

13. MEDICAL PRODUCT SAFETY

Number	Objective
1	Monitoring of adverse drug reactions
2	Approval of medical products
3	Response from managed care organizations regarding adverse drug reactions
4	Linked automated information systems
5	Drug alert systems
6	Provider review of medications taken by patients
7	Complementary and alternative health care
8	Safety-related labeling changes
9	Updates to drug alert systems
10	Patient information about prescriptions

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Medical Product Safety

Goal

Ensure the safest and most effective possible use of medical products.

Terminology

(A listing of all acronyms used in this publication appears on page 27 of the Introduction.)

Overview

Adverse drug reactions (ADRs) may be responsible for more than 100,000 deaths nationwide each year according to an article in the April 15, 1998, issue of *The Journal of the American Medical Association*.¹ This would rank ADRs between the fourth and sixth leading cause of death in the United States.

The Food and Drug Administration (FDA) approved 139 new drugs and biologic products in 1996, a record increase of 63 percent over the 85 such products approved in 1995. In 1997, another 132 products were approved. The 90 new molecular entities (NMEs) approved during this 2-year period more than doubled the number of approvals for a similar period 10 years ago. At the same time, over the past 10 years, the median approval time for NMEs has dropped by more than half to 13.4 months. For 33 of these 90 NMEs, the United States approval was the first approval anywhere in the world. For 14 more, the United States approval was only the second approval worldwide.

New drugs are becoming more powerful and more complex. Thus, patients, providers, and the health care system must learn to use a growing number of increasingly complex products in ever decreasing periods of time. The drug product safety objectives of Healthy People 2000 were an attempt to help accomplish this goal.

Still, drug misadventuring (problems emanating from improper prescribing, dispensing, and use of medications) is widespread and growing. It has been estimated that more than 50 percent of 1.8 billion prescriptions are used incorrectly and that drug-related problems, including ADRs, account for nearly 10 percent of all hospital admissions and up to 140,000 deaths annually in the United States.² Drug-related illness and death in the United States cost the American health care system approximately \$76 billion annually.³

Of elderly patients taking three or more prescription drugs for chronic conditions, over one-third are rehospitalized within 6 months of discharge from a hospital, with 20 percent of those readmissions due to drug problems.⁴ Twenty-eight percent of hospitalizations of older Americans are due to noncompliance with drug therapy and adverse reactions.⁵ Adverse drug events rank fifth among the top preventable threats to the health of older Americans, after congestive heart failure, breast cancer, hypertension, and pneumonia.⁶ Moreover, 32,000 senior citizens suffer hip fractures each year as a result of falls associated with the use of psychotropic drugs.⁷

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1 Growth in these numbers is expected, given the increasing number and potency of drug products being
2 developed and used and the increasing percentage of the population that is elderly (a subset that consumes
3 the greatest number and quantity of medications).⁸

4
5 There are basically four different types of risks associated with the use of medical products:

- 6
7 1. Those that are known but need to be better quantified (e.g., liver toxicities associated with
8 troglitazone).
- 9
10 2. Those that are not previously known but need to be quickly identified and communicated (e.g., the
11 recent phen/fen [phentermine in combination with fenfluramine or dexfenfluramine] cardiac effects
12 that were not previously known).
- 13
14 3. Those occurring from “medical misadventures” (e.g., misprescribing, inappropriate use of a medical
15 device).
- 16
17 4. Those occurring from improper use (user error or misuse).

18
19 Medical product safety is a matter of continuously developing information. The information must be
20 translated into words and formats that are readily understood by practitioners, caregivers, and patients.
21 The information must be disseminated in a timely fashion and incorporated into clinical practice and
22 patient behaviors.

23
24 Once a medical product is approved for marketing, additional information is developed by collecting and
25 analyzing reports of product experience, both patient benefits and adverse events. As the approval of new
26 products is accelerated, postmarketing surveillance becomes increasingly important. MEDWATCH, the
27 FDA Medical Products Reporting Program, is the avenue through which health professionals and
28 consumers can voluntarily report serious adverse events and problems with such medical products as
29 drugs, biologics, medical and radiation-emitting devices, and special nutritional products.

