* Earned premium must include adjustments to:

(1) Account for assessments paid to or subsidies received from Federal and State high risk pools.

(2) Account for portions of premiums associated with group conversion charges.

(3) Account for any experience rating refunds paid or received, excluding any rebate paid based upon an issuer's MLR.

(4) Account for unearned premium.

§ 158.140 Reimbursement for clinical services provided to enrollees.

(a) *General requirements.* The report required in § 158.110 of this subpart must include direct claims paid to or received by providers, including under capitation contracts with physicians, whose services are covered by the policy for clinical services or supplies covered by the policy. In addition, the report must include claim reserves associated with claims incurred during the MLR reporting year, the change in contract reserves, reserves for contingent benefits and the claim portion of lawsuits, and any experience rating refunds paid or received. Reimbursement for clinical services as defined in this section are referred to as "incurred claims."

(1) If there are any group conversion charges for a health plan, the conversion charges must be subtracted from the incurred claims for the aggregation that includes the conversion policies and this same amount must be added to the incurred claims for the aggregation that provides coverage that is intended to be replaced by the conversion policies.

(2) Incurred claims must include changes in unpaid claims between the prior year's and the current year's unpaid claims reserves, including claims reported in the process of adjustment, percentage withholds from payments made to contracted providers, claims that are recoverable for anticipated coordination of benefits (COB), and claim recoveries received as a result of subrogation.

(3) Incurred claims must include the change in claims incurred but not reported from the prior year to the current year. Except where inapplicable, the reserve should be based on past experience, and modified to reflect current conditions such as changes in exposure, claim frequency or severity.

(4) Incurred claims must include changes in other claims-related reserves.

(5) Incurred claims must include experience rating refunds and exclude rebates paid as required by § 158.240 based upon prior MLR reporting year experience.

(b) *Adjustments to incurred claims.* (1) Adjustments that must be deducted from incurred claims:

(i) Prescription drug rebates received by the issuer.

(ii) Overpayment recoveries received from providers.

(2) Adjustments that may be included in incurred claims:

(i) Market stabilization payments or receipts by issuers that are directly tied to claims incurred and other claims based or census based assessments.

(ii) State subsidies based on a stop-loss payment methodology.

(iii) The amount of incentive and bonus payments made to providers.

(3) Adjustments that must not be included in incurred claims:

(i) Amounts paid to third party vendors for secondary network savings.

(ii) Amounts paid to third party vendors for network development, administrative fees, claims processing, and utilization management. For example, if an issuer contracts with a behavioral health, chiropractic network, or high technology radiology vendor, or a pharmacy benefit manager, and the vendor reimburses the provider at one amount but bills the issuer a higher amount to cover its network development, utilization management costs, and profits, then the amount that exceeds the reimbursement to the provider must not be included in incurred claims.

(iii) Amounts paid, including amounts paid to a provider, for professional or administrative services that do not represent compensation or reimbursement for covered services provided to an enrollee. For example, medical record copying costs, attorneys' fees, subrogation vendor fees, compensation to paraprofessionals, janitors, quality assurance analysts, administrative supervisors, secretaries to medical personnel and medical record clerks must not be included in incurred claims.

(4) Adjustments that can be either included in or deducted from incurred claims:

(i) Payment to and from unsubsidized State programs designed to address distribution of health risks across issuers via charges to low risk issuers that are distributed to high risk issuers must be included in or deducted from incurred claims, as applicable.

(ii) [Reserved]

(5) Other adjustments to incurred claims:

(i) Affiliated issuers that offer group coverage at a blended rate may choose

whether to make an adjustment to each affiliate's incurred claims and activities to improve health care quality, to reflect the experience of the issuer with respect to the employer as a whole, according to an objective formula that will be defined prior to January 1, 2011, so as to result in each affiliate having the same ratio of incurred claims to earned premium for that employer group for the MLR reporting year as the ratio of incurred claims to earned premium calculated for the employer group in the aggregate.

(ii) [Reserved]

§ 158.150 Activities that improve health care quality.

(a) *General requirements.* The report required in § 158.110 of this subpart must include expenditures for activities that improve health care quality, as described in this section.

(b) *Activity requirements.* Activities conducted by an issuer to improve quality must meet the following requirements:

(1) The activity must be designed to:

(i) Improve health quality.

(ii) Increase the likelihood of desired health outcomes in ways that are capable of being objectively measured and of producing verifiable results and achievements.

(iii) Be directed toward individual enrollees or incurred for the benefit of specified segments of enrollees or provide health improvements to the population beyond those enrolled in coverage as long as no additional costs are incurred due to the non-enrollees.

(iv) Be grounded in evidence-based medicine, widely accepted best clinical practice, or criteria issued by recognized professional medical associations, accreditation bodies, government agencies or other nationally recognized health care quality organizations.

(2) The activity must be primarily designed to:

(i) Improve health outcomes including increasing the likelihood of desired outcomes compared to a baseline and reduce health disparities among specified populations.

(A) Examples include the direct interaction of the issuer (including those services delegated by contract for which the issuer retains ultimate responsibility under the insurance policy), providers and the enrollee or the enrollee's representative (for example, face-to-face, telephonic, web-based interactions or other means of communication) to improve health outcomes, including activities such as:

(*1*) Effective case management, care coordination, chronic disease management, and medication and care compliance initiatives including through the use of the medical homes model as defined in section 3606 of the Affordable Care Act.

(*2*) Identifying and addressing ethnic, cultural or racial disparities in effectiveness of identified best clinical practices and evidence based medicine.

(*3*) Quality reporting and documentation of care in non-electronic format.

(*4*) Health information technology to support these activities.

(*5*) Accreditation fees directly related to quality of care activities.

(B) [Reserved]

(ii) Prevent hospital readmissions through a comprehensive program for hospital discharge. Examples include:

(A) Comprehensive discharge planning (for example, arranging and managing transitions from one setting to another, such as hospital discharge to home or to a rehabilitation center) in order to help assure appropriate care that will, in all likelihood, avoid readmission to the hospital;

(B) Patient-centered education and counseling.

(C) Personalized post-discharge reinforcement and counseling by an appropriate health care professional.

(D) Any quality reporting and related documentation in non-electronic form for activities to prevent hospital readmission.

(E) Health information technology to support these activities.

(iii) Improve patient safety, reduce medical errors, and lower infection and mortality rates.

(A) Examples of activities primarily designed to improve patient safety, reduce medical errors, and lower infection and mortality rates include:

(*1*) The appropriate identification and use of best clinical practices to avoid harm.

(*2*) Activities to identify and encourage evidence-based medicine in addressing independently identified and documented clinical errors or safety concerns.

(*3*) Activities to lower the risk of facility-acquired infections.

(*4*) Prospective prescription drug Utilization Review aimed at identifying potential adverse drug interactions.

(*5*) Any quality reporting and related documentation in non-electronic form for activities that improve patient safety and reduce medical errors.

(*6*) Health information technology to support these activities.

(B) [Reserved]

(iv) Implement, promote, and increase wellness and health activities:

(A) Examples of activities primarily designed to implement, promote, and increase wellness and health activities, include—

(*1*) Wellness assessments;

(*2*) Wellness/lifestyle coaching programs designed to achieve specific and measurable improvements;

(*3*) Coaching programs designed to educate individuals on clinically effective methods for dealing with a specific chronic disease or condition;

(*4*) Public health education campaigns that are performed in conjunction with State or local health departments;

(*5*) Actual rewards, incentives, bonuses, reductions in copayments (excluding administration of such programs), that are not already reflected in premiums or claims should be allowed as a quality improvement activity for the group market to the extent permitted by section 2705 of the PHS Act;

(*6*) Any quality reporting and related documentation in non-electronic form for wellness and health promotion activities;

(*7*) Coaching or education programs and health promotion activities designed to change member behavior and conditions (for example, smoking or obesity); and

(*8*) Health information technology to support these activities.

(B) [Reserved]

(v) Enhance the use of health care data to improve quality, transparency, and outcomes and support meaningful use of health information technology consistent with § 158.151 of this subpart.

(c) *Exclusions.* Expenditures and activities that must not be included in quality improving activities are:

(1) Those that are designed primarily to control or contain costs;

(2) The pro rata share of expenses that are for lines of business or products other than those being reported, including but not limited to, those that are for or benefit self-funded plans;

(3) Those which otherwise meet the definitions for quality improvement activities but which were paid for with grant money or other funding separate from premium revenue;

(4) Those activities that can be billed or allocated by a provider for care delivery and which are, therefore, reimbursed as clinical services;

(5) Establishing or maintaining a claims adjudication system, including costs directly related to upgrades in health information technology that are designed primarily or solely to improve claims payment capabilities or to meet regulatory requirements for processing claims (for example, costs of implementing new administrative simplification standards and code sets

adopted pursuant to the Health Insurance Portability and Accountability Act (HIPAA), 42 U.S.C. 1320d–2, as amended, including the new ICD–10 requirements);

(6) That portion of the activities of health care professional hotlines that does not meet the definition of activities that improve health quality;

(7) All retrospective and concurrent utilization review;

(8) Fraud prevention activities, other than fraud detection/recovery expenses up to the amount recovered that reduces incurred claims;

(9) The cost of developing and executing provider contracts and fees associated with establishing or managing a provider network, including fees paid to a vendor for the same reason;

(10) Provider credentialing;

(11) Marketing expenses;

(12) Costs associated with calculating and administering individual enrollee or employee incentives;

(13) That portion of prospective utilization that does not meet the definition of activities that improve health quality; and

(14) Any function or activity not expressly included in paragraph (c) of this section, unless otherwise approved by and within the discretion of the Secretary, upon adequate showing by the issuer that the activity's costs support the definitions and purposes in this Part or otherwise support monitoring, measuring or reporting health care quality improvement.

§ 158.151 Expenditures related to Health Information Technology and meaningful use requirements.

(a) *General requirements.* An issuer may include as activities that improve health care quality such Health Information Technology (HIT) expenses as are required to accomplish the activities allowed in § 158.150 of this subpart and that are designed for use by health plans, health care providers, or enrollees for the electronic creation, maintenance, access, or exchange of health information, as well as those consistent with Medicare and/or Medicaid meaningful use requirements, and which may in whole or in part improve quality of care, or provide the technological infrastructure to enhance current quality improvement or make new quality improvement initiatives possible by doing one or more of the following:

(1) Making incentive payments to health care providers for the adoption of certified electronic health record technologies and their "meaningful use" as defined by HHS to the extent such payments are not included in reimbursement for clinical services as defined in § 158.140 of this subpart;

(2) Implementing systems to track and verify the adoption and meaningful use of certified electronic health records technologies by health care providers, including those not eligible for Medicare and Medicaid incentive payments;

(3) Providing technical assistance to support adoption and meaningful use of certified electronic health records technologies;

(4) Monitoring, measuring, or reporting clinical effectiveness including reporting and analysis of costs related to maintaining accreditation by nationally recognized accrediting organizations such as NCQA or URAC, or costs for public reporting of quality of care, including costs specifically required to make accurate determinations of defined measures (for example, CAHPS surveys or chart review of HEDIS measures and costs for public reporting mandated or encouraged by law.

(5) Tracking whether a specific class of medical interventions or a bundle of related services leads to better patient outcomes.

(6) Advancing the ability of enrollees, providers, issuers or other systems to communicate patient centered clinical or medical information rapidly, accurately and efficiently to determine patient status, avoid harmful drug interactions or direct appropriate care, which may include electronic Health Records accessible by enrollees and appropriate providers to monitor and document an individual patient's medical history and to support care management.

(7) Reformatting, transmitting or reporting data to national or international government-based health organizations for the purposes of identifying or treating specific conditions or controlling the spread of disease.

(8) Provision of electronic health records, patient portals, and tools to facilitate patient self-management.

(b) [Reserved]

§ 158.160 Other non-claims costs.

(a) *General requirements.* The report required in § 158.110 of this subpart must include non-claims costs described in paragraph (b) of this section and must provide an explanation of how premium revenue is used, other than to provide reimbursement for clinical services covered by the benefit plan, expenditures for activities that improve health care quality, and Federal and State taxes and licensing or regulatory fees as specified in this part.

(b) *Non-claims costs other than taxes and regulatory fees.* (1) The report required in § 158.110 of this subpart must include any expenses for administrative services that do not constitute adjustments to premium revenue as provided in § 158.130 of this subpart, reimbursement for clinical services to enrollees as defined in § 158.140 of this subpart, or expenditures on quality improvement activities as defined in §§ 158.150 and 158.151 of this subpart.

(2) Expenses for administrative services include the following:

(i) Cost-containment expenses not included as an expenditure related to an activity at § 158.150 of this subpart.

(ii) Loss adjustment expenses not classified as a cost containment expense.

(iii) Direct sales salaries, workforce salaries and benefits.

(iv) Agents and brokers fees and commissions.

(v) General and administrative expenses.

(vi) Community benefit expenditures.

§ 158.161 Reporting of Federal and State licensing and regulatory fees.

(a) *Federal taxes.* The report required in § 158.110 of this subpart must separately report:

(1) Federal taxes excluded from premium under subpart B which include all Federal taxes and assessments allocated to health insurance coverage reported under section 2718 of the PHS Act.

(2) Federal taxes not excluded from premium under subpart B which include Federal income taxes on investment income and capital gains as other non-claims costs.

(b) *State taxes and assessments.* The report required in § 158.110 of this subpart must separately report:

(1) State taxes and assessments excluded from premium under subpart B which include:

(i) Any industry-wide (or subset) assessments (other than surcharges on specific claims) paid to the State directly, or premium subsidies that are designed to cover the costs of providing indigent care or other access to health care throughout the State.

(ii) Guaranty fund assessments.

(iii) Assessments of State industrial boards or other boards for operating expenses or for benefits to sick employed persons in connection with disability benefit laws or similar taxes levied by States.

(iv) Advertising required by law, regulation or ruling, except advertising associated with investments.

(v) State income, excise, and business taxes other than premium taxes.

(vi) State premium taxes plus State taxes based on policy reserves, if in lieu of premium taxes.

(vii) One of the following types of payments:

(A) Payments to a State, by not-for-profit health plans, of premium tax exemption values in lieu of State premium taxes limited to the State premium tax rate applicable to for-profit entities subject to premium tax multiplied by the allocated premiums earned for individual, small group and large group;

(B) Payment by not-for-profit health plans for community benefit expenditures as described in paragraph (c) of this section limited to the State premium tax rate applicable to for-profit entities subject to premium tax multiplied by the allocated premiums earned for individual, small group and large group. These payments must be State based requirement to qualify for inclusion in this line item; or

(C) Payments made by (Federal income) tax exempt health plans for community benefit expenditures as defined in paragraph (c) of this section limited to the State premium tax rate applicable to for-profit entities subject to premium tax multiplied by the allocated premiums earned for individual, small group, and large group.

(2) State taxes and assessments not excluded from premium under subpart B which include:

(i) State sales taxes if the issuer does not exercise options of including such taxes with the cost of goods and services purchased.

(ii) Any portion of commissions or allowances on reinsurance assumed that represent specific reimbursement of premium taxes.

(iii) Any portion of commissions or allowances on reinsurance ceded that represents specific reimbursement of premium taxes.

(c) *Community benefit expenditures.* (1) A not-for-profit issuer exempt from Federal or State taxes and assessments, but required to make community benefit expenditures in lieu of taxes, must report to the Secretary such community benefit expenditures, multiplied by the allocated premiums earned for individual, small group and large group, but not to exceed the amount of the taxes they would otherwise be required to pay. Each expenditure must not be reported more than once, but may be split between Federal and State taxes as applicable.

(2) Community benefit expenditures means expenditures for activities or programs that seek to achieve the objectives of improving access to health services, enhancing public health and relief of government burden. This includes any of the following activities that:

(i) Are available broadly to the public and serve low-income consumers;

(ii) Reduce geographic, financial, or cultural barriers to accessing health services, and if ceased to exist would result in access problems (for example, longer wait times or increased travel distances);

(iii) Address Federal, State or local public health priorities such as advancing health care knowledge through education or research that benefits the public;

(iv) Leverage or enhance public health department activities such as childhood immunization efforts; and

(v) Otherwise would become the responsibility of government or another tax-exempt organization.

§ 158.170 Allocation of expenses.

(a) *General requirements.* Each expense must be reported under only one type of expense, unless a portion of the expense fits under the definition of or criteria for one type of expense and the remainder fits into a different type of expense, in which case the expense must be pro-rated between types of expenses. Expenditures that benefit lines of business or products other than those being reported, including but not limited to those that are for or benefit self-funded plans, must be reported on a pro rata share.

(b) *Description of the methods used to allocate expenses.* The report required in § 158.110 of this subpart must include a detailed description of the methods used to allocate expenses, including incurred claims, quality improvement expenses, Federal and State taxes and licensing or regulatory fees, and other non-claims costs, to each health insurance market in each State. A detailed description of each expense element must be provided, including how each specific expense meets the criteria for the type of expense in which it is categorized, as well as the method by which it was aggregated.

(1) Allocation to each category should be based on a generally accepted accounting method that is expected to yield the most accurate results. Specific identification of an expense with an activity that is represented by one of the categories above will generally be the most accurate method. If a specific identification is not feasible, the issuer should provide an explanation of why it believes the more accurate result will be gained from allocation of expenses based upon pertinent factors or ratios such as studies of employee activities, salary ratios or similar analyses.

(2) Many entities operate within a group where personnel and facilities are shared. Shared expenses, including expenses under the terms of a management contract, must be apportioned pro rata to the entities incurring the expense.

(3) Any basis adopted to apportion expenses must be that which is expected to yield the most accurate results and may result from special studies of employee activities, salary ratios, premium ratios or similar analyses. Expenses that relate solely to the operations of a reporting entity, such as personnel costs associated with the adjusting and paying of claims, must be borne solely by the reporting entity and are not to be apportioned to other entities within a group.

(c) *Disclosure of allocation methods.* The issuer must identify in the report required in § 158.110 of this subpart the specific basis used to allocate expenses reported under this Part to States and, within States, to lines of business including the individual market, small group market, large group market, supplemental health insurance coverage, health insurance coverage offered to beneficiaries of public programs (such as Medicare and Medicaid), and group health plans as defined in § 145.103 of this chapter and administered by the issuer.

(d) *Maintenance of records.* The issuer must maintain and make available to the Secretary upon request the data used to allocate expenses reported under this Part together with all supporting information required to determine that the methods identified and reported as required under paragraph (b) of this section were accurately implemented in preparing the report required in § 158.110 of this subpart.

Subpart B—Calculating and Providing the Rebate

§ 158.210 Minimum medical loss ratio.

Subject to the provisions of § 158.211 of this subpart:

(a) *Large group market.* For all policies issued in the large group market in a State during the MLR reporting year, an issuer must provide a rebate to enrollees if the issuer has an MLR of less than 85 percent, as determined in accordance with this part.

(b) *Small group market.* For all policies issued in the small group market in a State during the MLR reporting year, an issuer must provide a rebate to enrollees if the issuer has an

MLR of less than 80 percent, as determined in accordance with this part.

(c) *Individual market.* For all policies issued in the individual market in a State during the MLR reporting year, an issuer must provide a rebate to enrollees if the issuer has an MLR of less than 80 percent, as determined in accordance with this Part.

(d) *Adjustment by the Secretary.* If the Secretary has adjusted the percentage that issuers in the individual market in a specific State must meet, then the adjusted percentage determined by the Secretary in accordance with § 158.301 of this part *et seq.* must be substituted for 80 percent in paragraph (c) of this section.

