Just last week I met with Hunterdon County, New Jersey, Prosecutor Anthony Kearns on what law enforcement is doing on the ground level to fight this epidemic. In New Jersey, Mr. Speaker, the county prosecutor is the equivalent of the county district attorney in most States across the Nation.

Public servants like Prosecutor Kearns and others are doing all they can to protect our children and keep our local communities drug free, but this legislative package will help in their efforts and give them and other governmental entities more critical tools.

Those in Washington and local leaders need to be working together for the benefit of the American people. H.R. 4976 and the larger package will work toward that goal and ultimately help combat this drug abuse crisis.

Mr. GENE GREEN of Texas. Mr. Speaker, I yield 3 minutes to the gentleman from New York (Mr. SEAN PATRICK MALONEY), a cosponsor of this bill.

Mr. SEAN PATRICK MALONEY of New York. Mr. Speaker, I thank my good friend from Texas for yielding. I want to echo my thanks as well to Chairman UPTON and Ranking Member PALLONE and my good friend, Mr. LANCE of New Jersey.

I rise in support of my legislation, H.R. 4976, the Opioid Review Modernization Act.

Heroin and opioid addiction is a serious and growing epidemic, especially in the communities I represent in the lower Hudson Valley of New York. After more than 55 townhalls with my neighbors across the Hudson Valley in the last 3½ years, I can say there is no subject I have heard about more in visits to communities throughout my district. Really, everywhere I go, I hear heartbreaking stories of addiction and of loss, and we have had far too many funerals.

I spoke to a woman named Cynthia in Newburgh who told me her son struggles every day with addiction. He is trying to stay clean, but he can't find a meeting locally to visit.

A woman named Samantha from Brewster said she is worried about the basic lack of options for treating addicts like her son.

Patricia in Warwick has said the facilities there lack the basic necessities for treating addicts like her son.

We have a shortage of beds for patients who are seeking treatment. In Dutchess County, New York, alone, we have seen a 160 percent increase in the number of drug overdoses since 2009. This epidemic is being felt nationwide. It doesn't care about the color of your skin or the size of your paycheck.

Deaths from heroin overdoses have more than tripled since 2010 in our country, and it is often driven by an addiction first to prescription pain medicine. We now have more than 47,000 people dying a year, the equivalent of 125 Americans every day. It is a staggering figure, Mr. Speaker, and we in Congress can and must do more to fight this growing epidemic.

So my bill takes an important, but simple, step to avoid opioid addiction and to avoid further loss by using both new technologies and a little common sense.

Specifically, it would require the Food and Drug Administration to consult with expert advisory committees for the approval of new opioids that do not use deterrent properties, such as extended-release capsules. We know this can thwart the misuse of these products by people who are struggling with addiction.

Additionally, the legislation will encourage the development of generic opioids that utilize these abuse-deterrent properties. And, of course, the FDA can do more.

We can require them to evaluate and make recommendations on better programs to prevent prescribers of opioids from overprescribing, since we often hear that it is that overprescription that leads people into trouble with opioids and, later, with heroin.

As part of a comprehensive package of legislation to combat the opioid epidemic, my bill is just one more tool in our toolkit, providing incentives for pharmaceutical companies to use antiabuse technologies and create a plan to educate our well-meaning doctors about the potential dangers of prescription opioids.

I urge my colleagues to vote ''yes'' on this important measure.

Mr. GENE GREEN of Texas. Mr. Speaker, I yield back the balance of my time.

Mr. GUTHRIE. Mr. Speaker, I yield myself the balance of my time.

Mr. Speaker, this bill, the FDA's Opioid Action Plan, is important in our larger package of bills. I urge my colleagues to support this measure, H.R. 4976.

Mr. Speaker, I yield back the balance of my time.

Mr. PALLONE. Mr. Speaker, I wish to voice my support for H.R. 4976, which would complement the efforts taken by the Food and Drug Administration to combat the opioid abuse crisis.

The opioid epidemic has hit nearly all communities across the country—young and old, rich and poor, urban and rural. The Energy and Commerce Committee has held a number of hearings on this issue, inviting a wide range of stakeholders to come and share with us their suggestions on how Congress can help to address this crisis. What has been made clear is that there is not one solution. It will take the collaboration and expertise of a variety of agencies, and it must not only appropriately account for the need for access to opioids for those with acute and chronic pain, but it must also discourage misuse and diversion.

