

H.R. 3590

Pages 420 through 455

Analysis by: Jane Lindell Hughes, M.D., F.A.C.S.

I have read the stated pages, and my evaluation will adhere to the following format: Pages and section, Topic, Salient Features, Funding, and Comments.

This was an extremely difficult assignment for many reasons, not the least of which was the realization that the authors are by and large ignorant regarding medicine, surgery, and the etiology of disease. Obviously there was little or no input from practicing physicians. Even more distressing was an egregious lack of understanding of what is currently in place in the American Healthcare System, what needs reform rather than replacement, and the destructive potential of this bill.

I view this bill as the ultimate example of the failure and meltdown of our Federal Government. If one is to go about “transforming” a \$6 trillion a year industry, or about 16% of the private sector economy, a minimum requirement should be a thorough understanding of the system. When that industry affects each and every American in some of life’s most intimate and important moments, the flagrant rejection of debate and reason is indefensible. The manner in which it was passed represents dereliction of duty for every member of Congress who voted for it without reading it.

This bill has very little to do with improving access, decreasing costs, and improving quality. It has to do with the dismantling of the private sector practice of medicine, the economic destruction of medium and large private sector business via mandates and new taxes, the redistribution of wealth utilizing health care coverage as the vehicle, and the intrusion of the Federal Government into the day to day affairs of the American Citizen. In my opinion we must expose it as such with a concise and clear message utilizing examples from the bill itself. Hopefully this effort we have expended will translate into an effective public education campaign and culminate in the repudiation of the type of governance which led to the passage of this bill and with its repeal.

Page 420

Subtitle G/ Protecting and Improving Guaranteed Medicare Benefits

Salient Features: States nothing in the act shall result in the reduction or elimination of any benefits guaranteed by law to participants in Medicare Advantage plans.

Funding: “Such funds as may be necessary”

Comments: WSJ/Friday June 11, 2010 “Farewell, Medicare Advantage”...After the President reassured seniors that their benefits under H.R. 3590 will not change, even with the Medicare Advantage Plans, the WSJ reported Democrat plans to cut \$136 billion from Medicare Advantage over the next decade. The CBO says these cuts will cause enrollment to drop by 35%, and the Administration’s own Medicare actuaries predict a 50 % drop. They both take for granted that benefits will decline, according to the article.

Pages 420 to 428

Title IV- Prevention of Chronic Disease and Improving Public Health

Subtitle A- Modernizing Disease Prevention and Public Health Systems

Section 4001- National Prevention, Health Promotion and Public Health Council

Salient Features: Section 4001: President establishes within the department of Health and Human Services a “National Prevention, Health Promotion and Public Health Council”. Members headed by Surgeon General include Secretary of Health and Human Services, Secretary of Agriculture, Secretary of Education, Chairman of the Federal Trade Commission, Secretary of Transportation, Secretary of Labor, Secretary of Homeland Security, Administrator of the Environmental Protection Agency, Director of domestic Policy Council, Director of the Office of national Drug Control Policy, the Assistant Secretary of Indian Affairs, the Chairman of the Corporation for National and Community Service, and the head of any other Federal agency that the Chair deems appropriate.

The purpose and duties of the council are: “...coordination and leadership on the Federal level for prevention, wellness and health promotion practices...and after obtaining input from ‘relevant stakeholders’, develop a national prevention, health promotion, public health, and integrative health care strategy that incorporates the most effective and achievable means of improving the health status of Americans.” This is to be done by focusing on reduction in tobacco use, sedentary behavior, poor nutritional habits and obesity. This council will also consider and propose “evidence-based models, policies, and innovative approaches for the promotion of *transformative* models of prevention, integrative health, and public health *on individual and community levels* across the United States” (Italics my own). An advisory group will be established by the President and consist of not more than 25 non-Federal members *who will be appointed by the President*. First report to the President is due July 1, 2010 with list of national health priorities, strategies for corrective actions “to achieve lifestyle behavior modifications (smoking cessation, proper nutrition, appropriate exercise, mental health, behavioral health, substance abuse disorder, and *domestic violence screenings*,) and the preventive measures for the 5 leading disease killers in the United States.” This section requires that this council reports with specific plans to “ensure that all non-Department of HHS prevention programs are based on the science based guidelines developed by the CDC...”