§ 158.211 Requirement in States with a higher medical loss ratio.

(a) *State option to set higher minimum loss ratio.* For coverage offered in a State whose law provides that issuers in the State must meet a higher MLR than that set forth in § 158.210, the State's higher percentage must be substituted for the percentage stated in § 158.210 of this subpart.

(b) *Considerations in setting a higher minimum loss ratio.* In adopting a higher minimum loss ratio than that set forth in § 158.210, a State must seek to ensure adequate participation by health insurance issuers, competition in the health insurance market in the State, and value for consumers so that premiums are used for clinical services and quality improvements.

§ 158.220 Aggregation of data in calculating an issuer's medical loss ratio.

(a) *Aggregation by State and by market.* In general, an issuer's MLR must be calculated separately for the large group market, small group market and individual market within each State. However, if, pursuant to section 1312(c)(3) of the Affordable Care Act, a State requires the small group market and individual market to be merged, then the data reported separately under subpart A for the small group and individual market in that State may be merged for purposes of calculating an issuer's MLR and any rebates owing.

(b) *Years of data to include in calculating MLR.* Subject to paragraph (c) of this section, an issuer's MLR for an MLR reporting year is calculated according to the formula in § 158.221 of this subpart and aggregating the data reported under this Part for the following 3-year period:

(1) The data for the MLR reporting year whose MLR is being calculated; and

(2) The data for the two prior MLR reporting years.

(c) *Requirements for MLR reporting years 2011 and 2012.* (1) For the 2011 MLR reporting year, an issuer's MLR is calculated using the data reported under this Part for the 2011 MLR reporting year only.

(2) For the 2012 MLR reporting year—

(i) If an issuer's experience for the 2012 MLR reporting year is fully credible, as defined in § 158.230 of this subpart, an issuer's MLR is calculated using the data reported under this Part for the 2012 MLR reporting year.

(ii) If an issuer's experience for the 2012 MLR reporting year is partially credible or non-credible, as defined in § 158.230 of this subpart, an issuer's MLR is calculated using the data reported under this part for the 2011 MLR reporting year and the 2012 MLR reporting year.

§ 158.221 Formula for calculating an issuer's medical loss ratio.

(a) *Medical loss ratio.* (1) An issuer's MLR is the ratio of the numerator, as defined in paragraph (b) of this section, to the denominator, as defined in paragraph (c) of this section, subject to the applicable credibility adjustment, if any, as provided in § 158.232 of this subpart.

(2) An issuer's MLR shall be rounded to three decimal places. For example, if an MLR is 0.7988, it shall be rounded to 0.799 or 79.9 percent. If an MLR is 0.8253 or 82.53 percent, it shall be rounded to 0.825 or 82.5 percent.

(b) *Numerator.* The numerator of an issuer's MLR for an MLR reporting year must be the issuer's incurred claims, as defined in § 158.140 of this part, plus the issuer's expenditures for activities that improve health care quality, as defined in § 158.150 and § 158.151 of this part, that are reported for the years specified in § 158.220 of this subpart.

(1) The numerator of the MLR for the 2012 MLR reporting year may include any rebate paid under § 158.240 of this subpart for the 2011 MLR reporting year if the 2012 MLR reporting year experience is not fully credible as defined in § 158.230 of this subpart.

(2) The numerator of the MLR for the 2013 MLR reporting year may include any rebate paid under § 158.240 for the 2011 MLR reporting year or the 2012 MLR reporting year.

(3) The numerator of the MLR for policies that are reported separately under § 158.120(d)(3) of this part must be the amount specified in paragraph (b) of this section, except that for the 2011 MLR reporting year the total of the incurred claims and expenditures for activities that improve health care quality are then multiplied by a factor of two.

(4) The numerator of the MLR for policies that are reported separately under § 158.120(d)(4) of this part must be the amount specified in paragraph (b) of this section, except that for the 2011 MLR reporting year the total of the incurred claims and expenditures for activities that improve health care quality are then multiplied by a factor of two.

(c) *Denominator.* The denominator of an issuer's MLR must equal the issuer's premium revenue, as defined in § 158.130, minus the issuer's Federal and State taxes and licensing and regulatory fees, described in §§ 158.161(a) and 158.162(a)(1) and (b)(1) of this part.

§ 158.230 Credibility adjustment.

(a) *General rule.* An issuer may add to the MLR calculated under § 158.221(a) of this subpart the credibility adjustment specified by § 158.232 of this section, if such MLR is based on partially credible experience as defined in paragraph (c)(2) of this section. An issuer may not apply the credibility adjustment if the issuer's experience is fully credible, as defined in paragraph (c)(1) of this section, or non-credible, as defined in paragraph (c)(3) of this section.

(b) *Life-years.* The credibility of an issuer's experience is based upon the number of life-years covered by the issuer. Life-years means the total number of months of coverage for enrollees whose premiums and claims experience is included in the report to the Secretary required by § 158.110 of this part, divided by 12.

(c) *Credible experience.* (1) An MLR calculated under § 158.221(a) through (c) of this subpart is fully credible if it is based on the experience of 75,000 or more life-years.

(2) An MLR calculated under § 158.221(a) through (c) of this subpart is partially credible if it is based on the experience of at least 1,000 life-years and fewer than 75,000 life-years.

(3) An MLR calculated under § 158.221(a) through (c) of this subpart is non-credible if it is based on the experience of less than 1,000 life-years.

(d) If an issuer's MLR is non-credible, it is presumed to meet or exceed the minimum percentage required by § 158.210 or § 158.211 of this subpart.

§ 158.231 Life-years used to determine credible experience.

(a) The life-years used to determine the credibility of an issuer's experience are the life-years for the MLR reporting year plus the life-years for the two prior MLR reporting years.

(b) For the 2011 MLR reporting year, the life-years used to determine

credibility are the life-years for the 2011 MLR reporting year only.

(c) For the 2012 MLR reporting year-

(1) If an issuer's experience for the 2012 MLR reporting year is fully credible, the life-years used to determine credibility are the life-years for the 2012 MLR reporting year only;

(2) If an issuer's experience for the 2012 MLR reporting year only is partially credible, the life-years used to determine credibility are the life-years for the 2011 MLR reporting year plus the life-years for the 2012 MLR reporting year.

§ 158.232 Calculating the credibility adjustment.

(a) *Formula.* An issuer's credibility adjustment, if any, is the product of the base credibility factor, as determined under paragraph (b) of this section, multiplied by the deductible factor, as determined under paragraph (c) of this section.

(b) *Base credibility factor.* (1) The base credibility factor for fully credible experience or for non-credible experience is zero.

(2) The base credibility factor for partially credible experience is determined based on the number of life-years included in the aggregation, as determined under § 158.231 of this subpart, and the factors shown in Table 1. When the number of life-years used to determine credibility exactly matches a life-year category listed in Table 1, the value associated with that number of life-years is the base credibility factor. The base credibility factor for a number of life-years between the values shown in Table 1 is determined by linear interpolation.

TABLE 1 TO § 158.232: BASE CREDIBILITY FACTORS

Life-years	Base credibility factor
< 1,000	No Credibility.
1,000	8.3%.
2,500	5.2%.
5,000	3.7%.
10,000	2.6%.
25,000	1.6%.
50,000	1.2%.
≥ 75,000	0.0% (Full Credibility).

(c) *Deductible factor.* (1) The deductible factor is based on the average per person deductible of policies whose experience is included in the aggregation, as determined under § 158.231 of this subpart. When the weighted average deductible, as determined in accordance with this section, exactly matches a deductible category listed in Table 2, the value associated with that deductible is the deductible factor. The deductible factor for an average weighted deductible between the values shown in Table 2 is determined by linear interpolation.

(i) The per person deductible for a policy that covers a subscriber and the subscriber's dependents shall be calculated as follows: The lesser of the sum of the individual family members' deductibles or the overall family deductible for the subscriber and subscriber's family, shall be divided by the total number of individuals covered through the subscriber (including the subscriber).

(ii) The average deductible for an aggregation is calculated weighted by the life-years of experience for each deductible level of policies included in the aggregation.

(2) An issuer may choose to use a deductible factor of 1.0 in lieu of calculating a deductible factor based on the average of policies included in the aggregation.

TABLE 2 TO § 158.232: DEDUCTIBLE FACTOR

Health plan deductible	Deductible factor
$2,500	1.000
$2,500	1.164
$5,000	1.402
≥ $10,000	1.736

(d) *No credibility adjustment.* For the 2013 MLR reporting year, the credibility adjustment for an MLR based on partially credible experience is zero if both of the following conditions are met:

(1) The current MLR reporting year and each of the two previous MLR reporting years included experience of at least 1,000 life-years; and

(2) Without applying any credibility adjustment, the issuer's MLR for the current MLR reporting year and each of the two previous MLR reporting years were below the applicable MLR standard for each year as established under § 158.210 in this subpart.

§ 158.240 Rebating premium if the applicable medical loss ratio standard is not met.

(a) *General requirement.* For each MLR reporting year, an issuer must provide a rebate to each enrollee if the issuer's MLR does not meet or exceed the minimum percentage required by §§ 158.210 and 158.211 of this subpart.

(b) *Definition of enrollee for purposes of rebate.* For the sole purpose of determining whom is entitled to receive a rebate pursuant to this part, the term "enrollee" means the subscriber, policyholder, and/or government entity that paid the premium for health care coverage received by an individual during the respective MLR reporting year.

(c) *Amount of rebate to each enrollee.* (1) For each MLR reporting year, an issuer must rebate to the enrollee the total amount of premium revenue received by the issuer from the enrollee after subtracting Federal and State taxes and licensing and regulatory fees as provided in § 158.161(a), § 158.162(a)(1) and § 158.162(b)(1) of this part, multiplied by the difference between the MLR required by § 158.210 or § 158.211 of this subpart, and the issuer's MLR as calculated under § 158.221 of this subpart.

(2) For example, an issuer must rebate a pro rata portion of premium revenue if it does not meet an 80 percent MLR for the small group market in a State that has not set a higher MLR. If an issuer has a 75 percent MLR for the coverage it offers in the small group market in a State that has not set a higher MLR, the issuer must rebate 5 percent of the premium paid by or on behalf of the enrollee for the MLR reporting year after subtracting premium and subtracting taxes and fees as provided in paragraph (c) of this section. In this example, an enrollee may have paid $2,000 in premiums for the MLR reporting year. If the Federal and State taxes and licensing and regulatory fees that may be excluded from premium revenue as described in § 158.161(a), § 158.161(a)(1) and § 158.162(b)(1) of this subpart are $150 for a premium of $2,000, then the issuer would subtract $150 from premium revenue, for a base of $1,850 in premium. The enrollee would be entitled to a rebate of 5 percent of $1,850, or $92.50.

(d) *Timing of rebate.* An issuer must provide any rebate owing to an enrollee no later than August 1 following the end of the MLR reporting year.

(e) *Late payment interest.* An issuer that fails to pay any rebate owing to an enrollee or subscriber in accordance with paragraph (d) of this section or to take other required action within the time periods set forth in this Part must, in addition to providing the required rebate to the enrollee, pay the enrollee interest at the current Federal Reserve Board lending rate or ten percent annually, whichever is higher, on the total amount of the rebate, accruing from the date payment was due under paragraph (d) of this section.

§ 158.241 Form of rebate.

(a) *Current enrollees.* (1) An issuer may choose to provide any rebates owing to current enrollees in the form

of a premium credit, lump-sum check, or, if an enrollee paid the premium using a credit card or direct debit, by lump-sum reimbursement to the account used to pay the premium.

(2) Any rebate provided in the form of a premium credit must be provided by applying the full amount due to the first month's premium that is due on or after August 1 following the MLR Reporting year. If the amount of the rebate exceeds the premium due for August, then any overage shall be applied to succeeding premium payments until the full amount of the rebate has been credited.

(b) *Former enrollees.* Rebates owing to former enrollees must be paid in the form of lump-sum check or lump-sum reimbursement using the same method that was used for payment, such as credit card or direct debit.

§ 158.242 Recipients of rebates.

(a) *Individual market.* An issuer must meet its obligation to provide any rebate due to an enrollee in the individual market by providing it to the enrollee. For individual policies that cover more than one person, one lump-sum rebate may be provided to the subscriber on behalf of all enrollees covered by the policy.

(b) *Large group and small group markets.* An issuer must meet its obligation to provide any rebate to persons covered under a group health plan by providing it to the enrollee, in amounts proportionate to the amount of premium the policyholder and each subscriber paid.

(1) *Arrangement with policyholder to distribute rebates.* An issuer may meet its obligation to provide any rebate owing to a large group or small group enrollee by entering into an agreement with the group policyholder to distribute the rebate on behalf of the issuer, subject to all of the following conditions:

(i) The issuer must remain liable for complying with all of its obligations under this part.

(ii) The issuer must obtain and retain records and documentation evidencing accurate distribution of any rebate owing, sufficient to demonstrate compliance with its obligations under this subpart, subpart D, and subpart E. Such records and documentation include:

(A) The amount of the premium paid by each subscriber;

(B) The amount of the premium paid by the group policyholder;

(C) The amount of the rebate provided to each subscriber;

(D) The amount of the rebate retained by the group policyholder; and

(E) The amount of any unclaimed rebate and how and when it was distributed.

(2) [Reserved]

§ 158.243 *De minimis* rebates.

(a) *Minimum threshold.* An issuer is not required to provide a rebate to an enrollee based upon the premium that enrollee paid, under the following circumstances:

(1) For a group policy, if the total rebate owed to the policyholder and the subscribers is less than $5 per subscriber covered by the policy for a given MLR reporting year.

(2) In the individual market, if the total rebated owed to the subscriber is less than $5.

(b) *Distribution.* (1) An issuer must aggregate and distribute any rebates not provided because they did not meet the minimum threshold set forth in paragraph (a) of this section by aggregating the unpaid rebates by individual market, small group market and large group market in a State and use them to increase the rebates provided to enrollees who receive rebates based upon the same MLR reporting year as the aggregated unpaid rebates. An issuer must distribute such aggregated rebates by providing additional premium credit or payment divided evenly among enrollees who are being provided a rebate.

(2) For example, an issuer in the individual market has aggregated unpaid rebates totaling $2,000, and the issuer has 10,000 enrollees who are entitled to be provided a rebate above the minimum threshold for the applicable MLR reporting year. The $2,000 must be redistributed to the 10,000 and added on to their existing rebate amounts. The $2,000 is divided evenly among the 10,000 enrollees, so the issuer increases each enrollee's rebate by $0.20.

§ 158.244 Unclaimed rebates.

An issuer must make a good faith effort to locate and deliver to an enrollee any rebate required under this Part. If, after making a good faith effort, an issuer is unable to locate a former enrollee, the issuer must comply with any applicable State law.

§ 158.250 Notice of rebates.

For each MLR reporting year, at the time any rebate of premium is provided in accordance with this Part, an issuer must provide each enrollee who receives a rebate the following information in a form prescribed by the Secretary:

(a) A general description of the concept of an MLR;

(b) The purpose of setting a MLR standard;

(c) The applicable MLR standard;

(d) The issuer's MLR, adjusted in accordance with the provisions of this subpart;

(e) The issuer's aggregate premium revenue as reported in accordance with § 158.130, minus any Federal and State taxes and licensing and regulatory fees that may be excluded from premium revenue as described in §§ 158.161(a) and 158.162(a)(1) and (b)(1); and

(f) The rebate percentage and amount owed to enrollees based upon the difference between the issuer's MLR and the applicable MLR standard.

§ 158.260 Reporting of rebates.

(a) *General requirement.* For each MLR reporting year, an issuer must submit to the Secretary a report concerning the rebates provided to and on behalf of enrollees pursuant to this subpart.

(b) *Aggregation of information in the report.* The information in the report must be aggregated in the same manner as required by § 158.120.

(c) *Information to report.* The report required by this section must include the total:

(1) Number and percentage of enrollees who received a rebate;

(2) Number and amount of rebates provided:

(i) As premium credit; and

(ii) As lump sum check or lump-sum reimbursement to a subscriber's credit card or direct payment to a subscriber's bank account;

(3) Amount of rebates that were provided to enrollees, including a breakdown of the amounts provided based upon the portion of premiums paid by group policyholders and amounts provided based upon the portion of premium paid by subscribers;

(4) Amount of rebates that were *de minimis*, as provided in § 158.243, and a detailed description of how these rebates were disbursed; and

(5) Amount of unclaimed rebates, a description of the methods used to locate the applicable enrollees, and a detailed description of how the unclaimed rebates were disbursed.

(d) *Timing and form of report.* The data required by paragraphs (c)(1) through (4) of this section must be submitted with the report under § 158.110, on a form and in the manner prescribed by the Secretary. The data required by paragraph (c)(5) of this section must be submitted with the report under § 158.110 for the subsequent MLR reporting year.

§ 158.270 Effect of rebate payments on solvency.

(a) If a State's insurance commissioner, superintendent, or other responsible official determines that the payment of rebates by a domestic issuer in that State will cause the issuer's risk based capital (RBC) level to fall below the Company Action Level RBC, as defined in the NAIC's Risk Based Capital (RBC) for Insurers Model Act, the commissioner, superintendent, or other responsible official must notify the Secretary. In such a circumstance, the commissioner, superintendent, or other responsible official may request that the Secretary defer all or a portion of the rebate payments owed by the issuer.

(b) In the event an insurance commissioner, superintendent, or other responsible official makes the request set forth in paragraph (a) of this section, the following should be provided to the Secretary along with the notification:

(1) The domestic issuer's RBC reports for the current calendar year and the 2 preceding calendar years; and

(2) A calculation of the amount of rebates that would be owed by the domestic issuer pursuant to this Part.

(c) Upon receipt of the notification under paragraph (a), the Secretary will examine the information provided by the insurance commissioner, superintendent, or other responsible official along with any other information the Secretary may request from the issuer, and determine whether the payment of rebates by the issuer will cause its RBC level to fall below the Company Action Level RBC.

(d) When the Secretary determines that the payment of rebates by an issuer will cause its RBC level to fall below the Company Action Level RBC, the Secretary may permit a deferral of all or a portion of the rebates owed, but only for a period determined by the Secretary in consultation with the State. The Secretary will require that the issuer must pay these rebates with interest in a future year in which payment of the rebates would not cause the issuer's RBC level to fall below the Company Action Level RBC.

Subpart C—Potential Adjustment to the MLR for a State's Individual Market

§ 158.301 Standard for adjustment to the medical loss ratio.

The Secretary may adjust the MLR standard that must be met by issuers offering coverage in the individual market in a State, as defined in section 2791 of the PHS Act, for a given MLR reporting year if, in her discretion, she determines that application of the 80 percent MLR standard of section 2718(b)(1)(A)(ii) of the Public Health Service Act may destabilize the individual market in that State. Application of the 80 percent MLR standard may destabilize the individual market in a State only if there is a reasonable likelihood that application of the requirement will do so.

§ 158.310 Who may request adjustment to the medical loss ratio.

A request for an adjustment to the MLR standard for a State must be submitted by the State's insurance commissioner, superintendent, or comparable official of that State in order to be considered by the Secretary.

§ 158.311 Duration of adjustment to the medical loss ratio.

A State may request that an adjustment to the MLR standard be for up to three MLR reporting years.

§ 158.320 Information supporting a request for adjustment to the medical loss ratio.

