H.R. ____ Right Drug Dose Now Act of 2024 – Section by Section Summary

Summary:

Reps. Eric Swalwell and Dan Crenshaw are introducing the *Right Drug Dose Now Act of 2024*, legislation that will enable the use of evidence-based pharmacogenomic (PGx) testing to prevent adverse drug events and help ensure that patients receive medications tailored to their genetic makeup. PGx is the study of how genes affect the body's response to certain medicines, which is critical to understanding how safe and effective a particular drug can be for each person.

This legislation aims to update the National Action Plan for Adverse Drug Event Prevention by integrating advancements in pharmacogenomic research and testing. It seeks to enhance electronic health records (EHRs) with pharmacogenomic information to improve patient care and reduce adverse drug events. The *Right Drug Dose Now Act of* 2024 represents a significant step forward in integrating pharmacogenomic research into clinical practice. By updating the National Action Plan for Adverse Drug Event Prevention and enhancing EHR systems, this act aims to reduce adverse drug events, improve patient care, and pave the way for more personalized medicine approaches.

Section 1: Short Title

Title: "Right Drug Dose Now Act of 2024"

Section 2: Table of Contents

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Section 3: National Action Plan for Adverse Drug Event Prevention

Secretary's Duties: The Secretary of Health and Human Services is tasked to report on the current implementation of the National Action Plan for Adverse Drug Event Prevention within 180 days post-enactment.

The Federal Interagency Steering Committee for Adverse Drug Events will be convened to refresh the National Action Plan, incorporating recent scientific and technological advances in drug-gene interactions, the impact of pharmacogenomic testing, and the capability to identify genetic associations in adverse drug events.

Section 4: Education on Pharmacogenomics for Healthcare Professionals

Guidance Issuance: Directs the Secretary to provide educational materials for healthcare providers on:

- The potential of pharmacogenomic testing to prevent adverse drug reactions.
- When and how to engage with genetics providers regarding drug metabolism impacted by genetic variants.

- Encouraging the integration of pharmacogenomic testing into patient health care plans.
- The role of genetics and genomics specialists.
- Incorporating pharmacogenomics into comprehensive medication management.
- The importance of including pharmacogenomic information in adverse drug event reports to the FDA.

Section 5: Improving EHR Systems to Utilize Pharmacogenomic Information

Certification Criteria: Establishes criteria for EHR systems to automatically indicate the appropriateness of pharmacogenomic testing and drug-gene associations during medication ordering processes.

Drug-Gene Interaction Alert Systems: The Secretary is to issue and biannually update guidance on these systems in EHRs, incorporating new drug labels and peer-reviewed guidelines.

Adverse Drug Event Reporting: Encourages the development of EHR functionalities for direct adverse event reporting to the FDA.

FDA Adverse Event Reporting System (FAERS) Updates:
- FAERS is to be updated to allow reporting of drug-gene interactions and direct reporting from EHRs.
- Establishes patient-friendly electronic reporting options, including mobile applications.

GAO Study: A study on including drug-gene interaction information on drug labels, with recommendations to Congress.

Report on EHR Improvements: A report on additional EHR enhancements needed to support the development of real-world evidence in pharmacogenomics, including capturing test details.

Endorsed by: Personalized Medicine Coalition, American College of Medical Genetics and Genomics, Invitae, Association for Managed Care Pharmacy, American Society of Pharmacovigilance, American Pharmacogenomics Association, Genomind, OneOme, GenXys, Sanford Imagenetics, YouScript, Aransica, AccessDx, 2bPrecise, and the GTMRx Institute.