As the public health agency responsible for reviewing pain medications for safety and efficacy, the Food and Drug Administration should play a critical role in making clear how prescription opioids can be safely used, in encouraging the development of technologies to prevent abuse, and identifying what education would assist prescribers who treat patients with opioids.

In February, FDA outlined an action plan that included a number of steps focused on the agency's regulatory approach to opioids.

These actions included: reassessing the risk-benefit approval framework for opioid use; convening an expert advisory committee before approving any new drug application for an opioid that does not have abuse-deterrent properties; consulting with the Pediatric Advisory Committee regarding recommendations for pediatric opioid labeling before any new labeling is approved; updating the Risk Evaluation and Mitigation Strategy or REMS program for extended-release and long-acting opioids regarding prescriber training; developing changes to immediate-release opioid labeling to include additional warnings and safety information; reviewing options to make naloxone more accessible, such as availability over-the-counter; and strengthening post-market requirements, among other steps.

I was pleased by the agency's announcement as I believe it was an important step forward in improving regulatory oversight of opioids, and would help to take another step towards addressing the opioid crisis holistically.

H.R. 4976, the Opioid Review Modernization Act, was introduced by Representatives SEAN PATRICK MALONEY and LEONARD LANCE to build on the actions announced by the FDA. The legislation would require the agency to work closely with expert advisory committees before making critical product approval and labeling decisions, make recommendations regarding education programs for prescribers of extended-release and long-acting opioids, and would encourage the development and approval of generic opioids with abuse-deterrent properties.

These actions will be critical to improving the way we regulate opioids to ensure that these products are used safely and appropriately and I urge my colleagues to support this legislation.

The SPEAKER pro tempore (Mr. STEWART). The question is on the motion offered by the gentleman from Kentucky (Mr. GUTHRIE) that the House suspend the rules and pass the bill, H.R. 4976.

The question was taken; and (two-thirds being in the affirmative) the rules were suspended and the bill was passed.

A motion to reconsider was laid on the table.

CO-PRESCRIBING TO REDUCE OVERDOSES ACT OF 2016

Mr. GUTHRIE. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 3680) to provide for the Secretary of Health and Human Services to carry out a grant program for co-prescribing opioid overdose reversal drugs, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 3680

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Co-Prescribing to Reduce Overdoses Act of 2016''.

SEC. 2. OPIOID OVERDOSE REVERSAL DRUGS PRESCRIBING GRANT PROGRAM.

(a) ESTABLISHMENT.—

(1) IN GENERAL.—Not later than six months after the date of the enactment of this Act, the Secretary of Health and Human Services may establish, in accordance with this section, a five-year opioid overdose reversal drugs prescribing grant program (in this Act referred to as the ''grant program'').

(2) MAXIMUM GRANT AMOUNT.—A grant made under this section may not be for more than $200,000 per grant year.

(3) ELIGIBLE ENTITY.—For purposes of this section, the term ''eligible entity'' means a federally qualified health center (as defined in section 1861(aa) of the Social Security Act (42 U.S.C. 1395x(aa)), an opioid treatment program under part 8 of title 42, Code of Federal Regulations, any practitioner dispensing narcotic drugs pursuant to section 303(g) of the Controlled Substances Act (21 U.S.C. 823(g)), or any other entity that the Secretary deems appropriate.

(4) PRESCRIBING.—For purposes of this section and section 3, the term ''prescribing'' means, with respect to an opioid overdose reversal drug, such as naloxone, the practice of prescribing such drug—

(A) in conjunction with an opioid prescription for patients at an elevated risk of overdose;

(B) in conjunction with an opioid agonist approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for the treatment of opioid abuse disorder;

(C) to the caregiver or a close relative of patients at an elevated risk of overdose from opioids; or

(D) in other circumstances, as identified by the Secretary, in which a provider identifies a patient is at an elevated risk for an intentional or unintentional drug overdose from heroin or prescription opioid therapies.