A State must submit in electronic format the information required by §§ 158.321 through 158.323 of this subpart in order for the request for adjustment to the MLR standard for the State to be considered by the Secretary. A State may submit to the Secretary any additional information it determines would support its request. In the event that certain data are unavailable or that the collection of certain data is unduly burdensome, a State may provide written notice to the Secretary and the Secretary may, at her discretion, request alternative supporting data or move forward with her determination.

§ 158.321 Information regarding the State's individual health insurance market.

(a) *State MLR standard.* The State must describe its current MLR standard for the individual market, if any, and the formula used to assess compliance with such standard.

(b) *State market withdrawal requirements.* The State must describe any requirements it has with respect to withdrawals from the State's individual health insurance market. Such requirements include, but are not limited to, any notice that must be provided and any authority the State regulator may have to approve a withdrawal plan or ensure that enrollees of the exiting issuer have continuing coverage, as well as any penalties or sanctions that may be levied upon exit or limitations on re-entry.

(c) *Mechanisms to provide options to consumers.* The State must describe the mechanisms available to the State to provide consumers with options in the event an issuer withdraws from the individual market. Such mechanisms include, but are not limited to, a guaranteed issue requirement, limits on health status rating, an issuer of last resort, or a State-operated high risk pool. A description of each mechanism should include detail on the issuers participating in and products available under such mechanism, as well as any limitations with respect to eligibility, enrollment period, total enrollment, and coverage for pre-existing conditions.

(d) *Issuers in the State's individual market.* Subject to § 158.320 of this subpart, the State must provide:

(1) For each issuer who offers coverage in the individual market in the State its number of individual enrollees by product, available individual premium data by product, and individual health insurance market share within the State; and

(2) For each issuer who offers coverage in the individual market in the State to more than 1,000 enrollees, the following additional information:

(i) Total earned premium on individual market health insurance products in the State;

(ii) Reported MLR pursuant to State law for the individual market business in the State;

(iii) Estimated MLR for the individual market business in the State, as determined in accordance with § 158.221 of this part;

(iv) Total agents' and brokers' commission expenses on individual health insurance products;

(v) Estimated rebate for the individual market business in the State, as determined in accordance with § 158.221 and § 158.240 of this part;

(vi) Net underwriting profit for the individual market business and consolidated business in the State;

(vii) After-tax profit and profit margin for the individual market business and consolidated business in the State;

(viii) Risk-based capital level; and

(ix) Whether the issuer has provided notice of exit to the State's insurance commissioner, superintendent, or comparable State authority.

§ 158.322 Proposal for adjusted medical loss ratio.

A State must provide its own proposal as to the adjustment it seeks to the MLR standard. This proposal must include:

(a) An explanation and justification of how the proposed adjustment to the MLR was determined;

(b) An explanation of how an adjustment to the MLR standard for the State's individual market will permit issuers to adjust current business models and practices in order to meet

an 80 percent MLR as soon as is practicable;

(c) An estimate of the rebates that would be paid if the issuers offering coverage in the individual market in the State must meet an 80 percent MLR for the applicable MLR reporting years; and

(d) An estimate of the rebates that would be paid if the issuers offering coverage in the individual market in the State must meet the adjusted MLR proposed by the State for the applicable MLR reporting years.

§ 158.323 State contact information.

A State must provide the name, telephone number, e-mail address, and mailing address of the person the Secretary may contact regarding the request for an adjustment to the MLR standard.

§ 158.330 Criteria for assessing request for adjustment to the medical loss ratio.

The Secretary may consider the following criteria in assessing whether application of an 80 percent MLR, as calculated in accordance with this subpart, may destabilize the individual market in a State that has requested an adjustment to the 80 percent MLR:

(a) The number of issuers reasonably likely to exit the State or to cease offering coverage in the State absent an adjustment to the 80 percent MLR and the resulting impact on competition in the State. In making this determination the Secretary may consider as to each issuer that is reasonably likely to exit the State:

(1) Each issuer's MLR relative to an 80 percent MLR;

(2) Each issuer's solvency and profitability, as measured by factors such as surplus level, risked-based capital ratio, net income, and operating or underwriting gain;

(3) The requirements and limitations within the State with respect to market withdrawals; and

(4) Whether each issuer covers less than 1,000 life-years in the State's individual insurance market.

(b) The number of individual market enrollees covered by issuers that are reasonably likely to exit the State absent an adjustment to the 80 percent MLR.

(c) Whether absent an adjustment to the 80 percent MLR standard consumers may be unable to access agents and brokers.

(d) The alternate coverage options within the State available to individual market enrollees in the event an issuer exits the market, including:

(1) Any requirement that issuers who exit the State's individual market must have their block(s) of business assumed by another issuer;

(2) The issuers that may remain in the State subsequent to the implementation of the 80 percent MLR, as calculated in accordance with this Part, and the nature, terms, and price of the products offered by such issuers;

(3) The capacity of remaining issuers to write additional business, as measured by their risk based capital ratios;

(4) The mechanisms, such as guaranteed issue products, an issuer of last resort, or a State high risk pool, available to the State to provide coverage to consumers in the event of an issuer withdrawing from the market, and the affordability of these options compared to the coverage provided by exiting or potentially exiting issuers; and

(5) Any authority the State's insurance commissioner, superintendent, or comparable official may exercise with respect to stabilization of the individual insurance market.

(e) The impact on premiums charged, and on benefits and cost-sharing provided, to consumers by issuers remaining in the market in the event one or more issuers were to withdraw from the market.

(f) Any other relevant information submitted by the State's insurance commissioner, superintendent, or comparable official in the State's request.

§ 158.340 Process for submitting request for adjustment to the medical loss ratio.

(a) *Electronic submission.* A State must submit electronically, to an address and in a format prescribed by the Secretary, all of the information required by this subpart in order for its request for an adjustment to the MLR standard for its individual market to be considered by the Secretary.

(b) *Submission by mail.* A State may also submit by overnight delivery service or by U.S mail, return receipt requested, to an address and in a format prescribed by the Secretary, its request for an adjustment to the MLR standard for its individual market.

§ 158.341 Treatment as a public document.

A State's request for an adjustment to the MLR standard, and all information submitted as part of its request, will be treated as a public document and will be posted promptly on the Secretary's Internet Web site devoted to health care coverage.

§ 158.342 Invitation for public comments.

The Secretary will invite public comment regarding a State's request for an adjustment to the MLR standard. All public comments must be submitted in writing within 10 days of the posting of the request, and must be submitted in the manner prescribed by the Secretary. The Secretary will consider timely public comments in assessing a State's request for an adjustment to the MLR standard.

§ 158.343 Optional State hearing.

Any State that submits a request for adjustment to the MLR standard may, at its option, hold a public hearing and create an evidentiary record with respect to its application. If a State does so, the Secretary will take the evidentiary record of the hearing into consideration in making her determination.

§ 158.344 Secretary's discretion to hold a hearing.

The Secretary may, at her discretion, conduct a public hearing with respect to a State's request for an adjustment to the MLR standard. All testimony and materials received in connection with any public hearing will be made part of the public record, and shall be considered by the Secretary in assessing a State's request for an adjustment to the MLR standard.

§ 158.345 Determination on a State's request for adjustment to the medical loss ratio.

(a) *General time frame.* The Secretary will make a determination as to whether to grant a State's request for an adjustment to the MLR standard within 30 days after determining that the information required by this subpart has been received.

(b) *Extension at the discretion of the Secretary.* The Secretary may, in her discretion, extend the 30 day time period in paragraph (a) of this section for as long a time as necessary not to exceed 30 days.

§ 158.346 Request for reconsideration.

(a) *Requesting reconsideration.* A State whose request for adjustment to the MLR standard has been denied by the Secretary may request reconsideration of that determination. A request for reconsideration must be submitted in writing to the Secretary within 10 days of her decision to deny the State's request for an adjustment, and may include any additional information in support of its request.

(b) *Reconsideration determination.* The Secretary will issue her determination on a State's request for reconsideration within 20 days of receiving the reconsideration request.

§ 158.350 Subsequent requests for adjustment to the medical loss ratio.

A State that has made a previous request for an adjustment to the MLR standard must, in addition to the other information required by this subpart, submit information as to what steps the State has taken since its initial and other prior requests, if any, to increase the likelihood that enrollees who have health coverage through issuers that are considered likely to exit the State's individual market will receive coverage at a comparable price and with comparable benefits if the issuer does exit the market.

Subpart D—HHS Enforcement

§ 158.401 HHS enforcement.

HHS enforces the reporting and rebate requirements described in subparts A and B, including but not limited to:

(a) The requirement that such reports be submitted timely.

(b) The requirement that the data reported complies with the definitions and criteria set forth in this part.

(c) The requirement that rebates be paid timely and accurately.

§ 158.402 Audits.

(a) *Notice of Audit.* HHS will provide 30 days advance notice of its intent to conduct an audit of an issuer.

(b) *Conferences.* All audits will include an entrance conference at which the scope of the audit will be presented and an exit conference at which the initial audit findings will be discussed.

(c) *Preliminary Audit Findings.* HHS will share its preliminary audit findings with the issuer, which will then have 30 days to respond to such findings. HHS may extend, for good cause, the time for an issuer to submit such a response.

(d) *Final Audit Findings.* If the issuer does not dispute the preliminary findings, the audit findings will become final. Alternatively, if the issuer responds to the preliminary findings, HHS will review and consider such response and finalize the audit findings.

(e) *Corrective actions.* HHS will send a copy of the final audit findings to the issuer as well as any corrective actions that issuer must undertake as a result of the audit findings.

(f) *Order to pay rebates.* If HHS determines as the result of an audit that an issuer has failed to pay rebates it is obligated to pay pursuant to this part, it may order the issuer to pay those rebates, together with interest from the date the rebates were due, in accordance with § 158.240(d) of this part.

§ 158.403 Circumstances in which a State is conducting audits of issuers.

(a) If a State conducts an audit of an issuer's MLR reporting and rebate obligations, HHS may, in the exercise of its discretion, accept the findings of that audit if HHS determines the following:

(1) The laws of the State permit public release of the findings of audits of issuers;

(2) The State's audit reports on the validity of the data regarding expenses and premiums that the issuer reported to the Secretary, including the appropriateness of the allocations of expenses used in such reporting and whether the activities associated with the issuer's reported expenditures for quality improving activities meet the definition of such activities;

(3) The State's audit reports on the accuracy of rebate calculations and the timeliness and accuracy of rebate payments;

(4) The State submits final audit reports to HHS within 30 days of finalization; and

(5) The State submits preliminary or draft audit reports to HHS within 6 months of the completion of audit field work unless they have already been finalized and reported under paragraph (a)(4) of this section.

(b) If HHS accepts an audit conducted by a State, and if the issuer makes additional rebate payments as a result of the audit, then HHS shall accept those payments as satisfying the issuer's obligation to pay rebates pursuant to this part.

Subpart E—Additional Requirements on Issuers

§ 158.501 Access to facilities and records.

(a) Each issuer subject to the reporting requirement of this part must allow access and entry to its premises, facilities and records, including computer and other electronic systems, to HHS, the Comptroller General, or their designees to evaluate, through inspection, audit, or other means, compliance with the requirements for reporting and calculation of data submitted to HHS, and the timeliness and accuracy of rebate payments made under this part.

(b) Each issuer must also allow access and entry to the facilities and records, including computer and other electronic systems, of its parent organization, subsidiaries, related entities, contractors, subcontractors, agents, or a transferee that pertain to any aspect of the data reported to HHS or to rebate payments calculated and made under this part. To the extent that the issuer does not control access to the facilities and records of its parent organization, related entities, or third parties, it will be the responsibility of the issuer to contractually obligate any such parent organization, related entities, or third parties to grant said access.

(c) The Comptroller General, HHS, or their designees may inspect, evaluate, and audit through 6 years from the date of the filing of a report required by this part or through 3 years after the completion of the audit and for such longer period set forth below provided that any of the following occur:

(1) HHS determines there is a special need to retain a particular record or group of records for a longer period and notifies the issuer at least 30 days before the disposition date.

(2) There has been a dispute, or allegation of fraud or similar fault by the issuer, in which case the retention may be extended to 6 years from the date of any resulting final resolution of the dispute, fraud, or similar fault.

(3) HHS determines that there is a reasonable possibility of fraud or similar fault, in which case HHS may inspect, evaluate, and audit the issuer at any time.

§ 158.502 Maintenance of records.

(a) *Basic rule.* Each issuer subject to the requirements of this part must maintain all documents and other evidence necessary to enable HHS to verify that the data required to be submitted in accordance with this part comply with the definitions and criteria set forth in this part, and that the MLR is calculated and any rebates owing are calculated and provided in accordance with this part. This includes but is not limited to all administrative and financial books and records used in compiling data reported and rebates provided under this part and in determining what data to report and rebates to provide under this part, electronically stored information, and evidence of accounting procedures and practices. This also includes all administrative and financial books and records used by others in assisting an issuer with its obligations under this part.

(b) *Length of time information must be maintained.* All of the documents and other evidence required by this part must be maintained for the current year and six prior years, unless a longer time is required under § 158.501 of this subpart.

Subpart F—Federal Civil Penalties

§ 158.601 General rule regarding the imposition of civil penalties.

If any issuer fails to comply with the requirements of this part, civil penalties,

as described in this subpart, may be imposed.

§ 158.602 Basis for imposing civil penalties.

Civil penalties. For the violations listed in this paragraph, HHS may impose civil penalties in the amounts specified in § 158.606 of this subpart on any issuer who fails to do the following:

(a) Submit to HHS a report concerning the data required under this part by the deadline established by HHS.

(b) Submit to HHS a substantially complete or accurate report concerning the data required under this part.

(c) Timely and accurately pay rebates owing pursuant to this part.

(d) Respond to HHS inquiries as part of an investigation of issuer non-compliance.

(e) Maintain records as required under this part for the periodic auditing of books and records used in compiling data reported to HHS and in calculating and paying rebates pursuant to this Part.

(f) Allow access and entry to premises, facilities and records that pertain to any aspect of the data reported to HHS or to rebates calculated and paid pursuant to this part.

(g) Comply with corrective actions resulting from audit findings.

(h) Accurately and truthfully represent data, reports or other information that it furnishes to a State or HHS.

§ 158.603 Notice to responsible entities.

If HHS learns of a potential violation described in § 158.602 of this subpart or if a State informs HHS of a potential violation prior to imposing any civil monetary penalty HHS must provide written notice to the issuer, to include the following:

(a) Describe the potential violation.

(b) Provide 30 days from the date of the notice for the responsible entity to respond and to provide additional information to refute an alleged violation.

(c) State that a civil monetary penalty may be assessed if the allegations are not, as determined by HHS, refuted.

§ 158.604 Request for extension.

In circumstances in which an entity cannot prepare a response to HHS within the 30 days provided in the notice, the entity may make a written request for an extension from HHS detailing the reason for the extension request and showing good cause. If HHS grants the extension, the responsible entity must respond to the notice within the time frame specified in HHS's letter granting the extension of time. Failure to respond within 30 days, or within the extended time frame, may result in HHS's imposition of a civil monetary penalty based upon its determination of a potential violation described in § 158.602 of this subpart.

§ 158.605 Responses to allegations of noncompliance.

In determining whether to impose a civil monetary penalty, HHS may review and consider documentation provided in any complaint or other information, as well as any additional information provided by the responsible entity to demonstrate that it has complied with Affordable Care Act requirements. The following are examples of documentation that a potential responsible entity may submit for HHS's consideration in determining whether a civil monetary penalty should be assessed and the amount of any civil monetary penalty:

(a) Any evidence that refutes an alleged noncompliance.

(b) Evidence that the entity did not know, and exercising due diligence could not have known, of the violation.

(c) Evidence documenting the development and implementation of internal policies and procedures by an issuer to ensure compliance with the Affordable Care Act requirements regarding MLR. Those policies and procedures may include or consist of a voluntary compliance program. Any such program should do the following:

(1) Effectively articulate and demonstrate the fundamental mission of compliance and the issuer's commitment to the compliance process.

(2) Include the name of the individual in the organization responsible for compliance.

(3) Include an effective monitoring system to identify practices that do not comply with Affordable Care Act requirements regarding MLRs and to provide reasonable assurance that fraud, abuse, and systemic errors are detected in a timely manner.

(4) Address procedures to improve internal policies when noncompliant practices are identified.

(d) Evidence documenting the entity's record of previous compliance with Affordable Care Act requirements regarding MLRs.

§ 158.606 Amount of penalty—general.

A civil monetary penalty for each violation of § 158.602 of this subpart may not exceed $100 for each day, for each responsible entity, for each individual affected by the violation. Penalties imposed under this Part are in addition to any other penalties prescribed or allowed by law.

§ 158.607 Factors HHS uses to determine the amount of penalty.

In determining the amount of any penalty, HHS may take into account the following:

(a) *The entity's previous record of compliance.* This may include any of the following:

(1) Any history of prior violations by the responsible entity, including whether, at any time before determination of the current violation(s), HHS or any State found the responsible entity liable for civil or administrative sanctions in connection with a violation of Affordable Care Act requirements regarding minimum loss ratios.

(2) Evidence that the responsible entity has never had a complaint for noncompliance with Affordable Care Act requirements regarding MLRs filed with a State or HHS.

(3) Such other factors as justice may require.

(b) *The gravity of the violation.* This may include any of the following:

(1) The frequency of the violation, taking into consideration whether any violation is an isolated occurrence, represents a pattern, or is widespread.

(2) The level of financial and other impacts on affected individuals.

(3) Other factors as justice may require.

§ 158.608 Determining the amount of the penalty—mitigating circumstances.

For every violation subject to a civil monetary penalty, if there are substantial or several mitigating circumstances, the aggregate amount of the penalty is set at an amount sufficiently below the maximum permitted by § 158.606 of this subpart to reflect that fact. As guidelines for taking into account the factors listed in § 158.607 of this subpart, HHS considers the following:

(a) *Record of prior compliance.* It should be considered a mitigating circumstance if the responsible entity has done any of the following:

(1) Before receipt of the notice issued under § 158.603 of this subpart, implemented and followed a compliance plan as described in § 158.605(c) of this subpart.

(2) Had no previous complaints against it for noncompliance.

(b) *Gravity of the violation(s).* It should be considered a mitigating circumstance if the responsible entity has done any of the following:

(1) Made adjustments to its business practices to come into compliance with the requirements of this Part so that the following occur:

(i) Each enrollee adversely affected by the violation has been paid any amount

of rebate owed so that, to the extent practicable, that enrollee is in the same position that he, she, or it would have been in had the violation not occurred.

(ii) The rebate payments are completed in a timely manner.

(2) Discovered areas of noncompliance without notice from HHS and voluntarily reported that noncompliance, provided that the responsible entity submits the following:

(i) Documentation verifying that the rights and protections of all individuals adversely affected by the noncompliance have been restored; and

(ii) A plan of correction to prevent future similar violations.

(3) Demonstrated that the violation is an isolated occurrence.

(4) Demonstrated that the financial and other impacts on affected individuals is negligible or nonexistent.

(5) Demonstrated that the noncompliance is correctable and that a high percentage of the violations were corrected.

§ 158.609 Determining the amount of penalty—aggravating circumstances.

For every violation subject to a civil monetary penalty, if there are substantial or several aggravating circumstances, HHS may set the aggregate amount of the penalty at an amount sufficiently close to or at the maximum permitted by § 158.606 of this subpart to reflect that fact. HHS considers the following circumstances to be aggravating circumstances:

(a) The frequency of violation indicates a pattern of widespread occurrence.