30
31 Although regulations require manufacturers of medical products to work with FDA in the followup of
32 adverse reaction reports, there are no similar requirements for health care delivery organizations to
33 cooperate with manufacturers. FDA’s drug epidemiology reviewers report this is a particularly significant
34 problem for manufacturers needing to obtain spontaneous reports or followup on reports from managed
35 care organizations.

36
37 User facilities (hospitals and long-term care, ambulatory surgical, outpatient treatment, and outpatient
38 diagnostic facilities) are mandated medical device reporters, which includes the reporting of any death to
39 FDA **and** the manufacturer of the device within 10 working days of becoming aware of the event. Serious
40 illness/injury must be reported by the user facility to the device manufacturer within 10 working days of
41 becoming aware of the event (the report should be sent to FDA if the manufacturer is unknown). Further,
42 FDA encourages user facilities to report device malfunctions that do not result in death or serious injury
43 directly to the manufacturer, using the mandatory FDA 3500A form. Drug and biologic manufacturers can
44 receive copies of serious voluntary adverse event reports on new molecular entities or “important new
45 biologic(s)” from FDA through the MEDWATCH to Manufacturer Program. Nevertheless, there remains a
46 need for managed care organizations to work with manufacturers in the followup of these reports.

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1 FDA has been working to simplify drug labeling for both prescription and over-the-counter drug products.
2 The MEDWATCH Web site (www.fda.gov/medwatch) is FDA's centralized Internet location to find new
3 safety information that is of direct clinical importance. Regularly posted are such safety-related
4 notifications as "Dear Health Professional" letters, Public Health Advisories, Safety Alerts, and FDA Talk
5 Papers, which involve the range of medical products regulated by FDA. Further, MEDWATCH compiles
6 and posts summaries of safety-related drug labeling changes that are approved by FDA each month. The
7 goals of Healthy People 2010 can play an important role in speeding the incorporation of new information
8 into clinical practice.

9
10 In 1997, the American Medical Association (AMA) announced the formation of the National Patient
11 Safety Foundation (NPSF). The NPSF is a collaborative effort in pursuit of three goals: (1) serve as an
12 educational forum for building awareness among providers and the public about patient safety, errors in
13 health care, and prevention strategies; (2) support new research designed to analyze risk factors in health
14 care to develop practical tools and solutions; and (3) serve as a clearinghouse for research information,
15 "best practice" protocols, and prevention tools with respect to patient safety risk factors.

16
17 Finding a measure of harm and/or death due to medication error has proven difficult. In preparing bills,
18 hospitals may have incentives to assign diagnostic codes reflecting the illness for which therapy was
19 prescribed to the exclusion of any harm caused by the application of that therapy. A research letter,
20 recently published in *The Lancet*, analyzed death certificates, and found that 7,391 people died from
21 medication errors in 1993, more than twice as many as the 2,876 people who died from medication errors
22 in 1983.⁹ These numbers were derived by counting all death certificates with International Classification
23 of Disease (ICD) codes in the range E850-858. The working group sought counsel from the National
24 Center for Health Statistics (NCHS) as to whether these codes might provide for Healthy People 2010 a
25 measure of deaths due to medication errors. NCHS located a printout of these codes for 1995.

26
27 In 1995, there were 9,753 death certificates listing a code in the range of E850-858 as either an underlying
28 or secondary cause of death. However, of the 9,753 deaths, 2,258 were coded as E850.0 (heroin); 12 were
29 E854.1 (hallucinogens); 308 were E854.2 (psychostimulants—largely amphetamine); 1,456 were E855.2
30 (local anesthetics - largely cocaine); 2,135 were E858.8 (central appetite depressants); and 1,755 were
31 E858.9 (unspecified drug). It is thus likely that even though there exist additional ICD codes for
32 dependent and nondependent abuse of drugs (304-305), the bulk of what is being measured by E850-858
33 is death due to drugs of abuse.