Funding: Dealt with in section 4002. \$6 billion appropriated to get through 2015

Comments: The individuals appointed to this Council charged with transformative change in health care have little to no knowledge or expertise in medicine, have heavy responsibilities in their respective government positions, and they are all political appointees. This is especially true for the advisors to the council, who may be physicians and related healthcare professionals, but they are ALL appointed by the President. Much of what has been outlined as their purpose and duties is already in place. These “preventive measures” are a critical part of most primary care practices and public health clinics and have been for years. I did not see anything new regarding public health priorities in this section. What is “transformative” about these goals? How is behavior going to be modified? How is individual success going to be monitored? How is domestic violence *screening* accomplished? How is the Fed going to insure that private programs are in line?

Section 4003: Clinical and Community Preventive Services

Salient Features: Establishes the “Independent Preventive Services Task Force” made up of individuals with “appropriate expertise” to evaluate the “effectiveness, appropriateness, and cost effectiveness of clinical preventive services”. This task force will educate the healthcare community about such, to be published in the “Guide to Clinical Preventive Services” for individuals delivering clinical services. This will serve as a “best practices” Federal mandate. This section ends by proclaiming that the council and task force shall not be subject to political pressure.

Funding: “Authorization of such sums as may be necessary for each fiscal year to carry out the activities of the Task Force.”

Comment: This section essentially sets up Federal guidelines for clinical preventive medicine practices. What administrative burdens are involved with compliance to these guidelines? What if the guidelines are at odds with accepted medical or surgical practice, as the recent mammogram recommendations? What are the repercussions of failure to comply with the guidelines? Why is the Federal Government, rather than the medical community, developing “best practice” guidelines?

Section 4004: Education and Outreach Campaign Regarding Preventive Benefits

Salient Features: The Secretary of Health and Human Services shall set up a public-private partnership for a health outreach campaign to raise public awareness of potential health improvements across the life span when the Task Force recommendations are followed. The public is also apprised of the preventive services covered under health plans offered through a “Gateway”.

A media campaign is described which is to begin not later than one year after the enactment of H.R. 3590. It will address proper nutrition, regular exercise, smoking cessation, obesity reduction, and “specific chronic disease reduction”. The specific diseases are not enumerated. Bidding by media production entities will determine who will create the spots to be aired on radio, TV, the internet and any other commercial venues targeting specific age groups. The campaign may include “humor and nationally recognized positive role models”.

Healthcare providers who participate in Federal Programs will be required to disseminate the Federal information on health promotion and disease prevention consistent with *national priorities*. A website will be developed so that individuals can create their own Personalized Prevention Plans. These will be designed to be used as a source of “the most up-to-date scientific evidence relating to disease prevention for use by individuals.” The website shall contain a rubric for the individual to enter information and then obtain their risk for the 5 leading diseases in the United States and personalized suggestions for prevention of such diseases.

Funding: \$500,000,000 is appropriated

Comments: The media campaign is based on information that is almost entirely common knowledge in America by all walks of life. Past and present media campaigns cover these same issues. We have labels of potential danger on cigarettes, toys, paints, playground equipment, etc. Again, this is nothing new. Individuals will always decide to accept or reject advice. Personalized prevention plan website ideas are already in place in the private sector. My fitness Pal.com is an excellent example of a very effective site and it does not add a cent to the deficit. What are the 5 leading disease killers in the U.S.? I was gratified to learn they can be prevented. The verbiage in the bill suggests equality between advice from an expert, advice from a bureaucrat, a personal encounter with a physician, and logging on to WebMD. It is impossible for a group of political appointees acting by committee to establish credible “best practices” in any field of medicine.