(b) The violation(s) resulted in significant financial and other impacts on the average affected individual.

(c) The entity does not provide documentation showing that substantially all of the violations were corrected.

§ 158.610 Determining the amount of penalty—other matters as justice may require.

HHS may take into account other circumstances of an aggravating or mitigating nature if, in the interests of justice, they require either a reduction or an increase of the penalty in order to assure the achievement of the purposes of this Part, and if those circumstances relate to the entity's previous record of compliance or the gravity of the violation.

§ 158.611 Settlement authority.

Nothing in § 158.606 through § 158.610 of this subpart limits the authority of HHS to settle any issue or case described in the notice furnished in accordance with § 158.603 of this subpart or to compromise on any penalty provided for in §§ 158.606 through 158.610 of this subpart.

§ 158.612 Limitations on penalties.

(a) *Circumstances under which a civil monetary penalty is not imposed.* HHS does not impose any civil monetary penalty on any failure for the period of time during which none of the responsible entities knew, or exercising reasonable diligence would have known, of the failure. HHS also may not impose a civil monetary penalty for the period of time after any of the responsible entities knew, or exercising reasonable diligence would have known of the failure, if the failure was due to reasonable cause and not due to willful neglect and the failure was corrected within 30 days of the first day that any of the entities against whom the penalty would be imposed knew, or exercising reasonable diligence would have known, that the failure existed.

(b) *Burden of establishing knowledge.* The burden is on the responsible entity or entities to establish to HHS's satisfaction that no responsible entity knew, or exercising reasonable diligence would have known, that the failure existed.

§ 158.613 Notice of proposed penalty.

(a) *Contents of notice.* If HHS proposes to assess a penalty in accordance with this Part, it must provide the issuer written notice of its intent to assess a penalty, which includes the following:

(1) A description of the requirements under this Part that HHS has determined the issuer violated.

(2) A description of the information upon which HHS based its determination, including the basis for determining the number of affected individuals and the number of days or weeks for which the violations occurred.

(3) The amount of the proposed penalty as of the date of the notice.

(4) Any considerations described in § 158.607 through § 158.610 of this subpart that were taken into account in determining the amount of the proposed penalty.

(5) A specific statement of the issuer's right to a hearing.

(6) A statement that failure to request a hearing within 30 days after the date of the notice permits the assessment of the proposed penalty without right of appeal in accordance with § 158.615 of this subpart.

(b) *Delivery of Notice.* This notice must be either hand delivered, sent by certified mail, return receipt requested, or sent by overnight delivery service with signature upon delivery required.

§ 158.614 Appeal of proposed penalty.

Any issuer against which HHS has assessed a penalty under this Part may appeal that penalty in accordance with § 150.400 *et seq.*

§ 158.615 Failure to request a hearing.

If the issuer does not request a hearing within 30 days of the issuance of the notice described in § 158.613 of this subpart, HHS may assess the proposed civil monetary penalty indicated in such notice and may impose additional penalties as described in § 158.606 of this subpart. HHS must notify the issuer in writing of any penalty that has been assessed and of the means by which the issuer may satisfy the penalty. The issuer has no right to appeal a penalty with respect to which it has not requested a hearing in accordance with § 150.405 of this subchapter, unless the responsible entity can show good cause, as determined at § 150.405(b) of this subchapter, for failing to timely exercise its right to a hearing.

Dated: November 18, 2010.

Jay Angoff,

Director, Office of Consumer Information and Insurance Oversight.

Dated: November 18, 2010.

Kathleen Sebelius,

Secretary.

[FR Doc. 2010–29596 Filed 11–22–10; 8:45 am]

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FOR IMMEDIATE RELEASE
Thursday, October 21, 2010

Contact: HHS Press Office
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HHS Secretary Sebelius' Statement on NAIC Recommendations on Medical Loss Ratio

HHS Secretary Kathleen Sebelius released the following statement today regarding the National Association of Insurance Commissioners (NAIC) recommendations to HHS on medical loss ratio:

"We thank the NAIC for the recommendations, which the Commissioners finalized today on how best to implement the medical loss ratio policy, which will ensure consumers get the best value for their health care. We recognize that these recommendations are the result of many months of hard work by the Commissioners and their staff and we commend them for their open process and their responsible, thoughtful work.

"These recommendations are reasonable, achievable for insurers and will help to ensure insurance premiums are, for the most part, supporting health benefits for consumers. Not only do they ensure consumers receive better value for their health care dollar, they recognize special circumstances in different markets to preserve market stability and employee coverage as we transition to the new marketplace in 2014.

"The next step is for the Department of Health and Human Services to issue a medical loss ratio regulation that will provide clear guidance to stakeholders in the coming weeks.

"We will work quickly to promulgate this regulation, using the NAIC recommendations as a basis, because we believe these new policies will help ensure not only cost savings but higher quality care for consumers. We look forward to working closely with NAIC throughout the process."

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Note: All HHS press releases, fact sheets and other press materials are available at *http://www.hhs.gov/news*.

Last revised: January 03, 2011

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Insider intelligence on health care reform

OCIIO shows muscle at NAIC...Lobbying intensifies on credibility adjustments, broker fees...HHS releases Medicare ad budget...Layoffs strike at AHIP

By: SARAH KLIFF[1] & JENNIFER HABERKORN[2] on October 20, 2010 @ 5:05 AM

DRIVING YOUR (NAIC) DAY - A lobbying dash before the final vote on MLR regulation tomorrow. Commissioners and their staffs are rushing to finalize possible amendments, while lobby groups pull out last-ditch efforts on a number of key issues, including aggregation, confidence interval credibility adjustments and agent commissions.

--HHS PARACHUTES IN - Several top HHS officials arrived in Orlando Tuesday including OCIIO director Jay Angoff, who hinted (in a closed-door meeting with commissioners) that he approves of the NAIC process so far, several commissioners tell PULSE. "They're comfortable with our process and therefore comfortable [with] the recommendation that has come forward," NAIC President and West Virginia Insurance Commissioner Jane Cline tells PULSE. But other commissioners tell us they were frustrated Angoff couldn't answer specific questions about the regulation or the controversial issues (as the agency has been reluctant to do until NAIC formally hands over its work).

--SPOTTED - Liz Fowler, OCIIO deputy director of policy. Steve Larsen is expected on site today, Karen Pollitz spent yesterday with the Consumer Information Subgroup while Joel Ario held individual meetings with commissioners to talk Exchanges, an NAIC source tells PULSE. HHS's presence adds a level of intensity to the hallway discussions and the (rare) closed-door meetings around what to do with the aggregation and credibility issues, among other remaining issues in the MLR regulation.

--Angoff refused to speak with PULSE and an HHS spokeswoman in Washington declined to comment on why he came or what he said.

Good Wednesday morning from the NAIC

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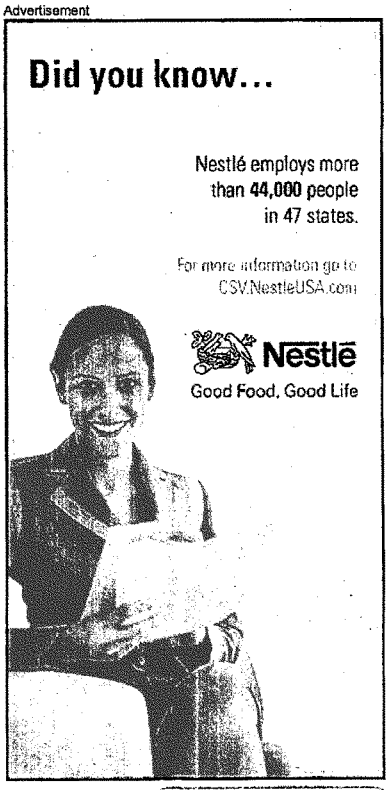

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Conference at the Orlando-area Gaylord Palms, where we've been quite impressed with the on-site alligators: http://twitpic.com/2z48ok[3]

LYRIC CONTEST – We have received a few Disney theme guesses – but guess again, PULSE wouldn't make it that easy! Keep your entries coming to **skliff@politico.com**[4] and **jhaberkorn@politico.com**[5] "I found myself in the riches: your eyes, your lips, your hair and Pulse was everywhere."

HHS: $3.3 MILLION TOTAL DROPPED ON ADS – The agency estimates it spent about $1 million to produce and air each of its three Medicare open enrollment ads that discuss health reform's benefits, GAO reported Tuesday. The report, a response to a House Republicans' query, also concluded that the ads "did not violate the publicity or propaganda prohibition," as had been alleged.

Kantar Media previously estimated for POLITICO that federal agencies had spent about $3 million on ad time alone just this month, although their estimate w ent up through October 14, whereas the HHS estimate cites as a source an October 8 phone conversation. GAO Report **http://bit.ly/cOkpo1**[6]

** A message from AdvaMed: Medical technology is one of America's most successful home-grown industries, supporting over 2 million good paying jobs in small towns and large communities across the country. **www.lifechanginginnovation.org**[7] **

DISNEY WORLD DISPATCH: MLR LOBBYING INTENSIFIES - Insurers, consumer groups and others are also stepping up ahead of the vote.

--**THE MOST CONTROVERSIAL ISSUE FEW UNDERSTAND** - There is a strong movement afoot to move the confidence interval credibility adjustments from 50 percent to 80 percent. Doing so would give insurers more latitude to reach the required MLR and not have to provide rebates. Commissioners who support the idea say insurers will need more latitude in the early years of MLR while they're still learning the system. Several commissioners PULSE spoke with – including Cline – say they haven't yet decided where they stand on the issue. Others say the ratio is fine where it is and they're reluctant to overturn the subgroup's earlier work. Milliman's latest report on credibility adjustments **http://politi.co/ak4bJx**[8]

--NAIC consumer representatives argue that moving the credibility figure will "gut" the MLR. "It would dramatically reduce the pressure on the insurance companies," Tim Jost, an NAIC consumer representative and Washington and Lee University Law School professor, tells PULSE. Several of the representatives tell PULSE that if the proposal passes, they would seriously consider asking HHS not to certify the MLR regulation.

--**AGENTS' COMMISSION ISSUE RESURFACES**— Expect an amendment to remove agents' commissions from the MLR calculation, which the

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agent/broker community has been working on all throughout the MLR process. NAIC's draft says the commissions belong in the administrative expense category. Agents/brokers don't want it in the calculation at all. This could be a tough one for many commissioners who say that if agents/brokers go out of business – because their commissions would decrease – they're going to get flooded with consumers inquiries and requests for help.

--Aggregation, whether to allow insurers to calculate MLR at the national or state level, is still an issue as well. It's also likely to come up as an amendment on Thursday.

SBA LIST WONT BACK DOWN – They launched a $50,000 radio ad campaign Tuesday attacking Rep. Steve Driehaus (D-Ohio) for his complaint with the Ohio Election Commission. "Steve Driehaus doesn't want you to know the truth...but you deserve to hear it," the spot alleges. "Steve Driehaus voted for taxpayer funding of abortion when he cast his vote for the health reform bill." The Commission has barred SBA List from erecting billboards claiming Driehaus voted to support taxpayer funded abortion because of concerns over the veracity of the claim.

AHIP LAYS OFF - The insurance lobby has let about 10 percent of its work force go, a move characterized by spokesman Robert Zirkelbach as "restructuring to meet the new advocacy and policy challenges facing our growing membership."

HHS TO STATES: NO WAIVERS UNTIL MLR IS DONE - Angoff told Iowa that HHS won't determine whether states can get MLR waivers until after the regulation is issued. The letter **http://politi.co/cDqnyJ**[9]

WHAT WE'RE READING:

Sen. Judd Gregg (R-N.H.) backs off of repealing health reform, the Hill reports. **http://bit.ly/9ZkoaY**[10]

Wendell Potter's NAIC dispatch for Huffington Post: "The insurance industry and other special interests are represented here by more than a thousand lobbyists. Like us, they are pacing the hallways waiting to pounce on the commissioners when they emerge from their 'regulator-to-regulator' meetings that are closed to the public and the media." **http://huff.to/bsl8cJ**[11]

ProPublica kicks off monster series examining doctors' ties to pharmaceutical companies. **http://bit.ly/dajTm9**[12]

WSJ takes HHS to task for offering waivers to "mini-med" plans. **http://bit.ly/aTqwSw**[13]

Orlando Sentinel: "Incoming House Speaker Dean Cannon of Winter Park has sent out a memo criticizing Gov. Charlie Crist's executive branch stewardship as the state starts phasing-in portions of the congressional health-care reform that task state agencies with enforcing federal mandates." **http://bit.ly/a11rhk**[14]

New website JunketSleuth investigating government

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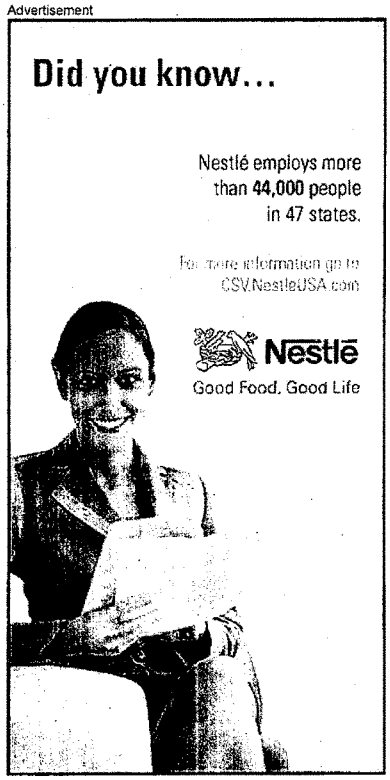

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agency travel finds HHS spent $530 million on trips between 2005 and 2009 (hat tip: Frates). **http://bit.ly/9mf1Y3**[15]

** A message from AdvaMed: A leading exporter of life changing innovation, America's medical technology companies contribute over $160 billion to the U.S. economy. Medical technology companies support more than 2 million good paying jobs in communities across the country—with salaries 40% higher than the national average. Create better patient outcomes, good paying jobs and a healthier economy. Support life changing innovation through policies that encourage continued medical progress and patient access to quality care. **www.lifechanginginnovation.org**[7] **

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As health care law rolls out, many insurers drop child-only policies

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BY JOHN DORSCHNER
THE MIAMI HERALD

As arguments about the constitutionality of health care reform reverberate through courtrooms in Florida and across the nation, two provisions that have already kicked in are sparking opposite reactions from insurers.

The requirement that children under 19 be granted insurance regardless of preexisting conditions has caused Blue Cross and Blue Shield of Florida and many other insurers to stop offering child-only coverage.

Insurers fear they will lose money because parents might sign up for coverage only when their children become sick. That is scheduled to change in 2014, when the law requires that virtually everyone have health insurance — a provision that a federal judge in Pensacola declared unconstitutional on Jan. 31.

But the provision requiring many employers to insure adult children up to age 26 through their parents' plans has glided into practice with virtually no opposition because health care consultants, insurance companies and major employers believe cost increases will be minimal and benefits widespread.

A key difference between the two provisions is that employers generally insist on a limited open enrollment period during which workers must sign up for coverage for themselves and their families, said Robert Zirkelbach, spokesman for America's Health Insurance Plans, the industry's trade group.

Federal regulators set no enrollment time limits for children younger than 19 to sign up for insurance under individual plans. If an uninsured child was diagnosed with a serious illness, the child's parents could sign up for insurance at that point — when costs are likely to be highest. That hurts insurers even more when parents haven't been paying into the system along the way.

"There's a powerful incentive to wait until after their children are sick" before signing up, Zirkelbach said.

Since that means families might tend not buy insurance for healthy children, the pool of insured children would probably have an inordinate percentage of those who are sick, said Randy Kammer, BCBSF's vice president of regulatory affairs. That would drive up insurance costs for everyone.

BCBSF still covers all children when families sign up for policies, but has stopped offering the individual child policies. Kammer said she has heard that insurers in 29 states have stopped offering kids-only policies. Zirkelbach agreed the stoppage is widespread, though he didn't have exact numbers.

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The Miami Herald

The Washington Post

Major health insurers to stop offering new child-only policies

By N.C. Aizenman
Monday, September 20, 2010; 10:46 PM

Some of the country's most prominent health insurance companies have decided to stop offering new child-only plans, rather than comply with rules in the new health-care law that will require such plans to start accepting children with preexisting medical conditions after Sept. 23.

The companies will continue to cover children who already have child-only policies. They will also accept children with preexisting conditions in new family policies.

Nonetheless, supporters of the new health-care law complain that the change amounts to an end run around one of the most prized consumer protections.

"We're just days away from a new era when insurance companies must stop denying coverage to kids just because they are sick, and now some of the biggest changed their minds," Ethan Rome, executive director of Health Care for America Now, an advocacy group, said in a statement. "[It] is immoral, and to blame their appalling behavior on the new law is patently dishonest."

Three insurers - WellPoint, Cigna and CoventryOne - all cited uncertainty in the health insurance market for their decisions. That incertitude and the resulting decision of other insurers to drop their child-only plans, according to WellPoint spokeswoman Kristin Binns, "has created an unlevel competitive environment."

CoventryOne spokesman Matthew D. Eyles said that the insurer was facing "unique challenges that could undermine our ability to offer value and meet our continued obligations to existing policyholders."

But officials of the Obama administration said the move contradicted a letter from the leader of one of the insurance industry's most important trade groups after the law's adoption in March. Karen Ignagni, president of America's Health Insurance Plans, expressed support for the law's provisions concerning children with preexisting conditions and promised to "fully comply" with them.

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ONE HUNDRED ELEVENTH CONGRESS

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ROBERT E. LATTA, OHIO

October 8, 2010

The Honorable Henry A. Waxman
Chairman
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Waxman:

We write to you today to request a hearing on reports that health insurers will no longer provide child-only insurance policies. As reported in *Politico, The Hill,* and *The Washington Post*, health plans in at least four states have announced that they are dropping children's coverage before new rules created by the Patient Protection and Affordable Care Act (PPACA) forbid those insurers from turning down children with pre-existing conditions. We know this is an important issue to you. Last week you wrote to Aetna Health of California urging the company to "reconsider the unfortunate decision by your company…to suspend the sale of child-only health insurance policies in California."

We believe that a hearing should address whether the PPACA regulations and requirements have made providing this type of insurance too costly and financially unstable. The *Washington Post* reported that insurers have "cited uncertainty in the health insurance market for their decisions" that, according to a Wellpoint spokesperson, "has created an unlevel competitive environment." The Vice President of Public Policy at Cigna told *Politico*, "We would love to stay in the market….you can't have guaranteed issue for this population and be the only one out there. You can't make it work financially."

If industry concerns are true, this is an extremely troubling effect of PPACA. Through PPACA, the Majority may have created market conditions where some of the most vulnerable members of our society will no longer be able to obtain private health coverage. While some children will still be able to enroll in family plans, the new law seriously limits the options available to American families. We must act quickly to learn whether this problem can be solved, and we believe a hearing involving all interested parties would enable everyone to determine how best to move forward.

Sadly, it appears this situation might have been preventable. Kansas Insurance Commissioner Sandy Praeger, who is Vice Chair of the Health Insurance and Managed Care Committee at the National Association of Insurance Commissioners, said: "This is one of those issues, had there been a [House-Senate] conference committee, it probably would have been worked out." As you are well aware, there was not a conference committee on PPACA because doing so may have jeopardized the Majority's ability to force its purely partisan bill on the American people.