34
35 A table in the *Lancet* letter shows the number of deaths reported as being due to adverse effects of drugs in
36 therapeutic use as being only a few hundred per year. This figure is at considerable variance with the
37 much higher estimates in papers previously cited and casts further doubt on the suitability of using death
38 certificate codes as a measure of medical product safety.

39
40 The U.S. Pharmacopeia (USP) has recently introduced MedMARx, an Internet-accessible (www.usp.org)
41 database software program designed to anonymously report, track, and benchmark medication error data in
42 a standardized format for hospitals nationwide. MedMARx is expected to provide a nationally projectable
43 measure of errors grouped according to categories (A through I) established by the National Coordinating
44 Council for Medication Error Reporting and Prevention.

45
46 Categories A through D are used when there was no actual harm. Categories E through H are assigned to
47 errors causing harm. A Category E error is one that resulted in the need for treatment or intervention and

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1 caused temporary patient harm. A Category F error is one that resulted in initial or prolonged
2 hospitalization and caused temporary patient harm. Category G is for errors resulting in permanent patient
3 harm. Category H means an error occurred that resulted in a near-death event (e.g., anaphylaxis, cardiac
4 arrest). A Category I error is one that resulted in patient death.

5
6 Preliminary discussions with USP provide confidence that baselines can be established by the year 2000.

7
8 In December 1997, the Health Care Financing Administration (HCFA) proposed Conditions of
9 Participation in Medicare and Medicaid that would require hospitals to routinely monitor for adverse drug
10 events and medication errors.¹⁰ Specifically, the proposed conditions would require that:

- 11
12 1. The hospital develop and operate a system (manual or electronic) to search active clinical records for
13 events that are likely to be associated with adverse drug events and refers these to the hospital's quality
14 assessment and performance program for action.
15
16 2. The hospital ensure that its overall medication error rate is no higher than 2 percent.
17
18 3. The hospital ensure that its patients experience no significant medication errors. For purposes of this
19 section, medication errors are considered "significant" if they actually jeopardize or cause serious
20 potential for jeopardizing the health and safety of the patient.

21
22 Because these conditions have not been finalized, they have not been incorporated into proposed objectives
23 at this time. When HCFA does issue a final rule, its conditions may be the basis for additional medical
24 product safety objectives.

25
26 Also, in its final report, The President's Advisory Commission on Consumer Protection and Quality in the
27 Health Care Industry called on interested parties to jointly develop a health care error reporting system to
28 identify errors and prevent their recurrence.¹¹

29
30 A final issue in the area of Medical Product Safety is unnecessary use of antimicrobial agents. Such use
31 both increases exposure to drugs that can cause adverse reactions and promotes the rapid emergence of
32 drug-resistant bacteria.

33
34 **Draft 2010 Objectives**

- 35
36 **1. (Developmental) By the year 2010, compatible with a requirement to protect the privacy of**
37 **each individual, there will be a population base of 20,000,000 individuals under close**
38 **electronically monitored safety surveillance for indicators of adverse events associated with**
39 **medical therapies.**

40
41 Particularly targeted should be staff-model health maintenance organizations (HMOs) or other health care
42 providers capable of producing a complete record of all health care given to the patient. At the present
43 time, there exists no standardized format for medical records. HMOs may have different systems at each
44 site or, where several organizations have come together to form a single large organization, each of the
45 original organizations may have preserved its own medical record system.

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1 HMOs might be encouraged to see safety surveillance data as a product that could be sold to government
2 and industry. Alternatively, large employers or government agencies might use their purchasing power to
3 demand safety surveillance as a deliverable under managed care contracts.
4

5 Because there is a need to look at populations, which are diverse in race, ethnicity, socioeconomic status,
6 and area of residence, it is likely that data will be needed from a multitude of provider organizations. A
7 relatively large number of individuals is necessary because so many individuals are lost to followup when
8 they move from one provider organization to another. If medical records ultimately transfer from one
9 provider to another, a number smaller than 20,000,000 may suffice to allow the needed ability to link
10 outcomes with prior therapies.
11