(b) APPLICATION.—To be eligible to receive a grant under this section, an eligible entity shall submit to the Secretary of Health and Human Services, in such form and manner as specified by the Secretary, an application that describes—

(1) the extent to which the area to which the entity will furnish services through use of the grant is experiencing significant morbidity and mortality caused by opioid abuse;

(2) the criteria that will be used to identify eligible patients to participate in such program; and

(3) how such program will work to try to identify State, local, or private funding to continue the program after expiration of the grant.

(c) USE OF FUNDS.—An eligible entity receiving a grant under this section may use the grant for any of the following activities, but may use not more than 20 percent of the grant funds for activities described in paragraphs (4) and (5):

(1) To establish a program for prescribing opioid overdose reversal drugs, such as naloxone.

(2) To train and provide resources for health care providers and pharmacists on the prescribing of opioid overdose reversal drugs, such as naloxone.

(3) To establish mechanisms and processes for tracking patients participating in the program described in paragraph (1) and the health outcomes of such patients.

(4) To purchase opioid overdose reversal drugs, such as naloxone, for distribution under the program described in paragraph (1).

(5) To offset the co-pays and other cost sharing associated with opioid overdose reversal drugs, such as naloxone, to ensure that cost is not a limiting factor for eligible patients.

(6) To conduct community outreach, in conjunction with community-based organizations, designed to raise awareness of prescribing practices, and the availability of opioid overdose reversal drugs, such as naloxone.

(7) To establish protocols to connect patients who have experienced a drug overdose with appropriate treatment, including medication assisted treatment and appropriate counseling and behavioral therapies.

(d) EVALUATIONS BY RECIPIENTS.—As a condition of receipt of a grant under this section, an eligible entity shall, for each year for which the grant is received, submit to the Secretary of Health and Human Services information on appropriate outcome measures specified by the Secretary to assess the outcomes of the program funded by the grant, including—

(1) the number of prescribers trained;

(2) the number of prescribers who have coprescribed an opioid overdose reversal drug, such as naloxone, to at least one patient;

(3) the total number of prescriptions written for opioid overdose reversal drugs, such as naloxone;

(4) the percentage of patients at elevated risk who received a prescription for an opioid overdose reversal drug, such as naloxone;

(5) the number of patients reporting use of an opioid overdose reversal drug, such as naloxone; and

(6) any other outcome measures that the Secretary deems appropriate.

(e) REPORTS BY SECRETARY.—For each year of the grant program under this section, the Secretary of Health and Human Services shall submit to the appropriate committees of the House of Representatives and of the Senate a report aggregating the information received from the grant recipients for such year under subsection (d) and evaluating the outcomes achieved by the programs funded by grants made under this section.

SEC. 3. PROVIDING INFORMATION TO PRESCRIBERS IN CERTAIN FEDERAL HEALTH CARE AND MEDICAL FACILITIES ON BEST PRACTICES FOR PRESCRIBING OPIOID OVERDOSE REVERSAL DRUGS.

(a) IN GENERAL.—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services (in this section referred to as the ''Secretary'') may, as appropriate, provide information to prescribers within Federally qualified health centers (as defined in paragraph (4) of section 1861(aa) of the Social Security Act (42 U.S.C. 1395x(aa))), and the health care facilities of the Indian Health Service, on best practices for prescribing opioid overdose reversal drugs, such as naloxone, for patients receiving chronic opioid therapy, patients being treated for opioid use disorders, and other patients that a provider identifies as having an elevated risk of overdose from heroin or prescription opioid therapies.

(b) NOT ESTABLISHING A MEDICAL STANDARD OF CARE.—The information on best practices provided under this section shall not be construed as constituting or establishing a medical standard of care for prescribing opioid overdose reversal drugs, such as naloxone, for patients described in subsection (a).

(c) ELEVATED RISK OF OVERDOSE DEFINED.—In this section, the term ''elevated risk of overdose'' has the meaning given such term by the Secretary, which—

(1) may be based on the criteria provided in the Opioid Overdose Toolkit published by the Substance Abuse and Mental Health Services Administration (SAMHSA); and

(2) may include patients on a first course opioid treatment, patients using extended-release and long-acting opioid analgesics, and patients with a respiratory disease or other co-morbidities.

SEC. 4. AUTHORIZATION OF APPROPRIATIONS.