With every passing day, the damaging effects of the PPACA become more apparent. Since passage, the law has failed to lower costs, resulted in an increased projection for national health expenditures, and caused private insurers to announce premium increases. And now we learn that the law will make fewer options available to children. Yet, since passage, this Committee still has yet to hold a single hearing on the law. We respectfully request that you end the Majority's practice of ignoring the effects of the law and schedule a hearing on this issue as soon as possible. Considering that the letter to Aetna was signed by you and four other Committee Members, we believe there is ample support for such a hearing.

Sincerely,

Joe Barton
Ranking Member

John Shimkus
Ranking Member
Subcommittee on Health

Michael Burgess
Ranking Member
Subcommittee on Oversight and Investigations

cc: The Honorable Henry A. Waxman, Chairman

The Honorable Frank Pallone, Chairman
Subcommittee on Health

The Honorable Bart Stupak, Chairman
Subcommittee on Oversight and Investigations

STATE OF TENNESSEE
DEPARTMENT OF FINANCE AND ADMINISTRATION
BENEFITS ADMINISTRATION
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Dave Goetz
COMMISSIONER

Laurie Lee
EXECUTIVE DIRECTOR

Date: September 17, 2010

To: Mr. James Mayhew

From: Laurie Lee, Executive Director, Benefits Administration, Department of Finance & Administration, State of Tennessee

Regarding: State of Tennessee Waiver Request of the Annual Limits Requirement of PHS Section 2711

I. Introduction and Background

The State of Tennessee seeks a waiver relating to annual limits for grandfathered health insurance plans for a state sponsored limited benefit plan called CoverTN. This waiver is sought pursuant to the authority granted the Secretary of Health and Human Services in Section 2711(a)(2) and the interim final regulations published on June 28, 2010, (codified as 26 CFR §54.9815-2719T; 29 CFR § 2590.715-2719; and 45 CFR §147.126) and in accordance to the guidance provided in the memo dated September 3, 2010, by Mr. Steve Larsen, Director, Office of Oversight. The waiver for the 2011 plan year (i.e., January 1, 2011 to December 31, 2011) would also apply to all new CoverTN policies that we execute with new members (including but not limited to spouses of current enrollees and new employees of participating employers) with an effective date on or after September 1, 2010.

During the 2006 legislative session of the Tennessee General Assembly, Governor Phil Bredesen proposed and the Tennessee General Assembly passed Public Chapter 867, which created a limited benefit health insurance plan for uninsured working Tennesseans called CoverTN. Currently funded at over eighteen million dollars for the State's 2010-2011 fiscal year (July 1 to June 30), the plan serves approximately twenty thousand members.

CoverTN's mission is to provide affordable, basic health insurance for small businesses, individuals, the self-employed and the recently unemployed that covers the most frequently used services. The eligibility criteria for the program varies slightly by enrollment category, but is generally open to individuals who do not qualify for Medicaid

yet earn less than two-hundred and fifty percent of the federal poverty level and who are between the ages of 19 and 64. Other key features of CoverTN include shared responsibility, first dollar coverage (no deductible), and portability. The premium costs are shared between the state, the employer and the employee—with the state paying one-third. BlueCross BlueShield of Tennessee, selected through a competitive bidding process, offers the fully-insured program for the state.

CoverTN has been a remarkable success with enrollment climbing steadily since its inception. The plan is affordable. Monthly premiums average less than sixty dollars a month for an enrollee with the employer and the state covering the remaining two-thirds in most instances. The plan is efficient, with a medical loss ratio for 2010 projected at 87.9%. Retained enrollment has averaged 79%. Most importantly, the plan has provided most of the coverage that most of the enrollees need, with enrollees hitting the annual benefit limits in strikingly low percentages.

Based on President Obama's commitment to permit individuals to keep their health insurance coverage if they are satisfied with it, it is our desire to continue to offer CoverTN through December 31, 2013. The program would then cease with the introduction of products and funding through the state insurance exchange.

We have carefully reviewed the *Patient Protection and Affordable Care Act, the Interim Final Rules for Group Health Plans and Health Insurance Coverage Relating to Status as a Grandfathered Health Plan, and the Interim Final Rules on Preexisting Condition Exclusions, Lifetime and Annual Limits, Rescissions, and Patient Protections*. We have determined that, working with BlueCross BlueShield of Tennessee, we can meet all of the requirements of the law and subsequent regulations with the exception of the annual limits.

In Par. 5. Section 54.9815-2711T (d)(3) of the *Interim Final Rules on Preexisting Condition Exclusions, Lifetime and Annual Limits, Rescissions, and Patient Protections*, a waiver authority is provided to the Secretary of Health and Human Services relating to annual limits "...for a group health plan or health insurance coverage that has an annual dollar limit on benefits below the restricted annual limits provided under paragraph (d)(1) of this section if compliance with paragraph (d)(1) of this section would result in a significant decrease in access to benefits under the plan or health insurance coverage or would significantly increase premiums for the plan or health insurance coverage."

We believe CoverTN meets both of these criteria. The following section presents the information required for a waiver in your office's memorandum dated September 3, 2010, titled Insurance Standards Bulletin Series—INFORMATION on the subject OCIIO Sub-Regulatory Guidance (OCIIO 2010 – 1): Process for Obtaining Waivers of the Annual Limits Requirements of PHS Act Section 2711.

Required Information

1. *The terms of the plan or policy form(s) for which a waiver is sought.*

Basic eligibility and benefits information follows. Member handbooks for the 2011 plan year are attached. More detailed information can be accessed at: http://www.bcbst.com/health-plans/cover-tennessee/covertn/

a. CoverTN Eligibility

CoverTN is designed for uninsured Tennesseans, at least 19-years-old, who work for qualifying small businesses, are self-employed or work but do not have health insurance. In addition, those who have recently become unemployed or had work hours reduced may also be eligible. The spouse of a CoverTN member may also be eligible for coverage under CoverTN.

Employers
- Located in Tennessee
- 50 or fewer full-time equivalent employees
- 50% of employees earn $55,000 or less per year
- Business offers plan to all employees
- Business must pay at least one-third share of premium
- Business has not offered employer-sponsored insurance in the previous six months or, if offered, employer has not paid 50% or more of the employee's premiums*

Employees at Participating Employers
- A U.S. citizen or qualified legal alien
- 19-years-old or older
- Works an average of at least 20 hours per week
- Has not had health insurance in the previous six months (individual or group coverage)*
- Must agree to pay one-third of the premium

Employees at Non-Participating Employers
- Tennessee resident for six months
- A U.S. citizen or qualified legal alien
- 19-years-old or older
- Works an average of 20 hours per week
- Earns $55,000 or less per year
- Has not had health insurance in the previous six months (individual or group coverage)*
- Must agree to pay two-thirds of the premium

Self-Employed Eligibility
Self-employed individuals are eligible to apply for CoverTN. Self-employed means that you are in business for yourself or are an independent contractor and your business does not have any employees. Self-employed applicants, to be eligible for CoverTN, must be

able to show income from the business equal to at least 20 hours per week at minimum wage, or about $6,800 per year.
• Tennessee resident for six months
• A U.S. citizen or qualified legal alien
• 19-years-old or older
• Works an average of 20 hours per week
• Earns $55,000 or less per year in adjusted gross income
• Has not had health insurance in the previous six months (individual or group coverage)*
• Must agree to pay two-thirds of the premium

Tennesseans Between Jobs
• Worked at least one 20-hour week in the previous six months or had work hours reduced to less than 20 hours per week
• Unemployed in the previous six months
• Earned $55,000 or less per year
• Tennessee resident for six months
• A U.S. citizen or qualified legal alien
• 19-years-old or older
• Must agree to pay two-thirds share of the premium
• Does not currently have health insurance

Coverage for Spouses
Spouses of CoverTN participants may be eligible for coverage if they meet the following eligibility requirements. An employer is not obligated to contribute to the spouse's premium and employees must pay whatever portion of the spouse's premium the employer does not cover. An employee must enroll in CoverTN in order for the spouse to be eligible.
• Tennessee resident for six months (exceptions apply)
• A U.S. citizen or qualified legal alien
• 19-years-old or older
• Has not had health insurance in the previous six months
• Must agree to pay two-thirds share of the premium

Coverage for Children
Children of CoverTN participants are not eligible for coverage under this program but may be eligible for coverage through CoverKids, the state's SCHIP program.

* Exception to the go-bare requirement may apply

b. Benefits

CoverTN is a limited-benefit health plan designed to cover the medical, pharmacy and behavioral health services needed by most people.

Offered by BlueCross BlueShield of Tennessee, CoverTN allows individuals to choose from two different plans — Plan A and Plan B. CoverTN is designed to provide coverage

for the most needed services and the plans have no deductible. Members pay low co-pays for medical services.

CoverTN has a 12-month pre-existing condition waiting period. No benefits will be paid for conditions that are present during the immediate six months prior to enrolling in CoverTN for the first 12 months of the policy. After the member has been enrolled in CoverTN for 12 months, CoverTN will begin covering these conditions.

CoverTN benefits include coverage for doctor visits, emergency treatment, inpatient and outpatient care, as well as pharmacy coverage. The chart below shows both plan options, including co-pays.

CoverTN members who become pregnant will remain enrolled in CoverTN but will receive maternity benefits and pregnancy-related services through CoverKids HealthyTNBabies or TennCare, the State's Medicaid program.

Benefit	Plan A	Plan B
Primary Care Doctor Visits *	$15 copay Up to 12 visits per year	$20 copay Up to 12 visits per year
Preventive Care	100% one free adult physical per year one free well woman visit per year (included in the 12 primary care visits per year)	100% one free adult physical per year one free well woman visit per year (included in the 12 primary care visits per year)
Preventive Mammogram	100% included with one well woman visit per year	100% included with one well woman visit per year
Specialist Visits	$15 copay; up to five visits per year	$20 copay; up to six visits per year
Inpatient	$100 copay; $10,000 annual maximum	$100 copay; $15,000 annual maximum
Emergency	two visits per year	two visits per year
Outpatient Surgery	$25 copay; two surgical visits per year	$25 copay; two surgical visits per year
Outpatient Diagnostic	$25 copay; three non-surgical visits per year	$25 copay; three non-surgical visits per year
Durable Medical Equipment (prosthetics, medical supplies)	100% $500 annual maximum	Not covered
Prescription Drugs	$10 copay generic Quarterly maximum $250	$8 copay generic Quarterly maximum $75
Insulin and Diabetic Test Strips	$10 brand copay; Does not count against the pharmacy maximum	$10 brand copay; Does not count against the pharmacy maximum
Diabetic Supplies (needles, syringes, lancets, alcohol swabs)	$5 copay	$5 copay

* Must see a primary care physician (PCP) - A PCP includes Internal Medicine, OB/GYN, Family Practice, General Practice and Nurse Practitioner.

Both plans have a maximum annual benefit limit of $25,000 per year. Individuals who reach the annual benefit maximum during the year are responsible for all expenses exceeding $25,000 until the next plan year begins. Members exceeding the $25,000 annual benefit maximum will continue to receive network discounts on their medical services and prescription drugs when they use network providers and pharmacies.

2. *The number of individuals covered by the plan or policy form(s) submitted.*

CoverTN had 20,205 enrollees covered and 20,373 approved for coverage as of August 31, 2010.

3. *The annual limit(s) and rates applicable to the plan or policy form(s)submitted.*

CoverTN, as a limited benefit plan, has a maximum annual benefit limit of $25,000 per year. Individuals who reach the annual benefit maximum during the year are responsible for all expenses exceeding $25,000 until the next plan year begins. Members exceeding the $25,000 annual benefit maximum continue to receive network discounts on their medical services and prescription drugs when they use network providers and pharmacies.

CoverTN's monthly premiums range from $112.59 to $327.09 with an average monthly premium of $176, the cost of which is shared between the State of Tennessee, the employer, and the enrollees, with the State paying one-third. Premiums are based on age, weight, and tobacco use with discounts provided in the latter two categories if the enrollee does not use tobacco and their weight is below a BMI of 30.

4. *A brief description of why compliance with the interim final regulations would result in a significant decrease in access to benefits for those currently covered by the plans or policies, or significant increase in premiums paid by those covered by such plans or policies, along with any supporting documentation.*

Given the current level of funding in the State's budget, absent a waiver CoverTN will have to disenroll some 20,000 Tennesseans at midnight on December 31, 2010, who were not served by the commercial market in Tennessee prior to their enrollment. It seems likely that the majority of these individuals would become uninsured. If CoverTN were to change its benefit structure to meet the annual limits specified in the interim final rules, we estimate that the monthly premiums would increase 86%. As this group of the insured market is highly price-sensitive, this level of increase would result in thousands of current members dropping coverage. Disenrollment of twenty thousand individuals before the state insurance exchange is in place or a huge percentage increase in costs is clearly undesirable. We seek to avoid this outcome with this waiver request.

5. *An attestation, signed by the plan administrator or Chief Executive Officer of the issuer of the coverage, certifying 1) that the plan was in force prior to September 23, 2010; and 2) that the application of restricted annual limits to such plans or policies would result in a significant decrease in access to benefits for those currently covered by such plans or policies, or a significant increase in premiums paid by those covered by such plans or policies.*

Please see enclosed attestation.

Thank you very much for your attention to this matter. Please do not hesitate to contact me at [redacted] should you require any addition information.

STATE OF TENNESSEE
DEPARTMENT OF FINANCE AND ADMINISTRATION
BENEFITS ADMINISTRATION
312 Eighth Avenue North
Suite 2600 William R. Snodgrass Tennessee Tower
Nashville, Tennessee 37243
Phone (615) 741-4517 or (866)-576-0029
FAX (615) 253-6556

Dave Goetz
COMMISSIONER

Laurie Lee
EXECUTIVE DIRECTOR

Date: September 17, 2010

To: Mr. James Mayhew

From: Laurie Lee, Executive Director, Benefits Administration, Department of Finance & Administration, State of Tennessee

Re: State of Tennessee Waiver Request of the Annual Limits Requirement of PHS Section 2711, Attestation in Response to Requirement Number 5.

1. This is to certify that CoverTN was in existence with policies in force prior to September 23, 2010.

2. This is to certify that the application of the restricted annual limits specified in the *Interim Final Rules on Preexisting Condition Exclusions, Lifetime and Annual Limits, Rescissions, and Patient Protections* to CoverTN would result in a significant decrease in access to benefits for those currently covered by CoverTN.

3. This is to certify that a significant increase in premiums would be required for those covered by CoverTN without the granting of the requested waiver.

Signed: Laurie Lee
Laurie Lee
Executive Director

Date: 9/17/2010

Ohio | Department of Insurance

Ted Strickland, Governor
Mary Jo Hudson, Director

50 West Town Street
Third Floor – Suite 300
Columbus, OH 43215-4186
(614) 644-2658
www.insurance.ohio.gov

November 23, 2010

James Mayhew
Office of Consumer Information and Insurance Oversight
Office of Oversight
Room 737-F-04
200 Independence Avenue SW
Washington, D.C. 20101

Re: Waiver of Annual Limits Restriction for 2010

Dear Mr. Mayhew,

The Ohio Department of Insurance (the Department) hereby respectfully requests a waiver of the requirements in Section 2711, of the Patient Protection and Affordable Care Act,(Affordable Care Act) which restrict annual limits to certain set minimum levels for essential health benefits for the policies which form its' HIPAA alternative mechanism. The Department is requesting a waiver for the prescribed policy forms created under statutory authority in Ohio Revised Code Section ("R.C.") 3924.10 et seq. by the Ohio Reinsurance Board. These policies, known as Ohio's Basic and Standard policy forms, are required to be offered by all carriers operating in the individual market to insure those who have been denied coverage elsewhere, including Federally Eligible Individuals (FEIs) and others who do not meet that definition, pursuant to R.C. 3923.58 and R.C. 3923.581, and also pursuant to R. C. Section 3923.122 as conversion policies offered to FEIs. Carriers and related data concerning these policies are attached.

The Department has determined that requesting a waiver on behalf of the many insurers in our individual market that issue Basic and Standard policies would result in a more organized HIPAA alternative mechanism market in Ohio and fewer individual requests for waiver that must be reviewed by HHS. We are applying for this waiver because we are concerned that Ohioans not be denied access to coverage due to the impact on premium that an increase in benefits may bring. At the same time, we support the Affordable Care Act goal of requiring policies to include certain minimum benefits to better protect consumers, therefore, if granted this waiver for our Basic and Standard plan design, we intend to require all of our carriers to offer both the current coverage which does not meet the minimum annual limit design as well as coverage that does meet the Affordable Care Act. In this way, Ohio consumers will have a choice of a lower cost policy with a $50,000 annual maximum or a policy with a higher premium and a $750,000 annual maximum from each company that offers Basic and Standard policies, whether to comply with open enrollment or conversion statutes.

1. The terms of the Basic and Standard policies for which we seek a waiver are attached.

2. The number of individuals covered by the policies: a canvass of Ohio insurers as of June 2010 reported that there were 1,286 lives covered by Basic or Standard policies for open enrollment. For calendar year 2009, Ohio insurers reported 2,519 lives covered by the Basic or Standard policy forms or an equivalent coverage for conversion. We estimate 80% of conversion policies are statutorily mandated offerings to FEIs.

3. The annual limit(s):

The calendar year maximum for a Basic plan per insured is $50,000. There are other internal, per service maximums for both plans listed on page 2 and 3 of the attachment, including:

a) Mental, nervous ($2,000 inpatient and $550 outpatient);
b) Organ transplant ($100,000);
c) Nursing or convalescent home ($5,000);
d) Outpatient prescription drugs ($2,500).

Not allowing a blanket waiver for all companies for Basic and Standard Open Enrollment and Group Conversion options would lead to an unlevel playing field. Some companies will seek waivers while others won't. Ultimately, adverse selection for some plans will result and premiums will increase even more for those plans, causing market disruption.

At this point, most carriers have not yet filed for a rate increase. We have approved four filings to date which have increase amounts attributable to PPACA mandates quantified. The average amounts of increase solely attributable to PPACA for Basic and Standard Open Enrollment for the four filings are as follows:

Basic: 11.3% Standard: 7.7%

Sample monthly premium rates for non-smoker residents in Columbus, OH, for the four carriers by Open Enrollment plan type:

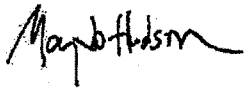
Carrier	Plan	Male Age 55	Female Age 55
A	Basic	$471	$509
B	Basic	$697	$694
C	Basic	$866	$934
D	Basic	$1,204	$1,251
A	Standard	$544	$588
B	Standard	$947	$944
C	Standard	$1,011	$1,086
D	Standard	$1,699	$1,766

As stated above, we are requesting a waiver because we are concerned that the increase in the annual limit will cause a significant increase in premium for those covered by the Basic and Standard plans which tend to have high premiums already because they are sold on a guaranteed issue basis to people with significantly worse than average health status. These policies are also used as conversion policies for both FEIs by law and others who are eligible for conversion when leaving their group health policy. If conversion policy premiums are increased due to PPACA requirements, we have the same concern. We believe granting a waiver for Open Enrollment without also granting it for conversion would shift enrollment from the conversion market and fill Open Enrollment quotas. This would result in fewer policies of this type being available to persons unable to get basic health insurance coverage by any other means.

