



## INTERNATIONAL SOCIETY *for* PHARMACOEPIDEMIOLOGY

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5272 River Road, Suite 630, Bethesda, MD 20816 • USA • Phone: 301-718-6500 • Fax: 301-656-0989  
E-mail: [ispe@pamgmt.com](mailto:ispe@pamgmt.com) • [www.pharmacoepi.org](http://www.pharmacoepi.org)

June 8, 2009

Secretary Kathleen Sebelius  
U.S. Department of Health & Human Services  
200 Independence Avenue, S.W.  
Washington, D.C. 20201

Dear Secretary Sebelius:

The International Society for Pharmacoepidemiology (ISPE) is very pleased to have the opportunity to offer our perspectives and suggestions, and submits for your consideration the following comments on the CMS document, "*Possible Medicare Part D public use and supplemental characteristics files*".

ISPE is an international, nonprofit, professional membership organization dedicated to promoting the health of the public by advancing pharmacoepidemiology, the science that applies epidemiological approaches to studying the use, effectiveness, values and safety of pharmaceuticals. ISPE is firmly committed to providing an unbiased scientific forum to the views of all parties with interests in drug, biologics, and devices development, delivery, use, costs and value, adverse and beneficial effects, and therapeutic risk management.

Moreover, the Society provides an international forum for the open exchange of scientific information among academia, government, and industry and for the development of policy; a provider of education; and an advocate for the fields of pharmacoepidemiology and therapeutic risk management.

The Society's more than 1,000 members represent 30 countries. ISPE members work in academic institutions, the pharmaceutical industry, government agencies, and non-profit and for-profit private organizations. ISPE members are researchers with background and training in epidemiology, biostatistics, medicine, public health, nursing, pharmacology, pharmacy, law, and health economics.

Our comments are based on a careful review of the CMS document by the Society's membership at-large as well as by ISPE Fellows, Past Presidents, members of the Board of Directors and Executive Committee and Public Policy Committee.

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These are the Society's consensus comments:

- ISPE welcomes CMS's decision to make part D data available for pharmacoepidemiologic research. The field of pharmacoepidemiology is solely interested in CMS Medicare Part D data for purposes of scientific *research*. As we understand, CMS will allow academic centers to apply for linked Medicare datasets (parts A, B, and D) for pharmacoepidemiologic research based on a positive review by institutional review boards (IRBs) and at ResDAC and a data use agreement (DUA). We believe that such arrangements should not be reserved for academic institutions, and these data should be available under similar conditions to any individual or organization that applies to use them for *research purposes*. These data will need to contain all the information elements necessary to achieve the research goals, for example (but not limited to) exact service dates, the possibility to link beneficiaries, providers, insurance plans, and pharmacies over time and with additional information (e.g., provider specialty), and geographic information. ISPE strongly encourages CMS to remove any hurdles for access to these data (e.g., high cost for data, overly restrictive DUAs) based on the current model of safeguards (IRB and DUA).
- ISPE would like to point out that while we agree that the intentional identification of patients is of serious concern, we have been unable to find actual examples of *researchers* using data to illicitly identify subjects and compromise their privacy. If in fact no such examples exist, then this problem may be more theoretical than actual. Further, ISPE would like to point out that many currently available healthcare claims data sources (Medicaid) do not have fuzzed service dates. In summary, we believe that the low likelihood of illicit identification of patients should be considered when making decisions, such as restricting data elements that could seriously hamper research.
- ISPE welcomes the availability of the proposed additional public use files because they will allow broad access to Medicare part D data. It is our understanding that these public use files will be available to anyone without the above mentioned safeguards (IRB and DUA). Under these conditions, ISPE understands CMS's proposal to restrict the data in some ways.
- However within the above safeguards (IRB and DUA), some of the proposed data restrictions for the public-use files should not be implemented, as they would seriously diminish the research value of these data. For example, the proposed "fuzzing" of service dates in the public use files severely limits the data's value for pharmacoepidemiologic research. CMS's point that the fuzzing doesn't hamper delineating episodes of care is well-taken, but in pharmacoepidemiology it is often necessary to examine medication-related effects that have a prompt onset. An example of these immediate effects is anaphylaxis for which estimation could easily be biased by changing actual dates to a Monday, Wednesday, or Friday format. Exact service dates are necessary to reduce or

- control systematic bias in pharmacoepidemiologic research. The construction of propensity score models and instrumental variable analysis are contingent upon exact service dates (Stukel TA, Fisher ES, Wennberg DE, Alter DA, Gottlieb DJ, Vermeulen MJ. Analysis of observational studies in the presence of treatment selection bias: effects of invasive cardiac management on AMI survival using propensity score and instrumental variable methods. JAMA 2007;297:278-85) Accurate dates are also essential to discern the timing of potential cause-effect relationships, for example whether myocardial infarction precedes drug initiation or vice versa. In summary, current and future pharmacoepidemiology methods are based upon exact service encounter dates.

Again, we thank CMS for allowing us the opportunity to comment on this document. ISPE welcomes any future dialogue on the proposed CMS Medicare Part D public use files.

Sincerely,

A handwritten signature in blue ink, appearing to read "Miriam Sturkenboom", is written over a horizontal blue line. The signature is stylized and cursive.

Miriam C JM Sturkenboom  
President