There is authorized to be appropriated to carry out this Act $5,000,000 for the period of fiscal years 2017 through 2021.

SEC. 5. CUT-GO COMPLIANCE.

Subsection (f) of section 319D of the Public Health Service Act (42 U.S.C. 247d–4) is amended by inserting before the period at the end the following: ''(except such dollar amount shall be reduced by $5,000,000 for fiscal year 2018)''.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Kentucky (Mr. GUTHRIE) and the gentleman from Texas (Mr. GENE GREEN) each will control 20 minutes.

The Chair recognizes the gentleman from Kentucky.

GENERAL LEAVE

Mr. GUTHRIE. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to revise and extend their remarks and insert extraneous materials in the RECORD on the bill.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Kentucky?

There was no objection.

Mr. GUTHRIE. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I rise today in support of H.R. 3680, the Co-Prescribing to Reduce Overdoses Act of 2016, introduced by my colleague on the Energy and Commerce Committee, Mr. SARBANES of Maryland.

In 1999, there were 6.1 overdose deaths per 100,000 Americans involving opioid analgesics and heroin. By 2014, that number doubled to 14.7 overdose deaths. The rate of overdose for individuals aged 24 to 34 nearly tripled, going from 8.1 overdose deaths per 100,000 to 23.1 overdose deaths.

Naloxone is an opioid antagonist that can prevent opioid overdose deaths by binding to the opioid receptors in the body and preventing the overdose. The World Health Organization estimated that, if naloxone was more widely available in the United States, more than 20,000 overdose deaths could be prevented annually.

H.R. 3680 is a step in promoting wider access of naloxone or other opioid-overdose reversal drugs that may come to market. It directs the Secretary of Health and Human Services to carry out a grant program for coprescribing opioid reversal drugs and helps develop best practices for doing so.

Mr. Speaker, I urge my colleagues to support this legislation.

I reserve the balance of my time.

Mr. GENE GREEN of Texas. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, I rise to voice my support for H.R. 3680, the Co-Prescribing to Reduce Overdoses Act. We must do more to prevent opioid addiction and ensure those currently suffering have access to potentially lifesaving treatments.

Naloxone has been proven effective in reversing opioid overdoses, and it is a cost-effective public health intervention. Naloxone blocks and reverses the effects of opioid medication and is used to treat narcotic overdose in emergency situations.

In addition to recent efforts to improve access to naloxone through first responders and community-based health organizations, providing naloxone to at-risk patients in a healthcare setting may reduce overdoses and encourage patients to use prescription drugs more safely.

□ 1645

The Co-Prescribing to Reduce Overdoses Act would create a demonstration grant program to facilitate coprescribing of naloxone when appropriate.

Coprescribing refers to the practice of prescribing that naloxone alongside an opioid prescription to patients with heightened risk of overdose. This could include patients who take significant doses of opioids for long-term chronic pain management, patients with a history of substance abuse, or patients who have been discharged from emergency care following poisoning or intoxication from an opiate.

The bill would further authorize funding to train healthcare providers and pharmacists on coprescribing, establish mechanisms for tracking patients and their health outcomes, and other efforts to expand access to naloxone.

We must act swiftly in order to save lives and stem the growing prescription drug epidemic in our country. The Co-Prescribing to Reduce Overdoses Act is an important step toward preventing overdose deaths, which is a critical part of the fight against our devastating drug crisis.

I want to thank the bill's sponsor, the gentleman from Maryland, Representative JOHN SARBANES, who is a member of our Subcommittee on Health, for his leadership in introducing this bill.

I urge my colleagues to support the Co-Prescribing to Reduce Overdoses Act.

Mr. Speaker, I reserve the balance of my time.

Mr. GUTHRIE. Mr. Speaker, I yield 3 minutes to the gentleman from Pennsylvania (Mr. SHUSTER), the distinguished chairman of the Committee on Transportation and Infrastructure.

Mr. SHUSTER. I thank the gentleman for yielding.

Mr. Speaker, I rise today in support of H.R. 3680, which is one of several initiatives being taken up by the House this week to combat the devastating opioid epidemic our Nation is facing.

Every person in my district knows someone who has been impacted by this crisis, and each day that we wait is another day we go without taking action to save the lives of the people feeling the terrible effects of this addiction.