4. The below signer certifies and attests that, to their knowledge based on reports by the issuers of such Ohio policies: 1) 1,286 lives were covered by Basic and Standard Open Enrollment Policies and 2,519 lives were covered by Basic and Standard Conversion Policies or an equivalent coverage prior to September 23, 2010; and 2) the application of restricted annual limits to such policies would result in a significant increase in premiums. In addition, the absence of a blanket waiver for both the open enrollment and conversion use of these Basic and Standard forms would likely result in making this coverage unavailable to a number of applicants that would otherwise be able to obtain it.

Thank you for your assistance with this matter. Please contact Kathy Melton at [redacted] or [redacted] if you have any questions.

Best regards,



Mary Jo Hudson
Director

OHIO OPEN ENROLLMENT ENROLLEE DATA
(PER JUNE 2010 CANVAS OF CARRIERS REQUIRED TO OFFER OPEN ENROLLMENT COVERAGE)

NAIC	COMPANY NAME	NUMBER OF COVERED LIVES		TOTALS
		BASIC	STANDARD	
60054	Aetna Life Ins Co	70	161	231
97179	American Medical Security Life Ins C	0	2	2
71773	American Natl Life Ins Co Of TX	1	0	1
60836	American Republic Ins Co	2	3	5
80799	Celtic Ins Co	0	1	1
10345	Community Ins Co	27	65	92
77828	Companion Life Ins Co	0	0	0
81973	Coventry Hlth & Life Ins Co*	6	12	18
62324	Freedom Life Ins Co Of Amer	0	3	3
62286	Golden Rule Ins Co	14	11	25
95677	Health Plan the Upper OH Valley In	42	15	57
73288	Humana Ins Co	11	35	46
26581	Independence American Ins Co	2	0	2
65080	John Alden Life Ins Co	0	0	0
95204	Kaiser Foundation Health Plan of Ohio	95	252	347
65781	Madison National Life Ins Co	3	1	4
77216	Mckinley Life Ins Co	18	7	25
29076	Medical Mut Of OH	49	25	74
57991	Mennonite Mut Aid Assn	3	0	3
66087	Mid West Natl Life Ins Co Of TN	0	0	0
98205	National Found Life Ins Co	0	0	0
67628	Pekin Life Ins Co	7	154	161
68462	Reserve Natl Ins Co	0	0	0
86355	Standard Life & Accident Ins Co	0	0	0
69078	Standard Security Life Ins Co Of NY	1	3	4
10649	Summa Ins Co Inc	125	29	154
69477	Time Ins Co	5	8	13
70629	World Ins Co	0	18	18
	TOTALS:	481	805	1286

06/18/2010 - CDWright

2009 OHIO CONVERSION HEALTH PLAN DATA
AS REPORTED BY CARRIERS IN THE OHIO ANNUAL REPORT OF HEALTH INSURANCE BUSINESS
(NOT INDEPENDENTLY VERIFIED)

NAIC	COMPANY NAME	POLICIES	LIVES	PREMIUM	CLAIMS	DIRECT LOSS RATIO
95109	AETNA HEALTH INC (PA)	53	54	527,356	894,799	169.7
60054	AETNA LIFE INSURANCE COMPANY	314	331	803,492	674,708	84.0
90611	ALLIANZ LIFE INSURANCE COMPANY OF NORTH AMERICA	1	1	3,528	-1,935	-54.8
60305	AMERICAN COMMUNITY MUTUAL INSURANCE COMPANY	1	1	4,051	39	1.0
60836	AMERICAN REPUBLIC INSURANCE COMPANY	4	5	41,593	7,556	18.2
80799	CELTIC INSURANCE COMPANY	12	12	136,628	40,424	29.6
10345	COMMUNITY INSURANCE COMPANY	1,217	1,256	11,490,619	10,437,810	90.8
62308	CONNECTICUT GENERAL LIFE INSURANCE COMPANY	4	9	185,773	250,457	134.8
62375	CONSUMERS LIFE INSURANCE COMPANY	3	4	32,598	15,710	48.2
62413	CONTINENTAL ASSURANCE COMPANY	2	3	7,416	6,203	83.6
13935	FEDERATED MUTUAL INSURANCE COMPANY	3	3	40,242	128,966	320.5
69140	FIRST ALLMERICA FINANCIAL LIFE INSURANCE COMPANY	1	1	9,199	307,682	3,344.7
62286	GOLDEN RULE INSURANCE COMPANY	134	138	1,236,631	2,065,140	167.0
64246	GUARDIAN LIFE INSURANCE COMPANY OF AMERICA	10	14	41,888	52,172	124.6
95677	HEALTH PLAN OF UPPER OH VALLEY INC	55	65	665,400	969,945	145.8
95348	HUMANA HEALTH PLAN OF OHIO INC	3	46	157,371	314,234	199.7
73288	HUMANA INSURANCE COMPANY	18	18	272,137	1,169,534	429.8
95204	KAISER FOUNDATION HEALTH PLAN OF OHIO	162	166	1,634,061	1,350,431	82.6
77216	McKINLEY LIFE INSURANCE COMPANY	56	83	375,627	661,832	176.2
95828	MEDICAL HEALTH INSURING CORPORATION OF OHIO	23	32	212,160	89,531	42.2
29076	MEDICAL MUTUAL OF OHIO	120	134	2,807,738	2,948,635	105.0
97055	MEGA LIFE AND HEALTH INSURANCE COMPANY, THE	1	1	6,325	3,429	54.2
66168	MINNESOTA LIFE INSURANCE COMPANY	1	1	1,780	0	0.0
95189	PARAMOUNT CARE INC	40	40	401,390	141,033	35.1
68241	PRUDENTIAL INSURANCE COMPANY OF AMERICA	27	33	21,433	25,165	117.4
25178	STATE FARM MUTUAL AUTOMOBILE INSURANCE COMPANY	5	5	49,182	56,868	115.6
60016	THP INSURANCE COMPANY INC	3	3	28,343	22,151	78.2
69744	UNION LABOR LIFE INSURANCE COMPANY, THE	1	1	235	0	0.0
95186	UNITEDHEALTHCARE OF OHIO INC	1	59	682,799	460,879	67.5
	TOTALS	2,275	2,519	$ 21,876,995	$ 23,093,398	106%

The following carriers have conversion products filed with ODI but did not report any conversion business in the 2009 Ohio Annual Report of Health Insurance Business:

NAIC	COMPANY NAME
19720	American Alt Ins Corp
71773	American Natl Life Ins Co Of TX
81973	Coventry Hlth & Life Ins Co
57991	Everence Assn Inc
74209	Everence Ins Co
71218	Grange Life Ins Co
26581	Independence Amer Ins Co
11518	Paramount Ins Co
61271	Principal Life Ins Co
69078	Standard Security Life Ins Co Of NY
10649	Summa Ins Co Inc
95202	Summacare Inc
79413	UnitedHealthcare Ins Co

11/8 Dup

November 1, 2010

Via email: healthinsurance@hhs.gov
and First Class Mail

HHS, Office of Consumer Information and Insurance Oversight, Office of Oversight
Attention James Mayhew
Room 737-F-04
200 Independence Ave. SW
Washington, DC 20201

Re: Waiver Application for the Rice Food Markets, Inc. Group Health Plan, Part-Time Union Employees ("Plan")

Dear Sir:

We respectfully request a waiver from the new restricted annual limit requirements for the Plan. The Plan has a plan year ending on December 31st and is offered to part-time union employees of Rice Food Markets, Inc. (the "Company") for the plan year ending December 31, 2010. The Company intends to continue the Plan for the plan year beginning January 1, 2011, but only if this waiver application is approved. This application is being submitted no less than 30 days before the beginning of the January 1, 2011 plan year.

1. The terms of the Plan for which a waiver is sought:

Please see the attached schedule of benefits for the Plan.

2. The number of individuals covered by the Plan:

There are currently 36 employees covered by the Plan.

3. The annual limit(s) and rates applicable to the Plan:

The Plan has a $15,000 annual limit on the dollar value of all benefits. The annual required contribution for employee-only coverage is $507.00. Dependent coverage is not offered under the Plan.

4. A brief description of why compliance with the interim final regulations would result in a significant decrease in access to benefits for those currently covered by the Plan, or significant increase in premiums paid by those covered by the Plan, along with any supporting documentation:

If the Plan's annual limit was increased from $15,000 to $750,000 for the plan year beginning January 1, 2011, and the other benefits under the Plan remained the same, the cost of the Plan would increase over 1000% in 2011. Due to adverse business conditions, the Company cannot afford to pay this 1000% increase and cannot reasonably expect part-time, union hourly employees who are covered by the Plan to be able to afford to pay a 1000% increase in their premiums. Therefore, the Company would be forced to terminate the Plan if this waiver is not granted for the 2011 plan year. In that event, the part-time union employees covered under the Plan would lose eligibility for any Company-provided health coverage.

In summary, if the restricted annual limit of $750,000 is applied to the Plan, the Company must either (1) terminate the Plan, resulting in the total loss of coverage for all covered employees or (2) increase employee premiums by 1000%. We thus respectfully request that you approve this application.

5. Required attestation:

As Plan Administrator of the Plan, I hereby certify that (1) the Plan was in force prior to September 23, 2010 (as well as prior to March 23, 2010) and (2) the application of restricted annual limits to the Plan would result in a significant decrease in access to benefits for those currently covered by the Plan, or a significant increase in premiums paid by those covered by the Plan.

By: _____
Name: Bruce M. Levy
Title: Executive Vice President, Plan Administrator
[redacted]

1/24/11 poss dup

Littler Mendelson, P.C.
1100 Superior Avenue
20th Floor
Cleveland, OH 44114

Neal B. Wainblat
[redacted]

January 20, 2011

Via Express Mail & E-Mail

Mr. James Mayhew
HHS, Office of Consumer Information and Insurance Oversight
Office of Oversight, Room 737-F-04
200 Independence Avenue, SW
Washington, DC 20201

Re: Ohio Conference of Teamsters & Industry Health & Welfare Fund/ Application for Waiver from the Restricted Annual Limits Set Forth in the Interim Final Regulations

Dear Mr. Mayhew:

Enclosed is an Application for Waiver from the Restricted Annual Limits Set Forth in the Interim Final Regulations and an Attestation Form for the Ohio Conference of Teamsters & Industry Health & Welfare Fund.

If there are any questions or if I can be of assistance to obtain favorable approval of the application, please call.

Very truly yours,

Neal B. Wainblat

Neal B. Wainblat

NBW/em
Enclosures

cc: Ohio Conference of Teamsters & Industry Health & Welfare Fund

Firmwide:99750845.1 056041.1000

Application for a Waiver From the Restricted Annual Limits Set Forth in the Interim Final Regulations

This application includes information in response to the five points outlined in the September 3, 2010 Insurance Standards Bulletin – Process for Obtaining Waivers of the Annual Limits Requirements of PHS Act Section 2177.

1. The terms of the plan or policy forms(s) for which a waiver is sought.

   A Summary list with the three benefit plans which a waiver is requested with the existing lifetime maximum, the required annual limit with waiver approval, number of retired or total and permanently disabled members covered by each benefit plan, the monthly participant contribution rate, the renewal monthly participant contribution rate, the monthly participant contribution rate (if the $750,000 annual limit was applied), and the percentage increase (if the $750,000 annual limit was applied), is enclosed.

2. The number of individuals covered by the plan or policy forms(s) submitted.

   The number of retirees or totally and permanently disabled members covered by each plan or policy form(s) submitted is enclosed on the Summary list.

3. The annual limit(s) and rates applicable to the plan or policy forms(s) submitted.

   The lifetime maximum appears in the Summary list. The annual maximum effective March 1, 2011 will equal the existing lifetime maximum set forth on the enclosed summary list. The percentage cost in increase in member cost needed to pay for an increase in the annual limit from its existing amount to $750,000 if this waiver request is not approved is set forth on the enclosed summary list.

4. A brief description of why compliance with the interim final regulations would result in a significant decrease in access to benefits for those currently covered by such plans or policies, or significant increase in premiums paid by those covered by such plans or policies, along with any supporting documentation.

   The Fund is a multiemployer health and welfare fund providing benefit coverage to employees working primarily in the warehouse or transportation retail industry. The benefit plans for retirees or totally and permanently disabled members provide access to comprehensive benefit coverage. The active employee plans have been designed to be paid by employer contributions with small or no employee contributions. This allows coverage to be provided to a high percentage of regular participant employees in the bargaining unit. No waiver is being requested this year for the active employees plans.

The Board of Trustees presently provides retiree benefit coverage to retirees or totally and permanently disabled participants at the subsidized cost of $214 per month. As shown on the attached chart, if the waiver of the $750,000 annual limit is not granted, then the retiree contribution will have to increase from $214 per month to either $314.26 or $342.12 per month depending on the Plan. That is a significant increase.

Even without any changes to the lifetime and annual limits other than changing lifetime limits to annual limits, the Fund will be facing increased costs from implementing other requirements of the Patient Protection and Affordable Care Act. Benefit plans generally provide dependent coverage and additional children up to age 26 will be enrolled effective March 1, 2011 at no cost to the employee, retirees or child for employees who either already have family coverage or who presently do not contribute for coverage. Also, there will be no preexisting condition exclusion for children under age 19. Increasing annual limits will result in the Fund paying significantly more out in benefits. As a result, employers will be required to significantly increase their contributions to the Fund. Since an employer contribution increase for retirees would be difficult to achieve in this economy, the Board of Trustees will need to address the need for increasing contributions with a combination of the following approaches to offset the increased cost:

A. Require significant increase in the amount of retiree and disabled employee contributions which will make coverage unaffordable resulting in a significant decrease in access for the individuals currently covered by the benefit plans.

B. Require that there be an increase in deductibles, retiree or disabled employee copayments and out-of-pocket maximums which will result in a significant decrease in access to coverage for the individuals currently enrolled in the benefit plans.

5. An attestation, signed by the plan administrator or Chief Executive Officer of the issuer of the coverage, certifying 1) that the benefit plans were in force prior to September 23, 2010; and 2) that the application of restricted annual limits to such plans or policies would result in a significant decrease in access to benefits for those currently covered by such plans or policies, or a significant increase in premiums paid by those covered by such plans or policies is attached.

Ohio Conference of Teamsters Industry
Health Welfare Fund

Plan	2010 Lifetime Limit	Annual Limit	2011 Annual Limit With Waiver Approval	Members	Current Member Contribution	Renewal Contribution	Increase In Monthly Costs	Contribution (If $750,000 Annual Limit Was Applied)	% Increase (If $750,000 Annual Limit Was Applied)
Retiree Plan	100,000	N/A	100,000	158	$214	$214	$128.12	$342.12	59.9%
Total/Permanent Disabled Members Plan*	100,000	N/A	100,000	0	$214	$214	$128.12	$342.12	59.9%
Retiree Plan	150,000	N/A	150,000	42	$214	$214	$100.26	$314.26	46.8%

*This Plan covers Total and Permanently Disabled Participants. There are currently no Participants which meet this eligibility requirement. However, if an active employee Participant becomes totally and permanently disabled, the active employee Participant would be eligible for benefits under this Plan.

ATTESTATION

I, Kenneth J. Lochtefeld, am Chairman of the Board of Trustees of the Ohio Conference of Teamsters & Industry Health & Welfare Fund. I am certifying that the benefit plans enclosed in this application were in force prior to September 23, 2010 and that for the reasons set forth in the Application For Waiver, the application of restricted annual limits to such plans or policies would result in a significant decrease in access to benefits for those currently covered by such plans or policies or a significant increase in premiums paid by those covered by such plans or policies.

Kenneth J. Lochtefeld

Jamba Juice.

12/17

December 15, 2010

James Mayhew
HHS
Office of Consumer Information and Insurance Oversight
Office of Oversight, Room 737-F-04, 200 Independence Ave. SW,
Washington, DC 20201

RE: Jamba Juice Request to Waive Annual Limits Requirements of PHS Act Section 2711

Dear Mr. Mayhew:

This letter serves to respectfully request a waiver from the Annual Limits Requirement of the Patient Protection and Affordable Care Act (PPACA) for the Voluntary Benefits Plan (the "Plan") offered to Jamba Juice's retail Team Members, Team Leader and Training Mentors. According to the Department of Health and Human Services September 3, 2010 regulatory guidance, we are submitting this application not less than 30 days before the beginning of the Plan year that begins on February 1, 2011. We have also included the following items that are listed as required in any waiver application in the above referenced September 3, 2010 guidance:

1. The terms of the plan or policy form(s) for which the waiver is sought.

We have attached as Exhibit A the Plan Summary Plan Description which outlines the plan. We have attached as Exhibit B a chart that illustrates the benefits for health care services received by participants of the Plan. Please note that the terms of the plan include benefit maximums. This Plan was put in place to offer a reasonably priced option to our low wage earners, and the benefit maximums included in the plan and policy forms are essential in order to accomplish this.

2. The number of individuals covered by the plan or policy form(s) submitted.

As of September 2010, there are approximately 131 employees enrolled in the plan.

3. The annual limit(s) and rates applicable to the plan or policy form(s) submitted;

The annual limits and rates that are applicable to the plan or policy form(s) submitted are attached as part of Exhibit B.

4. A brief description of why compliance with the interim final regulations would result in a significant decrease in access to benefits for those currently covered by such plans or policies, or significant increase in premiums paid by those covered by such plans or policies, along with any supporting documentation.

Attached as Exhibit C is Plan data compiled by Milliman, a nationally-respected actuarial consulting firm. Using standard actuarial principles, Milliman's data analysis provides supporting documentation proving that compliance with PPACA's annual limits

6475 Christie Avenue, Suite 150, Emeryville, CA 94608 • tel 510.596.0100 • fax 510.653.0484 • jambajuice.com

Jamba Juice.

requirement would significantly increase the premiums paid by those covered by the plan leading to a decrease in access to benefits for those participants.

A. Significant Increase in Premiums: Milliman estimates that the cost increase to apply the annual limits required by the PPACA would increase the Plan's annual medical and prescription drug claims by 213% to 406%. This variance in percentage between 213% to 406% depends on whether the current plan was modified to remove all dollar and day limits without providing coverage for additional benefits or if the current plan was replaced with one that provides 100% of all benefits, without exclusions, up to an annual limit of $750,000 per member. An increase in claims by between 213% and 406% would correspond to a similar significant increase in the premiums required in order for participants to access benefits covered by the Plan.

B. Decrease in Access to Benefits: An increase in premiums would impose a severe financial hardship on the population that purchases the Plan. Based on an average hourly salary of $8.78 and an average work week of 18 hours, it can be assumed the average team member's salary is $8,218.08 a year. Specifically, a team member's premium would go up annually as demonstrated in the following table:

[illegible]	[illegible]	[illegible]	[illegible]	[illegible]
Premier	Employee Only	$328.68	$1,028.77	$1,663.12
Premier	Employee + 2	$547.44	$1,713.49	$2,770.05
Premier Plus	Employee Only	$926.88	$2,901.13	$4,690.01
Premier Plus	Employee + 2	$1,578.48	$4,940.64	$7,987.11

Clearly, some employees' wages would be used substantially to pay health benefits with no remaining funds for food, rent, etc. This increase in premiums would create a significant hardship on these low income workers and make it difficult to afford the premium which would result in a decrease in access to benefits.

5. An attestation, signed by the plan administrator or Chief Executive officer of the issuer of the coverage, certifying 1) that the plan was in force prior to September 23, 2010; and 2) that the application of restricted annual limits to such plans or policies would result in a significant decrease in access to benefits for those currently covered by such plans or policies.

We have attached as Exhibit D attestation from our Chief Executive Officer certifying the information listed in Number 5.

