

RECOMMENDATIONS

NOVEMBER 2017 • MAKING MEDICINES AFFORDABLE: A NATIONAL IMPERATIVE

Below is a summary of the report's recommendations. To read the full text of the recommendations with relevant actors and other details, please see Chapter 4 of the report at nationalacademies.org/NASEMAffordableDrugs.

RECOMMENDATION A

ACCELERATE THE MARKET ENTRY AND USE OF SAFE AND EFFECTIVE GENERICS AS WELL AS BIOSIMILARS, AND FOSTER COMPETITION TO ENSURE THE CONTINUED AFFORDABILITY AND AVAILABILITY OF THESE PRODUCTS.

Specific implementation actions are:

- Vigorously deter manufacturers from paying other producers for the delayed entry of generics and biosimilars into the market.
- Expand the enforcement of policies that preclude mergers and acquisitions among companies possessing significant competing generics and biosimilars—either by preventing the mergers or acquisitions or by requiring the divestiture of potentially competing drug products to independent entities.
- Identify specific means to reduce “evergreening” of drug exclusivity via new patents or extensions on existing drugs.
- Seek reciprocal drug approval arrangements for generics and biosimilars between the regulatory agencies of the United States and the European Union, and such countries as Australia, Canada, Japan, and New Zealand.
- Reduce barriers to generic market entry and promote the expeditious market entry of additional domestic and international providers of generics and biosimilars, particularly including those not marketed by the original patent holder.
- Develop policies to restrict the use of “dispense as written” practice by prescribers that may unnecessarily impede the use of generics and biosimilars.

RECOMMENDATION B

CONSOLIDATE AND APPLY GOVERNMENTAL PURCHASING POWER, STRENGTHEN FORMULARY DESIGN, AND IMPROVE DRUG VALUATION METHODS.

Specific implementation actions are:

- Allow federal negotiation of drug prices, including on behalf of state agencies that wish to be represented.
- Test and further refine methods for determining the “value” of drugs and identify approaches to support value-based payments, formulary design, and price negotiation.
- Expand flexibility in formulary design to allow the selective exclusion of drugs, such as when less costly drugs provide similar clinical benefit.
- Amend the Medicaid Drug Rebate Program similarly to allow for exclusion of certain drugs from coverage under the rebate provisions.
- Expand demonstration projects that test alternative payment models for prescription drugs and assess the impact of such models on health care outcomes and costs.

RECOMMENDATION C

ASSURE GREATER TRANSPARENCY OF FINANCIAL FLOWS AND PROFIT MARGINS IN THE BIOPHARMACEUTICAL SUPPLY CHAIN.

Specific implementation actions are:

- Require biopharmaceutical companies and insurance plans to disclose net prices received and paid, including all discounts and rebates, at a National Drug Code level on a quarterly basis. Obtain, curate, and publicly report this collected information. Conduct analyses of these data and inform relevant congressional committees, and examine these data to identify and act upon any anti-competitive practices in the market.
- Require biopharmaceutical companies to submit an annual public report stating list prices; rebates and discounts to payers, including changes thereto; and the average net price of each drug sold in the United States. All net drug price increases that exceed the growth in the consumer price index for the previous year should be reported to the relevant congressional committees.
- Expand the disclosure requirements on all sources of income by organizations in the biopharmaceutical sector that are exempt from income tax under the Internal Revenue Code.

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www.nationalacademies.org/NASEMAffordableDrugs

RECOMMENDATION D

PROMOTE THE ADOPTION OF INDUSTRY CODES OF CONDUCT, AND DISCOURAGE DIRECT-TO-CONSUMER ADVERTISING OF PRESCRIPTION DRUGS AS WELL AS DIRECT FINANCIAL INCENTIVES FOR PATIENTS.