Each day without action is another day that our communities are ravaged by these drugs.

We can combat this crisis and repair our communities. This is a needed step that both Republicans and Democrats are working together to achieve.

I strongly support this legislation because it will provide funding to our health centers to coprescribe naloxone, a lifesaving drug.

My entire district has been plagued by the scourge of this crisis. The alarming rise in overdose deaths show the urgent need for naloxone to be readily available to both healthcare professionals and those with increased risk of overdose.

These efforts are one part of a broader solution that will undoubtedly save lives. I applaud my colleagues on both sides of the aisle for taking these steps, and I look forward to continuing to work to make our communities a safer place by ridding them of this epidemic.

I urge all my colleagues to support H.R. 3680.

Mr. GENE GREEN of Texas. Mr. Speaker, I am happy to yield 3 minutes to the gentleman from Maryland (Mr. SARBANES), my colleague on the committee.

Mr. SARBANES. I thank the gentleman for yielding.

Mr. Speaker, I first want to thank Ranking Members PALLONE and GREEN, as well as Chairmen UPTON and PITTS, for working diligently with me to bring this bill to the floor today.

This bipartisan bill, the Co-Prescribing to Reduce Overdoses Act, would create a demonstration project to encourage prescribing opioid overdose reversal drugs like naloxone to patients at an elevated risk of overdose, as well as to a close relative of such a patient.

Why is this bill needed, Mr. Speaker?

More than 100 Americans are dying every single day of preventable drug overdose, and overdose fatality is now the leading cause of accidental death in the Nation.

In 2014, in my home State of Maryland, there were 887 opioid-related deaths. In Baltimore, 192 people died from heroin overdoses. In Anne Arundel County in 2014, there were 360 opioid overdoses, fatal and nonfatal; 49 of those were fatal.

The problem is getting worse. From 2001 to 2013, there was a fivefold increase in the total number of deaths from heroin. This is an epidemic, but it is an epidemic that we can begin to stem if we take action.

Naloxone is a drug that safely and effectively reverses both opioid and heroin-induced overdoses, if administered in time. It has been used by nonmedical personnel with only minimal training for over 15 years, and has been proven to lower overdose mortality by almost 50 percent.

More people need access to this lifesaving medication. One part of that proactive approach is the idea of coprescribing naloxone to patients, or their caregivers, who are taking opioids and are at high risk of overdose.

The Co-Prescribing to Reduce Overdoses Act would create a demonstration project for federally qualified health centers, opioid treatment centers, and other providers, to encourage coprescribing of naloxone and other opioid reversal drugs.

This bill has been endorsed by the AMA, the American Society of Addiction Medicine; the American Academy of Family Physicians; and the Harm Reduction Coalition.

There are five Republican cosponsors, I am pleased to say, proving that this is a bipartisan issue affecting virtually every part of the country.

I am pleased as well to note that the bill received unanimous support in the Committee on Energy and Commerce.

I urge support of this bill today because I know that it will save lives and help begin to stem the tide of this terrible epidemic.

I also support the other bills being debated this evening, and believe that these are all important initiatives to address the opioid crisis.

However, it is just as critical that we provide adequate resources for all aspects of this epidemic to prevent addiction, to provide effective treatment, and to increase access to lifesaving opioid reversal drugs in order to truly bring an end to this epidemic.

Mr. Speaker, I urge support of this important legislation.

Mr. GUTHRIE. Mr. Speaker, one of the great privileges of the people's House, people come here from all walks of life with all different expertise.

I yield such time as he may consume to the gentleman from Georgia (Mr. CARTER), the only registered pharmacist that serves in the House of Representatives, who is here to speak on this and several of the bills today.

Mr. CARTER of Georgia. I thank the gentleman for yielding.

Mr. Speaker, I rise today in support of H.R. 3680, the Co-Prescribing to Reduce Overdoses Act, which gives patients the tools they need to protect themselves from opioid overdoses.

H.R. 3680 calls for the Department of Health and Human Services to create a grant program that will increase the ability for healthcare providers to coprescribe opioid reversal medication like naloxone when those providers prescribe opioid-based medications for patients.