Sincerely,

JAMES D. WHITE, President and Chief Executive Officer

6475 Christie Avenue, Suite 150, Emeryville, CA 94608 • tel 510.596.0100 • fax 510.653.0484 • jambajuice.com

September 21, 2010

Department of Health and Human Services
Office of Consumer Information and Insurance Oversight, Office of Oversight
Attention James Mayhew, Room 737-F-04
200 Independence Avenue SW
Washington DC 20201

Dear Mr. Mayhew,

Whelan Security Co respectfully submits this request for a waiver from annual limit restrictions for the $15,000 major medical insurance plan currently offered to our employees (United Healthcare Plan 7EJ Modified.) This is an annual, calendar year plan that will renew on January 1, 2011. There are 232 employees covered by this plan. The annual limit for this plan (per individual covered) is $15,000.

Monthly premiums for employee only coverage are shared between employer and employee based on an 80%/20% split. The employee's monthly premium contribution for each tier of coverage for the current plan year is:

Employee only	$65.00
Employee + spouse	$222.28
Employee + children	$291.82
Family	$477.28

A description of benefits for this plan is attached to this letter.

The motivation to request the waiver is based on our desire to protect the welfare of our employees. Whelan Security is engaged in the contract security guard industry. Our company employs more than 3,000 employees. Our industry is low wage and low margin. Health insurance is offered to employees only on contracts where the client agrees to pay for the employer share of the premium. Wages for employees who work on contracts for whom this insurance is available generally range from $7.25 to $12.00 per hour. For the vast majority of our employees, their employment with our company is their sole source for household income. As such, our employees often make economic decisions regarding the affordability of health insurance relative to their need to provide for other basic life necessities (e.g. food, shelter, transportation, etc.) Even with the monthly premium 80% subsidized by the employer, a large percentage of our employees

1750 S. HANLEY RD. ST. LOUIS, MO 63144
PHONE 314-644-1974 FAX 314-644-5252

choose to forgo health insurance in favor of other basic life necessities. Raising and then eventually eliminating the annual limit would certainly make the health insurance premiums prohibitively expensive for a significantly greater number of our employees, resulting in a far greater percentage of our employees not covered by any health insurance.

I attest that the plan for which this waiver is requested was in force prior to September 23, 2010. Given the statements made in the previous paragraph, absent approval of a waiver, our employees would suffer from an increase in premiums that would result from the raising and then eventually the elimination of annual limits.

I would be happy to discuss this with you in greater detail. Please advise if you have any question or comments. My contact information is shown below. I look forward to receiving your decision.

Respectfully,

Michael D. Basler
Senior Vice President & Chief Financial Officer
Whelan Security Co.

Attachment

Your local leader in nursing and rehabilitation services.

Nexion Health
6937 Warfield Ave
Sykesville, MD 21784

Via FedEx Overnight and
Email (without attachments) healthinsurance@hhs.gov

HHS Office of Consumer Information and Insurance Oversight,
Office of Oversight,
Attention James Mayhew
Room 737-F-04,
200 Independence Ave. SW
Washington, DC 20201

October 19, 2010

RE: Application for Waiver of PHS Act § 2711 Restricted Annual Limits

Dear Secretary Sebelius,

Nexion Health respectfully submits this application for waiver of the restricted annual limit provisions of the interim final regulations of June 28, 2010, as applies to the Indemnity Plan it offers its employees. This waiver request is for the plan year commencing November 1, 2010.

This application for waiver contains the information required by the Insurance Standards Bulletin issued by the Office of Oversight on September 3, 2010.

1) The terms of the plan or policy form(s) for which a waiver is sought
A waiver is sought for the Indemnity Plan offered by Nexion Health, Inc. to its employees and their families ("the Plan"). The full terms of the Plan are detailed in the Summary Plan Description attached to this application at Appendix A.

2) The number of individuals covered by the plan or policy form(s) submitted
As of the end of August 2010, 1449 individuals were covered by the Plan. 1033 employees participated in the Plan. Of these, 794 maintained coverage just for themselves, 80 maintained coverage for themselves and a spouse, 107 employees maintained coverage for themselves and one or more children, and 52 maintained coverage for themselves and some other family member.

3) The annual limit(s) and rates applicable to the plan or policy form(s) submitted
The annual limits and rates applicable to the Plan are detailed in the Summary Plan Description (SPD) attached to this application at Appendix A. Benefits described in the SPD fall into the following categories:

a) Physician's office visit including mental health providers
b) Wellness benefit
c) Diagnostic X-ray and lab benefit
d) Accident expense benefit
e) In-hospital benefit, including mental and substance disorders
f) Maximum number of days
g) Anesthesia
h) Outpatient surgery

4) A brief description of why compliance with the interim final regulations would result in a significant decrease in access to benefits for those currently covered by such plans or policies, or significant increase in premiums paid by those covered by such plans or policies, along with any supporting documentation

Nexion offers this "mini-med" plan in order to offer all its employees at least some protection from the potentially crippling cost of health care. A broad variety of employees and their families depend upon this Plan for access to medical care. Without a waiver for this Plan, these individuals will be unable to receive coverage, since not only are they ineligible for the PPO plans offered to salaried employees, the cost of these PPO offerings is often beyond their financial means.

The individuals who benefit from this Indemnity Plan are primarily certified nurse assistants (CNAs) and their families. Some other specialists and other low-wage, hourly employees benefit from the Plan's offerings.

The new requirements that the Affordable Care Act imposes upon the Plan increase the cost of operating the Plan. The employer will be absorbing some of these increased costs. Without a grant of this requested waiver, its costs would increase by more than ten (10) percent. Even with the grant of this requested waiver, the employer will be absorbing an increased burden because its costs will increase to meet other mandates and requirements.

However, the Plan is available to workers within a nursing home setting. The nursing homes' primary source of revenue is Medicaid reimbursement, with some Medicare, and little private pay. The employer therefore has no real ability to increase prices to pay for the full cost of the expansive benefit requirements imposed by PHS Act § 2711, so increased costs must also be borne by Plan enrollees.

Even if Nexion is granted a waiver of the restricted annual limit requirement for the Plan, premiums will have to increase by more than twelve (12) percent in order for the Plan to be compliant with other new requirements. Without a waiver, premiums would have to increase approximately sixteen (16) percent. That is, compliance with the restricted annual limit provisions of the interim final regulations, "would significantly increase premiums."

Approximately fifteen (15) percent of the 1033 low-wage employees who are currently enrolled in the Plan would simply not be able to afford these increased premiums, and would not renew their enrollment for this coming year. The denial of this waiver application would therefore "result in a significant decrease in access to benefits" for employees and their families as of November 1, 2010, as they are priced out of the market.

5) Plan administrator or corporate officer attestation

By my signature at the end of this application, I, Michael A. Newton, , in my capacity as Vice President of Human Resources for Nexion Health, do certify that:

1. The changes made to the Plan for the plan year beginning on November 1, 2010 do not cause the Plan to lose its 'Grandfathered' status, as set forth in Interim Final Rules published on June 17, 2010 at 75 Fed. Reg. 116, 34538. Applying the requirements of those Rules, the Plan was in force prior to September 23, 2010; and

2. The application of restricted annual limits to the Plan would result in a significant decrease in access to benefits for those currently covered by the Plan, or a significant increase in premiums paid by those covered by the Plan.

The information provided above demonstrates that the coverage provided by Nexion's Indemnity Plan meets the criteria for waiver of the restricted annual limits generally imposed for policy years beginning on or after September 23, 2010 and prior to January 1, 2014.

Therefore, and in order to ensure continued access to health benefits for its employees and their families, Nexion respectfully requests that this application for waiver be granted.

Sincerely,

Michael A. Newton
Vice President of Human Resources

SNOWMASS ASPEN MOUNTAIN ASPEN HIGHLANDS BUTTERMILK

ASPEN SNOWMASS
ASPEN SKIING COMPANY

Rec'd 9/29/10
gwA

Date: September 20, 2010

To: HHS, Office of Consumer Information and Insurance Oversight
Office of Oversight
Room 737-F-04
200 Independence Ave SW
Washington, DC 80201

Cc: Via email to: healthinsurance@hhs.gov (subject line "waiver")

From: Kim Terry, Director of Compensation and Benefits
and ERISA Plan Administrator for Aspen Skiing Company

Re: **PHSA Sec 2711-2011 Plan Year Waiver Application**

Pursuant to OCIIO's 9/3/2010 memorandum on this subject, Aspen Skiing Company (ASC) (http://www.aspensnowmass.com/) hereby requests a waiver be granted for its Silver and Bronze medical plans. Both plans include limited calendar and lifetime limits that allow them to provide valuable coverage at an affordable cost. ASC also offers a Gold Plan for which seasonal and non-full time employees are not eligible. A waiver is *not* being requested for the Gold Plan. ASC's Medical Plans are self insured and funded via both employer and employee contributions and operates on a Calendar Year basis.

Aspen Skiing Company is a Colorado based resort employing approximately 800 full and part time benefit eligible employees in the Summer season and 2600 in the Winter season in a wide variety of seasonal and year round positions in it's Hotel, Restaurant, Skiing and related operations.

The Silver and Bronze plans have been offered since 2000 and are specifically designed to meet the basic healthcare needs of the seasonal and part time young and mobile segments of our work force at an affordable cost to employees and the company. Please refer to attached Plan and rate information. Approximately 340 employees were enrolled during March 2010.

Compliance with PPACA requirements would cause the cost of the Silver and Bronze Plans to increase substantially which, especially in these very difficult economic in our industry, would render the plans unaffordable to both employees and ASC and require they be terminated.

P.O. Box 1248
Aspen, CO 81612-1248
970-925-1220
www.aspensnowmass.com

Printed on Recycled Paper.

We do, therefore, respectfully request a waiver be granted from the applicable section of this legislation for the plan year beginning 1/1/2011. Please contact me directly via email at [redacted] for any additional information you may require. We would appreciate your prompt response to this request and would appreciate confirmation that you've request this request and an estimated date by which we might expect a reply.

Respectfully

Kim Terry
Director of Compensation and Benefits

ATTESTATION

I hereby certify that:

1. The Silver and Bronze Plans were in force prior to September 23, 2010 and,
2. The application of restricted annual limits to such plans would result in a significant decrease in access to benefits for those currently covered by such plans or a significant increase in premiums paid by those covered by such plans.

Signed By: Kim Terry Signature Kim Terry
Title: Director of Compensation & Benefits
Dated: 9/20/10

Attachments:

2010 Plan Year - Gold/Silver/Bronze Medical Plan Eligibility
2010 Plan Year – Gold/Silver/Bronze Medical Benefits Summary
Summary of 2010 Participant Pay deductions (required contributions)

September 16, 2010

Mr. James Mayhew
Office of Consumer Information and Insurance Oversight
Department of Health and Human Services
200 Independence Avenue, SW
Room 737-F-04
Washington, DC 20201

Re: Waiver Application Requests – Annual Limits Requirements of PHS Act Section 2711
QK/DRD Policy Forms #358571

Dear Mr. Mayhew:

Public Health Service Act ("PHSA") § 2711(a)(2), as added by the Patient Protection and Affordable Care Act ("PPACA"), provides that effective for plan years beginning on or after September 23, 2010, a group health plan may not impose annual limits on the dollar value of essential benefits, *except* as permitted by the Secretary of Health and Human Services ("HHS") for plan years beginning prior to January 1, 2014.

Pursuant to the authority granted to the Secretary under Section 2711(a)(2) of the PHS Act, the interim final regulations published on June 28, 2010 (codified at 26 CFR § 54.9815-2719T; 29 CFR § 2590.715-2719; and 45 CFR § 147.126) provide that the Secretary may establish a program under which the requirements relating to annual limits may be waived for a group health plan that has an annual dollar limit if compliance with those requirements "would result in a significant decrease in access to benefits under the plan or health insurance coverage or would significantly increase premiums for the plan or health insurance coverage." On September 3, 2010, *OCIIO Sub-Regulatory Guidance (OCIIO 2010 – 1): Process for Obtaining Waivers of the Annual Limits Requirements of PHS Act Section 2711* was issued. This waiver application is being filed pursuant to this guidance.

REQUEST FOR WAIVER OF THE ANNUAL LIMITS REQUIREMENTS OF PHS ACT SECTION 2711 WITH RESPECT TO: QK/DRD #358571

1. Terms of the policy form(s) for which a waiver is sought.

The QK/DRD erisa self funded basic plan is designed to allow hourly employees the ability to participate in a open access (no referrals needed) PPO major medical plan, covering primary and specialist doctor visits at a co pay level, in/outpatient facility visits at a 80% level. All CIGNA's nationwide participating providers are available with this plan including the Mayo Clinic. Prior to the introduction of the QK/DRD the hourly basic plan, the hourly employees could NOT afford Qk/DRD, s traditional high limit PPO major medical coverage's,

2. Number of individuals covered by the plan submitted.

Approximately 65 individuals are covered currently under the plan.

3. Annual limit(s) and rates applicable to the plan submitted.

Benefit Limits	Benefits Offered
Doctor Office Visits* DOES NOT apply to OP Maximum	$15.00 Co-Payment/no deductible
Outpatient Care	$500 Calendar year Deductible 80% Co-Insurance $3000 annual maximum
Inpatient Care	80% Co-Insurance $3000 Annual Maximum
Add'l In-Hospital Surgery	80% Co-Insurance $3000 Annual Maximum
Add'l Maternity Benefit	80% Co-Insurance $3000 Annual Maximum
Wellness Benefit/ Preventative Care	None
Pharmacy	Cigna discount card
Injury/Accident	$500 Calendar Year Deductible 80%Co-Insurance $3000 ANNUAL MAXIMUM
Life and Accidental Death	$20,000

QK/DRD is a Denny's restaurant Franchisee, operating in 6 states, 75 Denny's restaurants

The Ifrs would literally eliminate the Hourly from participating in any Healthcare benefits due to the 750% increase in monthly costs. Prior to the introduction (10-1-2005) of the QK/DRD limited benefit plan, only 4 hourly employees nationwide participated in Qk/DRD, s major medical plans. Today we have 65 participating hourly employees.

The interim final regulations state that for plan years beginning on or after September 23, 2010, but before September 23, 2011, the restricted annual limits on the dollar value of essential benefits cannot be lower than $750,000.

The estimated monthly cost increase for the plan was it to comply with the restricted annual limit of $750,000 would be $39,000 per month. This represents a monthly premium increase of 750%. This would generate a significant increase in the cost for individuals covered by the plan, prohibiting the hourly employees from purchasing health benefits

5. Attestation

Attestation of the plan administrator is attached.

ATTESTATION OF

Thomas Beal/BEAL BENEFITS

I hereby certify the following:

1. I am the designated Plan Administrator for QK/DRD #358571
2. The plan has been offered to employees of QK/DRD prior to September 23, 2010.
3. The application of the restricted annual limits as specified in the interim final regulations published on June 28, 2010 (codified as 26 CFR 54.9815-2719T; 29 CFR 2590.71-2719; and 45 CFR 147.126) to the Plan would result in both a significant increase in premiums paid by those currently covered under the Plan and a significant decrease in access to benefits for those currently covered under the Plan.

Attested to by:

Thomas Beal

Date: September 16th, 2010

Plan Administrator

JOHNSON & TOWERS

MT. LAUREL
2021 Briggs Road
Mt. Laurel, NJ 08054
856-234-6990
856-222-2414 Fax
856-234-3570 Parts

BALTIMORE
500 Wilson Point Road
Baltimore, MD 21220
410-687-0500
410-687-5137 Fax
800-479-3677 Parts Fax

EGG HARBOR TOWNSHIP
2701 Fire Road
Egg Harbor Township, NJ 08234
609-272-1415
609-272-1868 Fax

www.JohnsonTowers.com

Authorized Distributor For

December 22, 2010

Department of Health and Human Services
Office of Consumer Information and Insurance Oversight
Room 737-F-04
200 Independence Ave. SW
Washington, DC 20201

Attn. James Mayhew

Dear Mr. Mayhew,

I am writing to you to apply for a waiver of the annual limit requirements for our healthcare plan. Below are 5 factors for your consideration when reviewing our application for a waiver.

- Based on Cost Estimates, compliance with the IFR would result in a significant increase in cost of 68%.
- Significant increase in costs would result in staff layoffs. Our sales are down 30% and profit is next to nothing. We have 165 employees and if the cap goes away we will have to lay off 10% of our work force.
- Reduced staff would impede on service model. We would not be able to service our customers and that is the only reason they come to Johnson & Towers.
- Decrease in sales/profit margins due to economic downturn. Johnson & Towers has had profit margins eroding beginning in 2008. If we lost the cap of our prescription plan it would force us to close 2 locations.
- In the Collective Bargained Agreements (OPEIU, Local 32 & Teamsters, Local 311) this benefit was agreed and compensation was structured accordingly. Adding this cost would result in renegotiating a new contract which has legal costs above what has already been spent to achieve a contract. Failure to reach an agreement could have further implications for a strike or shut down by all parties.

Thank you for your consideration in this matter.

Very Truly Yours,

JOHNSON & TOWERS, INC.

David Johnson
President

ATLANTA PLUMBERS & STEAMFITTERS FRINGE BENEFIT FUNDS

Administered by Southern Benefit Administrators, Incorporated

3835 Presidential Pkwy., Suite 123
Atlanta, Georgia 30340
Telephone (770) 455-3802 Toll Free (800) 382-6926
Fax (770) 455-6845

Date: November 9, 2010

Health and Human Services
Office of Consumer Information and Insurance Oversight
Office of Oversight – ATTN: James Mahew
Room 737-F-04
200 Independence Ave. SW
Washington, D.C. 20201

Re: Atlanta Plumbers and Steamfitters Health and Welfare Fund
EIN: 58-0625978

Pursuant to regulations published on June 28, 2010 the Atlanta Plumbers and Steamfitters Health and Welfare Fund is applying for waiver of the restricted annual limits. In compliance with these provisions we are enclosing a copy of the schedule of benefits which reflects the current benefit structure. The current Plan has an annual maximum of $250,000, and a lifetime limit of $1,000,000. This Plan was in existence prior to September 23, 2010.

The medical, prescription drugs, dental and vision benefits provided by this Plan are entirely self-funded. Family coverage is provided to employees who satisfy the eligibility requirements established by the Board of Trustees. The Plan's current eligibility rules require employees to have a total of $666.90 employer contributions made on their behalf each month. This Plan is a collectively bargained Taft Hartley Welfare Fund and managed by Employer and Employee Trustees.

Because of adverse employment conditions, employer contributions have decreased significantly over the past several months. As a result, benefit and other expenses exceed employer contributions. As the enclosed chart reflects, expenses exceeded contributions by $2.34 per eligible per month in 2008, by $94.05 in 2009, and by $133.54 during the first nine months of 2010. The Trustees are hopeful the Fund's reserves will help in getting through these conditions.

In order to comply with provisions of the Affordable Care Act (ACA), we have secured stop-loss quotes. Stop-loss coverage will protect the Fund in the event of catastrophic claims. We are enclosing a copy of the most competitive quote received. You will note the monthly premium is $20.04 per eligible per month. Based on 2,893 eligible employees, this would increase the Plan's costs by $695,708 per year. Although the premium can be reduced by having the Plan accept additional liability beyond $250,000, the annual cost is significant.