Specific implementation actions are:

- Terminate the tax deductibility of direct-to-consumer advertising expenses.
- Adopt industry codes of conduct that reduce or eliminate direct-to-consumer advertising of prescription drugs and support efforts to enhance public awareness of disease prevention and management.
- Prohibit patient coupon programs, in which pharmaceutical companies give payments or discounts to consumers who fill prescriptions for the company's drug, except in cases where no competing drug is available in the market.

RECOMMENDATION E

MODIFY INSURANCE BENEFITS DESIGNS TO MITIGATE PRESCRIPTION DRUG COST BURDENS FOR PATIENTS.

Specific implementation actions are:

- Establish limits on the total annual out-of-pocket costs paid by enrollees in Medicare Part D plans that cover prescription drugs by removing the cost-sharing requirement for patients who reach the catastrophic coverage limit.
- Modify the designs of plans offered through Medicare Part D and governmental health insurance exchanges to limit patients' out-of-pocket payments for drugs when there is clear evidence that treatment adherence for a particular indication can reduce the total cost of care.
- Calculate patient deductibles and copayments in all insurance policies through Medicare Part D and governmental health insurance exchanges as a fraction of net prices, not list prices. State and private prescription drug plans should be encouraged to follow this approach.
- Specifically include the costs and clinical effectiveness of prescription drugs and available treatment alternatives when determining patient cost-sharing rates. This evaluation should address, where feasible, the total costs of care rather than simply the costs of the drugs themselves.

RECOMMENDATION F

ELIMINATE MISAPPLICATION OF FUNDS AND INEFFICIENCIES IN FEDERAL DISCOUNT PROGRAMS THAT ARE INTENDED TO AID VULNERABLE POPULATIONS.

Specific implementation action is:

- Increase oversight and regulation of the 340B program to assure that participation by covered entities, contract pharmacies, and drug manufacturers is consistent with the intent of the original legislation focused on providing discounted drugs to eligible low-income patients. Oversight should include systematic collection and assessment of data from qualified medical providers and participating drug manufacturers regarding the volume of drug purchases eligible for 340B discounts, revenues generated from 340B program participation, and safety-net services funded by these revenues.

RECOMMENDATION G

ENSURE THAT FINANCIAL INCENTIVES FOR THE PREVENTION AND TREATMENT OF RARE DISEASES ARE NOT EXTENDED TO WIDELY SOLD DRUGS.

Specific implementation actions are:

- Promote agreements that enable concessions on launch price, annual price changes, or assistance in satisfying important public health goals.
- Ensure that drugs with orphan designation receive program benefits under the act only for the target rare disease, not for ancillary non-orphan indications.
- Eliminate unnecessary sub-classifications of disease categories that create artificial eligibility for orphan drug status, and limit eligibility to only one orphan condition per drug.
- Limit the market exclusivity awarded to orphan drugs to one 7-year extension.

RECOMMENDATION H

INCREASE AVAILABLE INFORMATION AND IMPLEMENT REIMBURSEMENT INCENTIVES TO MORE CLOSELY ALIGN PRESCRIBING PRACTICES OF CLINICIANS WITH TREATMENT VALUE.

Specific implementation actions are:

- Establish payment policies for drugs administered by clinicians in medical practices and hospitals that do not differentiate for the site of care (site neutral payment).
- Ensure that clinicians have readily accessible and routinely updated information regarding drug cost and efficacy to support sound prescribing decisions at the point of care. This information should include the relative clinical benefits of alternative treatment regimens and the relative financial costs of treatment settings to both patients and payers.
- Eliminate the practice of reimbursing clinicians, standalone and hospital-based clinics on the basis of list prices for drugs covered under the Medicare medical benefit. Replace the current reimbursement model with fixed fees supporting clinical care and the costs of storing and administering these drugs.
- Substantially tighten restrictions on pharmaceutical detailing visits, the acceptance and use of free drug samples, special payments, and other inducements paid by biopharmaceutical companies to clinicians, medical practices and hospitals.