12 To identify unknown events more rapidly, there must be an enhanced program of communication to health
13 professionals nationwide that builds on the work of MEDWATCH, encouraging the recognition of unique
14 and rare events. To evaluate and quantify newly identified events, there must be a significant population
15 base under close electronically based safety surveillance for indicators of adverse reactions. With due
16 regard for confidentiality, there must be a system for getting back to the original patient record.
17

18 Evolving automation offers the possibility of placing the entire patient record into an electronic format.
19 Electronic formats offer the possibility of automatically and instantaneously checking any new therapy for
20 incompatibilities with the product's appropriate indications and dosing range and the patient's current
21 therapies and contraindications (e.g., allergies, reduced hepatic or renal function). Electronic formats also
22 offer the possibility of looking at a diagnosis and seeing whether a patient (or his or her parents) has been
23 exposed to existing therapies in the past.
24

25 If the patient were to own physical access to his or her record, he or she would have the ability to provide
26 that access at will. For generations, the military has actually given patients their entire chart to carry from
27 one health facility to another. The same information, in electronic format, could be encoded onto a smart
28 card. In Europe, some encrypted medical records have been placed on the Internet, with the patient having
29 the ability to offer up to three levels of access to health care providers and researchers.
30

31 For almost two decades, FDA has had contracts to purchase and analyze computerized Medicaid claims
32 information. Computerization made these data readily searchable. Nevertheless, because the information
33 came from claims data, it lacked the richness of medical records and the data elements were limited to
34 those necessary for the filing of a claim. There was no link back to patient records. Diagnoses were
35 limited to those for which codes were provided. Long-term tracking of individual patients was difficult
36 because people would move on and off Medicaid rolls, or from one State to another, at frequent and
37 unpredictable intervals.
38

39 Recently, a commercial vendor introduced two new databases. One recruits physicians who agree to
40 provide electronic records for their patient encounters. Although there is the theoretical ability to link
41 outcomes with previous therapies, the system captures only those therapies ordered by the participating
42 physician. If a therapy is ordered by a different physician or procured without a physician's order, it does
43 not appear.
44

45 The second newly available database is based on agreements between the commercial vendor and several
46 large employers. The employers provide health insurance claims data from their employees. Because
47 employment relationships are expected to be more stable than Medicaid beneficiary status, there should be

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1 an increased ability to track individual patients. Nevertheless, utility remains limited because the data
2 elements are still only those required for payment and are limited by the available coding.

3
4 **2. (Developmental) Whenever there is a mutual commitment between the government agency**
5 **responsible for approval of a medical product and the product sponsor to perform a specific**
6 **postmarketing investigation related to the safety of that product, __ percent of those programs**
7 **will be implemented with conclusions and appropriate actions and contingencies.**

8
9 Faster approvals make more essential than ever the dedicated implementation of postmarketing
10 surveillance programs.

11
12 **3. (Developmental) Increase to __ percent the rate of satisfactory response from managed care**
13 **organizations when queried by medical product manufacturers following up on adverse event**
14 **reports.**

15
16 Baseline and followup could be established by survey of medical product manufacturers.

17
18 **4. (Developmental) Increase to __ percent the proportion of pharmacies and other dispensers**
19 **within integrated health care systems that use linked automated information systems to**
20 **facilitate information sharing between different components of health care.**

21
22 The American Society for Health Systems Pharmacists (ASHP) will be asked to provide a baseline prior to
23 the year 2000 and regular updates (every 2 or 3 years).

24
25 **5. (Developmental) Increase to __ percent the proportion of pharmacies and dispensers that utilize**
26 **automated information systems with functional drug alert systems.**

27
28 ASHP and the National Community Pharmacy Association (NCPA) will be asked to provide a baseline
29 survey prior to the year 2000 and regular updates (every 2 or 3 years).

30
31 Objective 12.5 of Healthy People 2000 called for increasing to 75 percent the proportion of dispensers of
32 prescription medications that use linked systems to provide warnings about potential ADRs among
33 medications dispensed by different sources to individual patients. By 1993, 95 percent of pharmacies
34 utilized computer systems.

35
36 For 2010, advances in computer technology should facilitate information sharing in a way that helps health
37 care professionals and researchers link drug products and outcomes in order to benefit both individual
38 patients and to discover previously unknown adverse reactions.