To make adjustments for this additional cost, the Trustees will be forced to eliminate the "non-essential" benefits and increase the eligibility requirements to reduce the number of eligible employees. Current employment conditions, ending of the COBRA subsidy, and the increased cost of self-contributions, will result in the loss of coverage for a significant number of employees and their families who have had coverage under this Plan for many years. The hardship being placed on this Plan will ultimately be borne by the employees.

The effective date for this Fund to be in compliance with ACA is January 1, 2011. I attest that the information I have presented is correct. Please let us know if you need anything further in regard to this request.

Please direct your response to my attention a[redacted]

Donny Dowlen
Plan Administrator

Heating, Piping and Refrigeration
Medical, Pension and Training Funds
Steamfitters Local Union 602 Retirement Savings Plan
9411 PHILADELPHIA ROAD, SUITE S BALTIMORE, MARYLAND 21237
Telephone Numbers: (800) 618-2879 (410) 444-3756 Fax (410) 444-0035

November 2, 2010

HHS
Office of Consumer Information and Insurance Oversight
Office of Oversight
Attention: James Mayhew
Room 737-F-04
200 Independence Ave, SW
Washington, DC 20201

Re: Waiver Application

Dear Mr. Mayhew,

As directed by OCIIO Sub-Regulatory Guidance 2010-1, please accept this application on behalf of the Heating, Piping & Refrigeration Medical Fund ("Fund") for waiver of the restricted annual limits requirement of PHS Act Section 2711(a)(2), as added by the PPACA. The Fund is a non-grandfathered plan, and its plan year begins on January 1, 2011.

1. Terms of the Plan for Which Waiver is Sought

Please find the Summary Plan Description attached hereto as Attachment 1.

2. Number of Individuals Covered by the Plan

Currently, the Fund covers approximately **9710** individuals eligible for benefits.

3. Current Annual Limit

Currently, the Fund has a maximum annual benefit of $250,000 per person.

4. Compliance Hardships

Compliance with the interim final regulations requiring restricted annual limits will pose a hardship on participants and beneficiaries. By way of background, the Fund is a self-insured multiemployer plan comprised of craftsmen performing work within the steamfitter industry. The Fund is funded primarily through contributions made pursuant to collective bargaining agreements ("CBAs") entered into between participating unions and signatory employers.

The CBAs set out an hourly contribution rate per hour worked by each employee. The employers signatory to the CBA contribute this sum to the Fund.. The current master CBA setting out the standard contribution rate to the Fund will expire in August 2013. The Fund's Board of Trustees has no direct authority to alter the contribution rate, which is set by the bargaining parties. Thus, the Fund does not have an independent funding mechanism that would enable it to increase revenue immediately through employer contribution when its expenses increase due to a rise in claims or compliance with regulatory changes (e.g., PPACA annual limits requirements).

The Board of Trustees' only avenue to address revenue shortfalls is to decrease benefits. For example, the Trustees have the authority to increase deductibles or copayments. Such benefit changes result in cost-shifting to the participants.

As a result of required PPACA compliance, particularly the mandates for greatly expanding the annual limits, the Fund is now faced with the prospect of having to find resources to pay higher benefit costs. The increased costs present the Board of Trustees with difficult decisions, all of which may seriously – and adversely – impact the participants. The Board of Trustees would like to maintain the current level of benefits. The Board does not wish to reduce benefits, and it does not view depletion of its reserves as a viable solution. To the contrary, it is a short-term option that could have dire consequences for the Fund and its participants if reserves are depleted to unacceptable levels or if unexpected catastrophic claims arise.

The Fund's consultant has further advised that, if the Fund is required to raise the current annual limit of $250,000 and adopt a restricted annual limit of $750,000 per participant, the cost to the Fund is estimated to be $1,000,000 for the 2011 plan year. *See* Attachment 2. The total cost of PPACA compliance for 2011 is estimated at $2,330,000, including preventive care costs of $700,000 and adult child coverage costs of $630,000. Estimates on stop loss insurance to cover large medical claims are projected to be $1,100,000 per year. Accordingly, the overall estimated cost of PPACA compliance, including providing adult child coverage and preventive services and obtaining stop loss insurance, would be approximately $2,430,000 for the 2011 Plan Year. *See* Attachment 2. The Fund believes that absorbing this increase will be difficult to attain and sustain.

The Fund's consultant has opined that one way the Fund may pay for these added costs is by cutting benefits. The Fund could, for example, increase the participant cost-sharing by more than doubling the calendar year in-network deductible -- currently set at $200 -- to $450. *See* Attachment #2. In addition, the Fund would have to reduce the co-insurance amount, currently set at 80%, to 75%. Finally, the Fund would be forced to increase the calendar year out-of-pocket maximum, currently set at $7,000, to $8,000. *See* Attachment #2. The Fund may also have to consider adjustments on retiree coverage. Currently, the Fund subsidizes a very substantial portion of the cost of retiree benefits, which may not be sustainable if the Fund has to comply with the restricted annual limits requirement.

A temporary waiver of the PPACA restricted annual limits requirement will give the Fund some additional time to find new sources of funding, explore additional ways to save costs for both the Fund and its participants, or restructure benefits to provide the participants and their dependents with the best plan of benefits possible within the Fund's financial means.

5. Plan Administrator Attestation

Please see enclosed Attachment 3.

Thank you for your consideration. If you have any questions or require additional information or documentation, please do not hesitate to contact me a[redacted] or the address above.

Sincerely,

Benefits Administration Corporation, Inc.
Administrator
By: Joseph R. Swann, CEBS

SEGAL

THE SEGAL COMPANY
1920 N Street NW Suite 400 Washington, DC 20036-1659
T 202.833.6400 F 202.833.6490 www.segalco.com

MEMORANDUM

To: Board of Trustees
Heating, Piping & Refrigeration Medical Fund

From: Ron Merritt

Date: November 3, 2010

Re: Supplemental Financial Information for Annual Dollar Limit Waiver Certification

Dear Trustees:

The information that follows provides current, historical and projected financial information with regard to the Fund's operations for the purpose of the Annual Dollar Limit Waiver process:

1. On a continued fully self-insured basis, we have estimated the overall cost of PPACA compliance to be $2,330,000 in 2011 ($.35 per hour). This is the sum of the estimated cost of coverage for adult children of $630,000 ($.09 per hour), the estimated cost of increasing the current annual maximum of $250,000 to $750,000 of $1,000,000 ($.15 per hour) and the added cost of providing the preventive care benefits as a non-grandfathered plan of $700,000 ($.10 per hour) on a self-funded basis.

2. If the liability for claims between $250,000 and $750,000 were insured through the purchase of stop-loss insurance, we have estimated the overall cost of PPACA compliance to be $2,430,758 in 2011 ($.36 per hour). This is the sum of the estimated cost of coverage for adult children of $630,000 ($.09 per hour), the estimated annual cost of the non-grandfathered preventive care benefits of $700,000 ($.10 per hour) and the estimated annual cost of purchasing stop-loss insurance of $1,100,000 ($.16 per hour).

3. The annual limits and rates applicable to the plans submitted.

The Waiver is being requested for the overall annual medical benefit.

	Current annual maximum offered through 12/31/2010	Requested annual maximum for which waiver is submitted Effective 1/1/2011-12/31/2011
Annual medical maximum, excluding prescription drugs	$250,000	$250,000

4. The premium equivalents (i.e., rates) for the 2010 and 2011 plan years are as follows:

Current 2010	2011 with no change in Annual Maximum	2011 with $750,000 Annual Maximum	% Change over 2010
$888.97	$911.80	$961.90	+8.2%

- Note: "Premium rate equivalent" is the estimated cost of self-insured coverage. It is a composite rate, and therefore the rate for individual, individual + child, individual + spouse, and family coverage are all the same.

5. A brief description of why compliance with the interim final regulations would result in a significant decrease in access to benefits for those currently covered by such plans, or significant increase in premiums paid by those covered by such plans, along with any supporting documentation.

The Fund's compliance with the restricted annual dollar limits contained in the Interim Final Regulations (i.e., increasing the annual limit from $250,000 to $750,000 for the Plan Year commencing January 1, 2011) would result in a significant decrease in access to benefits for current participants for the following reasons:

- The additional cost associated with the increase in the maximum annual benefit would not be offset by the ability to obtain additional employer contributions due to existing collective bargaining agreements. Even if additional employer contributions were feasible, the added costs would be highly burdensome in this highly competitive industry, which would result in further job losses, and as a result, fewer employees working sufficient hours to either obtain or retain benefit eligibility.

- Any increases in participant out of pocket expenses (e.g. increase in the deductible, decrease in coinsurance and increase in annual out of pocket maximum) to offset the cost impact of the higher annual maximum benefit may cause delayed or foregone medical treatment for a significant portion of the covered population.

- To finance the increased costs, the Plan would have to make benefit reductions, including a substantial increase in the calendar year deductible for in-network services ($200 to $450), a reduction in the coinsurance amount (from 80% to 75%) and an increase in the calendar year out-of-pocket maximum ($7,000 to $8,000).

Cc: John Bohman, Esq.
Joseph Swann

From: Andrews, Jane (HHS/OCIIO)
Sent: Wednesday, December 08, 2010 4:26 PM
To: Habit, Sandra (HHS/OCIIO)
Subject: FW: attached spreadsheet and application information
This is Vestal app

Jane W. Andrews
OCIIO
7501 Wisconsin Ave
Bethesda, MD 20814
[redacted]

INFORMATION NOT RELEASABLE TO THE PUBLIC UNLESS AUTHORIZED BY LAW:
This information has not been publicly disclosed and may be privileged and confidential. It is for internal government use only and must not be disseminated, distributed, or copied to persons not authorized to receive the information. Unauthorized disclosure may result in prosecution to the full extent of the law.

From: Keith Shope [redacted]
Sent: Wednesday, December 08, 2010 2:41 PM
To: Andrews, Jane (HHS/OCIIO)
Subject: RE: attached spreadsheet and application information

Dear Ms. Andrews,

Thanks for talking with me this morning and helping me better understand your request. I hope I did not take too much of your time, but this is a very serious and important issue for our company. I think it is important to note that our company has provided health care benefits to our employees for 40+ years. We currently have a self funded plan simply because it has been the most cost effective method of providing benefits in health care. As a self funded plan, we pay the claim amounts to BCBS of Tennessee every week (the amount is actually ACHed out of our account) and we pay BCBC a TPA fee for the handling and processing of all claims. Therefore, there is no "middle" man profit or insurance company profit to pay. On occasion, I do test the insurance market with fully insured quotes, but in all cases the cost to insure vs. self funding is significantly higher. In self funding however the exposure all falls to the employer. This is where the $400,000 life time max (now an annual max) comes into play. The $400,000 maximum was negotiated with the union employees and they have chosen other benefits such as additional paid holidays, defined benefit pension plans, additional paid vacations, etc instead of an increase to the $400,000 max. This lower max enabled us to operate a self insured plan. At the proposed $750,000 (which will almost double our exposure for every employee and their covered family members) the risk will be too great and in fact would today bankrupt this company if a claim of this magnitude was to occur. Our current claims, paid on a monthly basis, will range anywhere from $35,946.02 this past February to $186,713.00 for last December. It just depends on how many employees have claims and also the seriousness of the claims. Going back to 2005 and averaging the claims paid for the past five years through 2009, the average for those years was $1,315, 757 per year. For the year to date 2010, claims are $885,634 with the month of December to go. It appears that this year will be down in total dollar claims paid due to the decreased number of employees we have as a result of the economy. Our business is tied to housing starts and the housing market has been devastated for the past two + years. Regarding the additional exposure and our inability to pay a claim of that magnitude, we operate our business on a line of credit from a local bank. That line is capped at $1,800,000. I have a standing LOC that is required from the State of Tennessee for $207,000 as financial assurance for an onsite landfill used for our foundry sands. In other words I must provide the state with financial assurance that the landfill will be taken care of in the event that we are no longer in business. It has a renewal requirement annually and is adjusted every year for

inflation. This amount is deducted from our line of credit and thus the amount to operate the business is $1,597,000. We cannot exceed that amount. And while we have never exceeded that amount we have come close a number of times, and currently the line amount stands at approximately $1,200,000. This line of credit fluctuates all the time. In other words I have seen the line requirement be as low as approximately $650,00 this year and as high as $1,473,000 this year. It is always moving based on our sales and our collections and our purchases of raw materials, wages for employees, insurance, etc. All our expenses are paid from this line of credit. An all our collections (receivables) for our products that we sell go to reduce this line of credit. One $750,000 claim today would exceed the available cash fund we have to draw on and effectively put us out of business. Regarding reserves or funds, please understand there are no reserves. The claims are simply paid every week as a cost of doing business the same as a utility bill or wages or raw material purchases would be paid. The only difference is that for the other expenses we have a general idea of what they will be. Group medical claims are different in that we never know what they will be until they are taken out of our account. And as I said earlier I have seen this monthly amount be as low as $36K and as high as $187K. Now regarding the current contribution amounts for the employees and employer: Our employees pay for their insurance as follows. For single coverage (employee only) the employee pays today $20.90/week or $90.56/month or $1,086.72/annually for his medical insurance. For this the company pays all his claims less deductibles ($750.00 annually) at an 80/20 ratio. The employee has an out of pocket limit that if met, all claims are then paid at 100%. So if an employee has a $100,000 illness/hospital stay, his portion will be $4,750.00 while the company portion will be the balance - $95,250.00. For family coverage (includes spouses and children) the employee cost is today $45.22/week or $195.95/month or $2351.44/year. They have a family deductible of $1500.00 and all claims are then paid at 80/20 until the out of pocket limit is met ($6,000.00 for total family). After that all claims are paid at 100%. These two examples work for any and all claims. If the claims cost were $15,000 instead of $100,000, the same deductibles and out of pocket limits apply, the same 80/20 applies and the same 100% applies after the annual limit. One last subject I wish to touch on is the economy and the nature of our business. We manufacture residential building products for new home construction. As stated earlier this market has been devastated for the past two years or more. Our sales have actually declined by more than half during this time and we have lost money for the past two years. We are hopeful that we will make a very small profit this year but it is too early to tell. Increasing the maximum to $750,000 beginning 1-1-2011 could have very serious implications for this company and all of our employees. For all these reasons I respectfully ask for your consideration and granting of this waiver. If I can provide any additional information, please do not hesitate to ask for it.

Regards,
Keith E. Shope
President/CEO
Vestal Manufacturing Enterprises, Inc.

From: Andrews, Jane (HHS/OCIIO) [mailto:Jane.Andrews@hhs.gov]
Sent: Wednesday, December 08, 2010 10:51 AM
To: [redacted]
Cc: Habit, Sandra (HHS/OCIIO)
Subject: attached spreadsheet and application information

Dear Applicant:

Thank you for your application for the Waiver of the Annual Limits Requirements of the Public Health Service Act (PHS Act) Section 2711. In order to expedite your application, please provide the following information:

In your original application you mention contributions going up in 2012 to employees (when the CBA

expires), but do you have any current contribution amounts for the employer, employee and total contributions for the current year? Also, you mention the serious financial implications in that a claim of $750,000 would bankrupt the company. Do you have any information on the fund or reserves to support the statement about possible bankruptcy? It is this information that I am lacking at this point and to be able to completely process your application.

Please complete the annual limits spreadsheet, [attached to the email] with the information requested above. Please return the completed spreadsheet to this email address as an attachment. If a cell on the spreadsheet does not pertain to your plan, please write "None," and/or provide an explanation regarding why you are unable to complete that particular cell in a separate document.

In order to complete your application, please provide this information by 5:00 pm, December 10, 2010. Once this information is received and the application is complete, it will be processed by the Department of Health and Human Services (HHS). As stated in our September 3, 2010 Sub-Regulatory Guidance, HHS will issue a decision within 30 days of receiving a complete application. You will receive an e-mail from HHS notifying you of the waiver decision.

Thank you.

Jane W. Andrews
OCIIO
7501 Wisconsin Ave
Bethesda, MD 20814
[redacted]

INFORMATION NOT RELEASABLE TO THE PUBLIC UNLESS AUTHORIZED BY LAW:
This information has not been publicly disclosed and may be privileged and confidential. It is for internal government use only and must not be disseminated, distributed, or copied to persons not authorized to receive the information. Unauthorized disclosure may result in prosecution to the full extent of the law.

United State House of Representatives
Energy and Commerce Committee
Subcommittee on Oversight and Investigations
Cliff Stearns (R -FL), Chairman

Re: Hearing - Health Care Issues Involving the Center for Consumer Information and Insurance Oversight

Dear Energy and Commerce Committee Members:

The Hemophilia Federation of America (HFA) supports many insurance reforms within the Affordable Care Act. We work to ensure individuals affected by bleeding disorders have access to a healthcare system that provides high-quality, affordable, comprehensive and preventative health care services. This is why we are asking you to help maintain the private insurance reforms included in the Affordable Care Act, which allows individuals with high-cost conditions, such as hemophilia, access to adequate and affordable coverage. Past insurance industry practices made it extraordinarily difficult for individuals with bleeding disorders to access high quality, affordable coverage. Without these protections, insurance coverage will be out of reach for the patients who need it most. Please help us the prohibition on lifetime limits on health insurance coverage and the gradual elimination of annual limits on health insurance coverage.

Hemophilia is a rare, chronic bleeding disorder affecting about 20,000 people in the U.S. Hemophilia is treated with factor replacement therapy. This therapy involves the intravenous infusion of blood clotting products to replace the missing or deficient protein needed for the blood to clot. Infusions must be given as soon as possible after the start of bleeding. An individual can also take regular doses of factor, as a preventative treatment called prophylaxis to prevent debilitating and life-threatening internal bleeding. Clotting factor is extremely expensive, for example the average cost of treatment for an individual with severe hemophilia can be $300,000 or up to $1 million if an individual develops a complication as a result of treatment, surgery, or other trauma.

With the costs associated with treatment of hemophilia, in the recent past an individual could easily reach a lifetime limit imposed by an insurance company and currently can reach their annual limit in a very short period of time. These patients and their families have to find other ways to pay for medical costs, which involves a combination of paying more out-of-pocket, finding new public or private insurance sources – often through Medicaid, or cutting back on needed medical care and treatment. The choice of not treating a bleeding episode in order to save costs can be a life threatening or disabling for an individual with hemophilia. Each bleed, when not treated, invariably does damage and ultimately causes severe chronic pain and disability.

For example Jenni Dunham of Tennessee, whose husband Chris and son Jacob both have von Willebrand disease (another rare bleeding disorder), the future has gotten "much more hopeful" since the passage of the Affordable Care Act. Jenni estimates that Jacob, now three, would have reached the lifetime cap on his insurance by the time he was thirteen years old. Now she no longer has to worry about that. "I know families with bills $100,000 a month," she said. "Luckily it's not going to work out that way [for us.]"

Chris is currently covered through his work insurance, but has had no other options, having been told multiple times that he was ineligible for private insurance due to his bleeding disorder and accompanying health issues. Jacob is covered under Cover Kids, a Tennessee-based program for uninsured children, which has cut down on the bills but still has high co-pays. "It affects every decision we make, to make sure we have health insurance," said Jenni, who previously had to pay out-of-pocket for every ER visit. To the people who are against the health care reform, Jenni simply says "Until they have lived with a chronic medical condition... They couldn't appreciate what this means to our family."

Since Hemophilia is a rare disorder and expensive to treat, it is critically important that patients have health insurance coverage that does not restrict to access to health care providers that are knowledgeable about the disease and access to effective treatments only based on cost concerns.

Sincerely,
The Hemophilia Federation of America