This new direction by HHS will work to decrease the risk of fatally overdosing on opioids while also allowing healthcare providers to learn more about the opioid reversal medication benefits.

In addition, with the grant money, providers will be able to track patient outcomes to make sure that the reversal medication has the desired effect.

As a lifelong pharmacist, I consider it my duty to always care for my patients and give them every tool I can to protect and serve them the best way I can, and I have carried this duty to the United States House of Representatives.

The Co-Prescribing to Reduce Overdoses Act does just this and is a major step in the right direction to ending the opioid addiction deaths in America.

I encourage all of my colleagues to support this bill.

Mr. GENE GREEN of Texas. Mr. Speaker, I yield back the balance of my time.

Mr. GUTHRIE. Mr. Speaker, I appreciate the gentleman from Maryland (Mr. SARBANES) bringing this forward and all the bipartisan work that was put into it. I urge my colleagues to support this legislation.

I yield back the balance of my time.

Ms. JACKSON LEE. Mr. Speaker, I rise in support of H.R. 3680 the "Co-Prescribing To Reduce Overdoses Act of 2015."

This bill requires the Department of Health and Human Services (HHS) to establish a grant program to support prescribing opioid overdose reversal drugs, such as naloxone, for patients at an elevated risk of overdose, including patients prescribed an opioid.

Opioids are drugs with effects similar to opium, such as heroin and certain pain medications.

The Centers for Disease Control and Prevention reports that nearly 259 million opioid prescriptions were written in 2012, more than enough for every adult in the United States.

In 2013 nearly 4.5 million people in the United States without a valid medical need were using prescription painkillers.

Both states and the federal government have begun responding to this growing public health crisis.

The Obama administration has awarded $94 million to community health centers to improve and expand the delivery of substance abuse services.

H.R. 3680 would encourage and train health care providers to prescribe lifesaving overdose reversal drugs.

Enacting this legislation will help reduce drug overdoses across the country by giving at-risk patients better access to lifesaving overdose reversal drugs.

The plague of opioid overdose deaths across the nation is disturbing, but there are ways to combat this trend.

H.R. 3680 is supported by the American Medical Association, the American Society of Addiction Medicine and the Harm Reduction Coalition.

A party, or organization receiving a grant under this legislation will use the grant for the following reasons:

1. To establish a program for co-prescribing opioid overdose reversal drugs.

2. To train and provide resources for health care providers and pharmacists on the co-prescribing of opioid reversal drugs.

3. To establish mechanisms and processes for tracking patients participating in the program.

4. To purchase opioid overdose reversal drugs for distribution.

5. To offset the copays and other cost sharing associated with opioid overdose reversal drugs to ensure that cost is not a limiting factor for eligible patients.

6. To conduct community outreach, in conduction with community based organizations, designed to raise awareness of co-prescribing practices and the availability of opioid overdose reversal drugs.

7. To establish protocols to connect patients who have experienced a drug overdose with appropriate treatment, including medications assisted treatment and appropriate counseling and behavioral therapies.

Mr. Speaker, the mounting number of people adversely affected and the over 25,000 lives lost expressly demonstrates the need for this type of legislation.

H.R. 3680 is a positive step in the right direction and I urge all members to support this important legislation.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Kentucky (Mr. GUTHRIE) that the House suspend the rules and pass the bill, H.R. 3680, as amended.

The question was taken; and (two-thirds being in the affirmative) the rules were suspended and the bill, as amended, was passed.

A motion to reconsider was laid on the table.

NURTURING AND SUPPORTING HEALTHY BABIES ACT

Mr. GUTHRIE. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 4978) to require the Government Accountability Office to submit to Congress a report on neonatal abstinence syndrome (NAS) in the United States and its treatment under Medicaid, as amended.

The Clerk read the title of the bill.

The text of the bill is as follows:

H.R. 4978

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

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Nurturing And Supporting Healthy Babies Act'' or as the ''NAS Healthy Babies Act''.

SEC. 2. GAO REPORT ON NEONATAL ABSTINENCE SYNDROME (NAS).

(a) IN GENERAL.—Not later than one year after the date of the enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Finance and the Committee on Health, Education, Labor and Pensions of the Senate a report on neonatal abstinence syndrome (in this section referred to as ''NAS'') in the United States.