Subtitle B-Increasing Access to Clinical Preventive Services

Section 4101: School Based Health Centers

Salient Features: The Secretary of Health and Human Resources shall award grants to eligible entities to build and support school based comprehensive health clinics for children and adolescents. The school district would have to match the grants by 20%, and the funding is only appropriated through 2014. These grants would be for land acquisition, construction of the clinics in the schools, equipment, and replacing portions of schools to accommodate the clinics. These clinics would operate during school hours and offer comprehensive health assessments, diagnosis and treatment of minor, acute, and chronic medical conditions, and referrals and follow-up for specialty care and oral health services. Mental health, crisis intervention, counseling, and emergency psychiatric care are included. Abortion services are not included. Neither is the ability to verify eligibility status. Preference for grants will go to schools with a high number of Medicaid children and adolescents. There will be on- site access during the academic day, and 24 hour coverage with an on call system when school is not in session or it is after hours.

Health services will be coordinated with school personnel such as “administrators, teachers, nurses, counselors, and support personnel.” *The school assumes all responsibility for the administration, oversight, and operations of the school based health clinic.* Funding not designated as construction in nature will be used to pay *salaries for physicians, nurses, and other paramedical personnel.*

The Secretary of HHS will develop and implement the means to evaluate the school based comprehensive health clinics and monitor the quality of care. The bill makes the assurance that only “age appropriate” services will be provided.

Funding: “Such sums as may be necessary for each of the fiscal years of 2010 through 2014.

Comments: I served as a Trustee on the Northside Independent School District School Board in San Antonio, Texas for two terms. We had 80,000 students and just under a \$400,000,000 budget. I was the chair of the Finance Committee and the Academics Committee. This portion of the bill is beyond rational consideration. The cost of baseline school construction is astronomical, and in high growth areas the school districts must repeatedly return to the local voters for passage of bond issues for school construction. This translates into higher property taxes and in some cases resultant forced home sales. A baseline comprehensive school health clinic added on to a school is a prohibitively expensive proposition. Furthermore, Medicaid recipients are already funded to see physicians in their private offices eliminating all administrative and building costs. Perhaps the thought is the physician on salary will be able to cut costs of care enough to pay for the clinic.

There is not a principal in the country who is equipped to manage, nor would they agree to manage a comprehensive health care clinic. Their school administration job is full time. Furthermore, integrating a healthcare clinic into a busy academic day is a disruption that schools will be unwilling and unable to undertake. The liability, documentation burdens, federal regulations, cost, tax impact on property, and major privacy issues make this an unworkable law.

Pages 432-435

Part T-Oral Healthcare Prevention Activities

Section 399LL Oral Healthcare Prevention Education Campaign

Salient Features: Establishes a 5 year public education campaign *in culturally and linguistically appropriate* manner regarding oral care, periodontal disease, and oral cancer. Target messages would include water fluoridation and dental sealants. School based sealant programs would be established. Grants for research into dental caries would be issued. States would be required to submit reports to the Secretary of HHS on the effectiveness of these programs by measurements mandated by HHS. One thing mandated is “tooth level surveillance” which is defined as “an

examiner looking at each dental surface on each tooth in the mouth.” The PRAM program (Pregnancy Risk Assessment Monitoring System) is included in these mandatory evaluations of oral health. This section also includes a National Oral Health Surveillance System which is already running in 16 states. It includes measurement of early childhood caries. The goal is to get all 50 states to participate.

Funding: If available, “such sums as may be necessary”, and only through 2014.

Comments: It was my understanding that the causes of dental caries have been identified. It appears that what is meant by media campaigns is to direct individuals to the government programs rather than disseminate new information. The public service announcements heard on the radio come to mind. They are paid for by taxpayers. They inform citizens about the entitlements for which they may be eligible. What is a “culturally and linguistically appropriate manner”?

Pages 435-440 (Pages 438-440: Unintelligible)

Sections 4103-4105: Medicare Coverage of Annual Wellness Visit

Providing Personalized Prevention Plan

Salient Features: Secretary of HHS establishes guidelines for a risk assessment that must be completed by the individual prior to the Annual Wellness Visit. The elements of the visit are established by the Secretary and are outlined in the bill! They include: measurement of height, weight, waist circumference, blood pressure, and other routine measures. Detection screening for cognitive impairment and the establishment of a 5 to 10 year screening schedule *which is to be based on the United States Preventive Services Task Force and Advisory Committee recommendations*. A physical exam as described in subsection ww1 shall be performed. A behavior modification and risk reduction plan will be furnished to the Medicare beneficiary for self management. Wellness education will address weight loss, quitting smoking, proper nutrition, physical activity, and fall prevention. Electronic medical records and personal health records will be encouraged. Section 4104 is entitled, “Evidence Based Coverage of Preventive Services in Medicare.” It appears to give the Secretary of HHS the authority to eliminate or modify coverage of any preventive services.

