

THE OPIOID CRISIS ACCOUNTABILITY ACT OF 2018

SEC 1. SHORT TITLE

SEC 2. PROHIBITION OF CERTAIN MARKETING AND DISTRIBUTION PRACTICES WITH RESPECT TO OPIOIDS

- Bans any form of direct-to-consumer marketing of an opioid that falsely suggests that the product has no addiction-forming or addiction-sustaining qualities or risks; companies in violation of this provision will be fined 25 percent of the profits from their opioid products
- Prevents companies from supplying a state or a community with a quantity of opioids that is not medically reasonable.
- Requires an individual to report to the HHS Secretary any pattern of orders of opioids that would seem medically unreasonable.
- Bans individuals who work for a company that manufactures or distributes an opioid product from engaging in certain marketing and distribution practices.
- Creates criminal liability for top company executives. Penalties include fines equal to the executive's compensation package, or a minimum of ten years in prison
- Requires a company found liable for contributing to the opioid epidemic to be fined \$7.8 billion, in addition to the penalties listed above, to offset the total economic impact of the crisis
- Establishes an "Opioid Reimbursement Fund", administered by the HHS Secretary in consultation with the FDA; all penalties collected under this Act will be deposited in the Fund
- Gives priority for receipt of such funds to SAMHSA, DOL, DOJ and the Dept. of Ed., as well as to Head Start programs.

SEC 3. REDUCED EXCLUSIVITY

- Penalizes drug manufacturers who illegally advertise, market or distribute an opioid product by stripping them of any remaining period of market exclusivity for such product.
- Reduces the remaining period of market exclusivity by one half of the time remaining for all other opioid products made by the company.
- Prohibits any new or additional exclusivity from being awarded to the offending drug manufacturer with an application for an opioid product before the FDA or for a product advertised as a result of product hopping.

SEC 4. REIMBURSEMENT FOR OPIOIDS DEVELOPED USING FEDERAL FUNDING

- Requires any drug manufacturer or distributor that violates this Act and that received federal funding to develop the opioid to reimburse the amount of federal funding received

SEC 5. TREATMENT OF CERTAIN TAXPAYERS VIOLATING ILLEGAL MARKETING AND DISTRIBUTION PRACTICES

- Prohibits manufacturers who are found to be in violation of this Act from receiving certain tax credits and requires them to pay an increased amount in taxes that is equal to the amount that they would have received in tax credits.