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|  | Centers for Medicare & Medicaid  Services  42 CFR Parts 417, 422, 423, and 483  [CMS–4157–P]  RIN 0938–AQ86  Medicare Program; Proposed Changes  to the Medicare Advantage and the  Medicare Prescription Drug Benefit  Programs for Contract Year 2013 and  Other Proposed Changes; Considering  Changes to the Conditions of  Participation for Long Term Care  Facilities  **Public Comment from the International Institute for Pharmaceutical Safety**  **December 10, 2011**  DrugDisposalLogopurple_000C:\Users\Gressitt\Desktop\Marshall_University_logo.gif |

The International Institute of Pharmaceutical Safety would like to endorse fully the concept of Daily Cost-Sharing in order to reduce waste and to synchronize prescription duration. There is another reason we support it and that is the opportunity to review the second prescription in the light of effects, side effects, or lack of effect during the first short fill. We acknowledge the delineation of specific forms of medication. This applies to solid dosage forms (e.g., tablets, capsules) as gels and liquids do present packaging issues.

As members of the Maine Benzodiazepine Study Group, we also wish to commend the reversal of the benzodiazepine exclusion, agreeing with the many others who presented on this topic.

In order to discover the nature of what medications are being wasted, CMS had a previous expectation that unused drug ought to be returned to pharmacies, counted and reported back to them. While we understand why this is not in its most recent strategy for a variety of reasons, such as the complications with controlled substances, we believe that it is of great importance that data on drug waste be collected. Without that data, the full impact of medication non-adherence will be difficult to assess. With DEA Regulations pending shortly for controlled drug disposal, perhaps this should be added after the DEA Regulations are promulgated. We have been able to sample Long Term Care Facility, Mailback and Takeback medication waste and reviewed the literature to find that far more research is needed to drive appropriate policy. Without that kind of data, it will be difficult to engineer prevention plans or waste minimization protocols, rules or practices. That would be less than optimal for overall health system efficiency improvement.

As it was our group ‘s data that led to the recommendation to the State of Maine that it institute the 15 day rule, we would like to comment first that indeed there was very good acceptance. As Medical Director of the Office of Adult Mental Health at that time, I received a call from a former President of the Maine Association of Psychiatric Physicians who told me that it was such a good idea, she was extending it as a part of her practice to all prescriptions and regardless of payer. There was on the other hand significant confusion as to how the State informed prescribers and significant effort had to be put into ensuring that the confusion was addressed. Once done, there were virtually no complaints by either patients or prescribers.

The question as to whether unused drugs when disposed into the environment are likely more impactful than the volume of increased packaging and recyclables is an important one. From our research on unused drugs mailed back from the consumer via the Maine Mailback Program, 17% of unused drugs are controlled substances. A sampling during the latest DEA Take Back revealed 8% controlled drugs. We believe that reducing the generation of that waste will significantly reduce the potential for diversion, misuse, and abuse. We believe that the word “environment” should not artificially remove humans from environmental impact statements. In addition, a full environmental impact assessment should include the effects and costs of the following: medication misuse, drug diversion, arrests, prosecutions, incarcerations, lost productivity, homeowner insurance, health insurance, social programs to support victims of drug related crime, therapy, taxpayer subsidies for that drug abuse, unemployment insurance and~~,~~ workers’ compensation. The listing above, while incomplete, is to be balanced against the inability we have had in finding one human being hospitalized from the effects of drugs disposed into the environment. We recognize that household accidental ingestion of medication is in a different category than environmental disposal/exposure. We are certainly aware of wildlife effects of pharmaceuticals, perhaps best exemplified by the die-off of vultures in Southeast Asia, or, in the US, the deaths of Bald Eagles from improper disposal of euthanized animals. We agree that environmentally disposed medication may present a risk in general, but believe the research to date demonstrating its negative effects is far outweighed by the impact of household drugs diverted for abuse.

Finally, we disagree that a voluntary approach to the short first fill is the preferred method, given the rationale that Medicare Part D is voluntary. We would point out that the ACA is explicitly not voluntary and Medicare is woven in some ways with that. We believe that the 15-day rule in Maine does bear refinement, in expanding to all drugs and with shorter first fills for some specific classes. For instance, we see no reason for benzodiazepines to be issued for a first 7 day fill. We also fear clinical inertia for continuation of past prescribing habits and practices may seriously erode expectations of CMS on savings unless a fixed, standard first short fill is selected as policy.

Above in response to Federal Register at:

<http://www.gpo.gov/fdsys/pkg/FR-2011-10-11/pdf/2011-25844.pdf>

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