Funding: The next three pages concerning amendments of existing funding rubrics were unintelligible.

Comments: This is a flagrant intrusion of the Federal Government into the doctor/patient relationship and the practice of medicine. The simplistic approach and assumption promoted is that most disease can be prevented. Unfortunately cancer, renal calculi, AVM’s, brain tumors, Parkinson’s, AMLS, etc happen. Medicare patients and physicians are regarded as widgets in the system by restating the obvious in preventive messages mandated to be delivered, and spelling out how often and what screenings an individual may receive. The recent mammogram recommendation comes to mind.

Pages 442-446

Sections 4107 and 4108

Coverage of Comprehensive Tobacco Cessation Services for Pregnant Women in Medicaid, and Incentives for Prevention of Chronic Diseases in Medicaid

Salient Features: Full payment for programs offering prescription and non-prescription tobacco cessation products, counseling, and behavior modification as deemed effective by the Secretary of HSS. The section on Medicaid and chronic diseases is a grant program to States to set up approaches that encourage behavior modification in preventive health measures such as weight loss, tobacco cessation, addiction therapy, etc. These preventive programs are described as evidence based, uniquely suited to Medicaid populations. They are reliant on incentives

given to individuals who successfully complete the program. The media campaign is to make beneficiaries aware of these programs available to them. The States pay for the public awareness campaigns. The Federal grants last for four years. The States must track and report the results, including adoption of healthy behaviors by beneficiaries. The Federal Government will monitor the effectiveness of the various State programs, including accessibility and quality of health services provided through the program.

Funding: \$100,000,000 above current allocations for Medicaid.

Comments: This section seems to throw money at programs that mimic practices that already take place in the United States healthcare system. Public health clinics, University clinics, and private practices that accept Medicaid all have wellness programs as well as preventive care recommendations, including weight loss, not smoking, and physical exercise. All of these are admirable goals we all share as physicians. The government did not invent them.

Pages 446-455

Subtitle C- Creating Healthier Communities

Community Transformation Grants, Healthy Aging, Living well; Evaluation of Community Based Wellness Programs

Sections 4202-4205

Salient Features: Essentially Feds issue grants to State agencies, local governmental agencies, a “*national network of community-based organizations*” and State or local non-profit organizations for the purpose of developing programs that promote healthy living and reduce disparities in access and quality of care. They focus on school programs, Public Health programs for individuals ages 55 to 64, infrastructure changes in cities to promote active living, access to nutritious foods, safe environments, and social and emotional wellbeing. No area is left unmentioned in the programs that will bring the whole community into a grand scale health and wellness transformation. Much is said of addressing racial and ethnic disparities, individuals with disabilities, and monitoring results. The Secretary of HHS is the director of the transformation activities and the evaluator of the results. There is a prohibition for “using any funds on video games or other activities that may lead to higher rates of obesity or inactivity”. There is a list of the previously mentioned targets of preventive health care and wellness and activities to achieve them. Secretary of HHS must approve screening measures. There is also a re-statement of the American’s With Disabilities Act with increased scrutiny to ensure there are no barriers to access. Section 4204 re-states the immunization requirements.

Funding: Secretary of HHS can transfer funds from the Social Security Trust Fund in such proportion as she deems appropriate up to \$50,000,000. Otherwise, “such sums as may be required”

Comments: This is one section that must be read to be believed. Presumably in Transformation Land, no one has time to hold a job with all of the workouts and preventive health seminars and measurements, everyone cares about living healthier, all diseases are prevented, and ACORN has succeeded in the great transformation with a little assistance from the Federal Government. Unfortunately there are massive costs shifted to the States, many of which are already facing insolvency, and nightmarish administrative burdens. One of the provisions is to suspend the applicability of the Paperwork Reduction Act. There is also a massive shift from patient/physician centered care to government centered, committee based care.

