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United States Senate

CHARLES E. GRASSLEY

WASHINGTON, DC 20510–1501

April 29, 2016

VIA ELECTRONIC TRANSMISSION

The Honorable Sylvia Burwell
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Re: 42 CRF Part 511 Medicare Program; Part B Drug Payment Model; Proposed Rule

Dear Secretary Burwell:

On March 11, 2016 the Centers for Medicare Medicaid Services (CMS) issued a proposed rule for comment. The proposed rule puts forward for consideration a new Medicare payment model under section 1115A of the Social Security Act (SSA). The proposal is a two-phase model that would test whether an alternative drug payment system will lead to a reduction in Medicare Part B expenditures. The first phase would involve reducing the 6 percent add-on to the Average Sales Price (ASP) that is currently used to a 2.5 percent add-on plus a flat fee. The second phase would test the use of value-based purchasing tools[1].

I am concerned that throughout this proposed rule two terms are repeatedly used - "study" and "test." These terms seem to indicate there is a component of research going on in this proposal. I am writing you today to see if that is true and if that is true, are adequate protections in place for the Medicare beneficiaries who will be research participants.

In 1979, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral research wrote the Belmont Report[2]. This landmark document was the foundation for U.S. federal policy for the protection of human subjects in research. This policy was published as the "Common Rule" in 1991 and then codified through regulation (45 CFR part 46, subpart A) to apply to all of the departments and agencies listed below:

Agency for International Development

[1] https://www.federalregister.gov/articles/2016/03/11/2016-05459/medicare-program-part-b-drug-payment-model
[2] http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html
[3] http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#subparta
[4] *Ibid*
[5] *Ibid*

Consumer Product Safety Commission
Department of Agriculture
Department of Defense
Department of Education
Department of Energy
Department of Health and Human Services
Department of Housing and Urban Development
Department of Justice
Department of Transportation
Department of Veterans Affairs
Environmental Protection Agency
National Aeronautics and Space Administration
National Institute of Standards and Technology
National Science Foundation[3]

In addition, the following departments and agencies must also comply with 45 CFR part 46:

Central Intelligence Agency
Department of Homeland Security
Social Security Administration

Among other protections, the Common Rule requires any researcher to obtain "legally effective informed consent"[4]. Furthermore, the law says a person participating in research should do so of his or her own free will. Undue influence or coercion to participate in a study is prohibited.

It is my understanding that there are certain exceptions that allow government agencies to perform research without the informed consent of an individual. One exception is "research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

(i) Public benefit or service programs;
(ii) procedures for obtaining benefits or services under those programs;
(iii) possible changes in or alternatives to those programs or procedures;
(iv) possible changes in methods or levels of payment for benefits or services under those programs[5].

[1] https://www.federalregister.gov/articles/2016/03/11/2016-05459/medicare-program-part-b-drug-payment-model
[2] http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html
[3] http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#subparta
[4] *Ibid*
[5] *Ibid*

However, it is my understanding that the proposed study for Part B of Medicare will be testing the hypothesis that a change in payment methodology will change a doctor's prescribing habits resulting in a Medicare beneficiary receiving a different medication. To me, that seems to be going beyond the intention of the exception in the Common Rule. By randomizing people to different payment methodologies, it seems possible that patients might receive a drug that is less effective for them. And, that seems to be a clinical trial. Therefore, please answer the following:

1. Is the Medicare Part B proposal research? If not, why not?
2. If this is research, how do you intend to obtain legally effective informed consent?
3. If this is research, how does HHS intend to collect and report adverse events?
4. If this is research, does HHS need to report findings at ClinicalTrials.gov?
5. If the results of this study are negative, that is it fails to show savings in Part B, will the results be made public?
6. Does HHS have any responsibility to inform physicians that they are participating in research? If not, why not?
7. Have other study designs to evaluate payment change been considered?

Please contact my staff, Karen Summar, with questions and with your answers.
Karen_Summar@Grassley.Senate.Gov

Sincerely,

Chuck Grassley

Charles E. Grassley
U.S. Senator

[1] https://www.federalregister.gov/articles/2016/03/11/2016-05459/medicare-program-part-b-drug-payment-model
[2] http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html
[3] http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#subparta
[4] *Ibid*
[5] *Ibid*

Cc: Andrew Slavitt, Acting Adminstrator, Centers for Medicare and Medicaid Services
Patrick Conway, M.D., MSc, Deputy Administrator for Innovation and Quality & CMS Chief Medical Officer
Jerry Menikoff, M.D., Director of the Office for Human Research Protections (OHRP), HHS

[1] https://www.federalregister.gov/articles/2016/03/11/2016-05459/medicare-program-part-b-drug-payment-model
[2] http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html
[3] http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#subparta
[4] *Ibid*
[5] *Ibid*