

Right Drug Dose Now (Right) Act: Section-by-Section Summary

Section 1. Short Title

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Section 3. Assessment and Update of the 2014 National Action Plan for Adverse Drug Event Prevention

The Right Act would require the Department of Health and Human Services (HHS), in consultation with other federal health agencies, to report to Congress on the implementation of the 2014 National Action Plan for Adverse Drug Event Prevention (ADE Action Plan). Additionally, it would reconvene the Federal Interagency Steering Committee for Adverse Drug Events to update the ADE Action Plan, ensuring that they consider new information on the role of drug-drug-gene interactions in causing ADEs and PGx testing's ability to prevent ADEs. Lastly, the Committee would be tasked with evaluating the FDA Adverse Event Reporting Systems (FAERS) and how it could better enable pharmacogenomics research.

Section 4. Promotion of Adverse Drug Event and Pharmacogenomic Testing Awareness

The Right Act would require the National Human Genome Research Institute (NHGRI), in partnership with other federal government entities, to develop and implement two educational campaigns for the general public and healthcare providers to improve knowledge about ADEs and clinically appropriate use of PGx testing. The public education campaign would provide evidence-based messages and materials about ADEs and associated risk factors, basic information about PGx testing and comprehensive medication management, and information to allow individuals and their healthcare providers to consider whether PGx testing is appropriate as part of their healthcare plan. NHGRI would be instructed to ensure that educational efforts reach rural and underserved communities. To support the public education campaign, HHS would be able to award grants or contracts to help establish national multimedia campaigns focused on educating the public about ADEs and PGx. The healthcare professional education campaign would be focused on educating a range of healthcare providers that play a role in providing PGx information and related services, drug interaction alerting systems, and how to implement information gleaned from PGx testing. NHGRI would be able to award grants to nonprofit organizations to assist the Institute with carrying out the healthcare professional education campaign. Lastly, NHGRI would be required to publish data every three years on the impact and outcomes of these programs. The bill authorizes \$50 million for this section for each of fiscal years 2022 through 2027.

Section 5. Updating Electronic Health Record Systems to Improve the Use of Pharmacogenomic Information and Reporting Systems

The Right Act would require HHS to update certification criteria for health information technology (HIT) to incorporate drug-gene and drug-drug-gene interactions into HIT alerting systems when medications are prescribed and ordered. Additionally, HHS would be required to establish regulations that ensure interaction alerting systems are continuously updated with new scientific information. HHS would also be required to facilitate the reporting of ADEs and any association related to a patient's genetic status to the FDA Adverse Event Reporting System from electronic health record systems. Lastly, the bill would require an update of the FDA Adverse Event Reporting System to make it more patient-friendly, accept information directly from a healthcare provider's EHR, and create a selection tool to easily allow for reporting of an ADE that is associated with a drug-gene interaction.

Section 6. Authorize Sustained Funding for Pharmacogenomic Research

The Right Act would authorize \$7,000,000 to be appropriated to the National Institutes of Health for FY2022 through FY2025. Funds would be used to conduct, support, and maintain PGx implementation research through the Genomic Community Resources program, a program led by NHGRI to support the development and distribution of genomic resources to the research community.

Section 7. Definitions

This section defines the terms 'adverse drug event' and 'comprehensive medication management' for the purposes of carrying out the Right Act.