Pages 455 to 458

Section 4205: Nutrition Labeling of Standard Menu Items and Chain Restaurants

Salient Features: Any retail food establishment and vending machine company of twenty or more shall be required to disclose the nutritional content of each food item adjacent to the item on the menu and menu board. Also, the suggested daily caloric intake of each nutritional category, as specified by the Secretary, must be included. Written pamphlets with the information must also be available. All self serve buffets must also post the menu info adjacent to the food item. Vending machines must have this information next to each selection button or food item. These mandates may be extended to include standardization of recipes, methods of preparation, reasonable (and unreasonable) variation in serving size, and formulation....variation in ingredients and *other factors* as determined by the Secretary.

Funding: None specified, presumably the involved business owners “absorb” the expense.

Comments: Having nutritional information available is an excellent idea, and many retail food establishments have pamphlets with this information available to the public. However, these intrusive and dictatorial mandates are ludicrous, impractical, and expensive to implement.

Page 458

Section 4206: Demonstration Project Concerning Individualized Wellness Plan

Salient Features: Establishes a “pilot program” to test the impact of providing at risk populations who utilize community health centers with individual wellness plans to decrease risk factors for preventable conditions. The targeted behaviors are enumerated as nutritional counseling, a physical activity plan, alcohol and tobacco cessation, stress management and dietary supplements which must be approved by the Secretary.

Funding: Such sums as may be necessary

Comments: Where have the authors of this bill been for the past 40 years? Not only have primary care physicians been stressing the benefits of adoption of these lifestyle habits, but 100% of individuals attending public schools have received this information all throughout their school experiences since the 1950's. How many “pilot projects” does the Secretary envision to re-invent the wheel?

Page 459

Section 4207: reasonable Break Time for Nursing Mothers

Salient Features: The employer must provide “reasonable break time” for nursing mothers to pump milk until the child is one year old. A private room, not the restroom, must be provided. The employer is not required to pay the employee for the nursing break. Businesses under 50 employees are exempt.

Funding: None specified. Evidently the employer must assume the cost of building a nursing/pumping room.

Comments: There are several unintended consequences readily apparent in this section. There could be a subtle negative attitude fostered if an employee costs the employer more than another of equal skills, either in inconvenience, resources (new construction), or the extra accounting required to calculate the different pay checks in each pay period for each nursing mother/employee. Many female employees work and pump already, doing so on their breaks. This Federal intrusion is unnecessary.

Page 460

Data Collection, Analysis, and Quality

Salient Features: Requires a report no later than two years after any Federal mandated program or project from the participating entity. They must submit data on race, ethnicity, sex, primary language, and disability status on all participants. There was emphasis on individuals with disability access. National standards for data collection and management shall be established by the Secretary and be disseminated through the National Coordinator for Health Information Technology. Electronic medical records are suggested as a mandate for participants. Data analysis is performed for the stated purpose of monitoring healthcare disparities based on the above demographics. The results will be made available to the Office of Minority Health, the National Center on Minority Health and Health Disparities, The Indian Health Service, etc. Reporting on the data collected and analyzed will be publically posted on the website of HHS *and any other disseminating mechanisms deemed appropriate by the Secretary. Data may not be used to determine eligibility or continued eligibility in health plans.*

Funding: Authorize such funds as may be necessary through year 2014.

Comments: This section clearly makes illegal aliens eligible for public health programs by prohibiting validation of eligibility from the data collected. The analysis mandates stressing disparities which connotes a preconceived bias that they exist. With the longstanding availability of public health clinics, community outreach, the war on poverty, etc., it would be interesting to compare access to baseline care and special programs to individuals of minority status compared to individuals in the same economic group without minority status. The compliance mandates on reporting are the reason why this legislation suspends the Paperwork Reduction Act.

Page 464

Section 1946: Addressing Health Care Disparities

Salient Features: Enumerates the reporting requirements for all of the programs in the healthcare “transformation” with mandates for ongoing, accurate and timely collection and evaluation of data on disparities on the basis of race, ethnicity, sex, primary language, and disability. Four years into implementation the Secretary shall report to Congress ways to improve *identifying disparities*, (not ways to solve disparities, if they exist.)