(b) INFORMATION TO BE INCLUDED IN REPORT.—Such report shall include information on the following:

(1) The prevalence of NAS in the United States, including the proportion of children born in the United States with NAS who are eligible for medical assistance under State Medicaid programs under title XIX of the Social Security Act at birth and the costs associated with NAS through such programs.

(2) The services for which coverage is available under State Medicaid programs for treatment of infants with NAS.

(3) The settings (including inpatient, outpatient, hospital-based, and other settings) for the treatment of infants with NAS and the reimbursement methodologies and costs associated with such treatment in such settings.

(4) The prevalence of utilization of various care settings under State Medicaid programs for treatment of infants with NAS and any Federal barriers to treating such infants under such programs, particularly in non-hospital-based settings.

(5) What is known about best practices for treating infants with NAS.

(c) RECOMMENDATIONS.—Such report also shall include such recommendations as the Comptroller General determines appropriate for improvements that will ensure access to treatment for infants with NAS under State Medicaid programs.

SEC. 3. EXCLUDING ABUSE-DETERRENT FORMULATIONS OF PRESCRIPTION DRUGS FROM THE MEDICAID ADDITIONAL REBATE REQUIREMENT FOR NEW FORMULATIONS OF PRESCRIPTION DRUGS.

(a) IN GENERAL.—The last sentence of section 1927(c)(2)(C) of the Social Security Act (42 U.S.C. 1396r–8(c)(2)(C)) is amended by inserting before the period at the end the following: '', but does not include an abuse-deterrent formulation of the drug (as determined by the Secretary), regardless of whether such abuse-deterrent formulation is an extended release formulation''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to drugs that are paid for by a State in calendar quarters beginning on or after the date of the enactment of this Act.

SEC. 4. LIMITING DISCLOSURE OF PREDICTIVE MODELING AND OTHER ANALYTICS TECHNOLOGIES TO IDENTIFY AND PREVENT WASTE, FRAUD, AND ABUSE.

(a) IN GENERAL.—Title XI of the Social Security Act is amended by inserting after section 1128J (42 U.S.C. 1320a–7k) the following new section:

''SEC. 1128K. DISCLOSURE OF PREDICTIVE MODELING AND OTHER ANALYTICS TECHNOLOGIES TO IDENTIFY AND PREVENT WASTE, FRAUD, AND ABUSE.

''(a) REFERENCE TO PREDICTIVE MODELING TECHNOLOGIES REQUIREMENTS.—For provisions relating to the use of predictive modeling and other analytics technologies to identify and prevent waste, fraud, and abuse with respect to the Medicare program under title XVIII, the Medicaid program under title XIX, and the Children's Health Insurance Program under title XXI, see section 4241 of the Small Business Jobs Act of 2010 (42 U.S.C. 1320a–7m).

''(b) LIMITING DISCLOSURE OF PREDICTIVE MODELING TECHNOLOGIES.—In implementing such provisions under such section 4241 with respect to covered algorithms (as defined in subsection (c)), the following shall apply:

''(1) NONAPPLICATION OF FOIA.—The covered algorithms used or developed for purposes of such section (including by the Secretary or a State (or an entity operating under a contract with a State)) shall be exempt from disclosure under section 552(b)(3) of title 5, United States Code.

''(2) LIMITATION WITH RESPECT TO USE AND DISCLOSURE OF INFORMATION BY STATE AGENCIES.—

''(A) IN GENERAL.—A State agency may not use or disclose covered algorithms used or developed for purposes of such section except for purposes of administering the State plan (or a waiver of the plan) under the Medicaid program under title XIX or the State child health plan (or a waiver of the plan) under the Children's Health Insurance Program under title XXI, including by enabling an entity operating under a contract with a State to assist the State to identify or prevent waste, fraud, and abuse with respect to such programs.

''(B) INFORMATION SECURITY.—A State agency shall have in effect data security and control policies that the Secretary finds adequate to ensure the security of covered algorithms used or developed for purposes of such section 4241 and to ensure that access to such information is restricted to authorized persons for purposes of authorized uses and disclosures described in subparagraph (A).

''(C) PROCEDURAL REQUIREMENTS.—State agencies to which information is disclosed pursuant to such section 4241 shall adhere to