Funding: None specified. Again, the documentation burden appears to be the administrative cost of the “participating entities”.

Comments: Anyone ever participating in a drug study can visualize the nightmare of data collection, analysis, and reporting required in the construct designed by bureaucrats. The major features of reporting do not appear to be identification of successful programs, but rather the identification of race based disparity in care.

Page 465

Part U- Employer Based Wellness Program

Section 399mm: Technical Assistance for Employee Based Wellness Programs

Salient Features: *“In order to expand the utilization of evidence-based prevention and health promotion approaches in the workplace, the Director shall provide small, medium, and large employers” . . . technical assistance, consultation, etc. to implement and evaluate employer based wellness programs. These will include standardized measures that assess policy and system changes necessary to have a “positive impact on employee health behaviors.” Also included are methods the employer must use to assess the expected changes in health status, productivity, absenteeism and rate of workplace injuries. The employer based health programs will be evaluated by a “national worksite health policies and programs” required survey. The last paragraph of this section prohibits Federal workplace wellness requirements.*

Comments: With this section ObamaCare shifts the implementation and cost of wellness programs for non-indigent and non-Medicare populations to the *employer*. This unfunded mandate also shifts the resources and attention of the employer away from the product of the business to a mandated wellness program. When is the employee participation in these mandated programs to occur- during business hours? If not, must the employer pay for overtime? What about privacy issues and HIPPA mandates? What employee wants their employer, much less the Federal Government, to get involved in their personal healthcare matters? An injury in the workplace will look like the BP oil spill in terms of response with this mandate- unless of course it occurs in a Federal workplace.

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Subtitle C: Strengthening Public Health Surveillance Systems

Salient Features: Grants will be made available to assist public health agencies to improved surveillance and response to infectious diseases.

Funding: \$190,000,000 per year from 2010 through 2013.

Comments: There are existing community and national communicable disease centers that already receive Federal and State funding. No mention is made of what the current funding is, what these organizations can not currently perform because of lack of funding, and what that funding shortfall is.

Section 4305: Advancing Research and treatment for Pain Management

Salient Features: Convenes a conference on pain via the Institute of Medicine of the National Academies with the intent of recognizing pain as a significant public health problem, and to “identify ethnic, racial, gender, age and other demographic groups that may be disproportionately affected by inadequacies in pain care.” In addition, this sections establishes an “Inter-agency Pain Research and Coordination Committee” of mostly non-physicians appointed by the Secretary. Their purpose is to define critical gaps in basic science and clinical research on the symptoms and causes of pain, and to summarize advances in pain care research. It closes with a program to educate healthcare professionals in pain care.

Funding: Such sums as may be required from 2010 through 2012.

Comments: Almost everything in this section has been done, and with more knowledge and skill than the committee members could ever achieve given the dearth of physicians and healthcare scientists on the committee. The national anesthesiology, neurology, neurosurgery, spine, orthopedic surgery, and rehabilitation associations have active pain management and interdisciplinary approaches to pain management literature and symposia. This section vividly illustrates the ignorance of the authors.

Pages 469 to 470

Subtitle E: Miscellaneous Provisions

Section 4401: Sense of the Senate Concerning CBO Scoring

Salient Features: “The Senate finds that the costs of prevention programs are difficult to estimate due in part because prevention initiatives are hard to measure and results may occur outside the 5 and 10 year budget windows. It is the sense of the Senate that Congress should work with the CBO to develop better methodologies for scoring progress to be made in prevention and wellness programs.”

Comments: Even Congress is skeptical of the estimates of cost, where those are even mentioned, and the difficulty of predicting those cost and whether or not the cost is justified by difficult to measure nebulous outcomes.

Section 4402: Effectiveness of Federal Health and Wellness Initiatives

Salient Features: Determines if existing Federal health and wellness initiatives are effective. It entails monitoring individual employee food and beverage choices, individual productivity, absenteeism, etc.

Funding: Not specified

Comments: Now they tell us! The Feds don't have a clue whether or not their existing "wellness programs" (unspecified) have worked. Enough said. The authors should consult the private sector physicians. May I suggest cardiologists and primary care physicians? They could shed some evidence-based light on lifestyle changes that have measured impact on wellness and quality of life.