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- 1 **6. (Former 12.6) Increase to 75 percent the proportion of primary care providers and dispensers**
2 **who routinely review with their patients aged 65 and over and their patients with chronic illness**
3 **or disabilities all prescribed and over-the-counter medicines taken by their patients each time a**
4 **new medicine is prescribed or dispensed.** (Baseline was established through surveys conducted in
5 1992: nurse practitioners [55 percent]; obstetrician/gynecologists [60 percent]; internists [77 percent];
6 and family physicians [63 percent])
7

8 **Target Setting Method:** Retain year 2000 target.
9

10 **Data Source:** Primary Care Providers Survey, ODPHP.
11

- 12 **7. (Developmental) Increase to __ percent the proportion of primary care providers and**
13 **dispensers who query patients and make entry in the patient record regarding the use of**
14 **complementary and alternative health care.**
15

16 In 1997, the American Medical Association's House of Delegates passed a resolution calling upon
17 physicians to query their patients regarding the use of complementary and alternative therapies. The use of
18 these therapies is widespread in this country and particularly common among minority populations.
19 Potential effects and interactions of complementary and alternative therapies can be identified only when
20 their use is part of the medical record. A developmental objective calls for primary care providers to query
21 and document the use of alternative therapies.
22

- 23 **8. (Developmental) Increase to __ percent the proportion of health care providers who have**
24 **reviewed within the past 3 months any safety-related labeling changes for drug products that**
25 **they prescribe or administer.**
26

27 Vendors might be encouraged to develop computer programs capable of using information already
28 available through FDA's MEDWATCH Web site (www.fda.gov/medwatch) to produce updates customized
29 to the needs of individual providers. (Similar programs already exist to produce financial updates
30 customized to the needs of individual investors.) Data could be provided through surveys conducted by
31 health care provider organizations.
32

- 33 **9. (Developmental) Increase to __ percent the proportion of pharmacies using drug alert systems**
34 **that have fully updated those systems within the past 3 months.**
35

36 Data could be provided through surveys conducted by pharmacy organizations or by vendors of alert
37 systems used by pharmacies.
38

39 When HCFA does finalize a requirement that hospitals routinely monitor adverse drug events, the Healthy
40 People 2010 Medical Product Safety Work Group would expect to propose an additional developmental
41 objective tracking implementation of that regulation and, if the available data make this possible, the actual
42 incidence of ADRs.
43

44 Objective 12.7 of Healthy People 2000 is a measure of how well health care providers understood the FDA
45 message that they should be selective in reporting to the Agency's MEDWATCH program only serious
46 adverse reactions. MEDWATCH was established in 1993 as an outreach program to encourage reporting.
47 The baseline was 69 percent of reported adverse reactions being regarded as serious. This figure was

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1 based on 7 months of 1993. As the number of products increases, new adverse reactions are identified
2 more quickly, and new information is posted to online data sources, it becomes more important than ever
3 that health care providers update their knowledge regularly.
4

5 **10. By the year 2006 and through the year 2010, increase to 95 percent the proportion of patients**
6 **receiving, at the time their prescriptions are dispensed, information that conforms to the Action**
7 **Plan for the Provision of Useful Prescription Medicine Information.** (Baseline: FDA survey: 14
8 percent from prescribers and 32 percent from dispensers)
9

10 Regarding the measurement of medication errors, the Healthy People 2010 Medical Product Safety Work
11 Group has reviewed the possible use of ICD codes from death certificates. The Group has held
12 preliminary discussions with USP regarding the MedMARx program and is awaiting finalization of
13 HCFA's proposed Conditions of Participation. Nevertheless, the work group has not suggested a health
14 care error reporting system in fulfillment of the mandate of the Final Report of the President's Advisory
15 Commission on Consumer Protection and Quality in the Health Care Industry because the mandate is for
16 interested parties to work together. Members of the work group hope to be involved in developing that
17 plan and to make the accomplishment of its goals a part of Healthy People 2010.
18

19 Objective 12.8 of Healthy People 2000 sought to increase to at least 75 percent the proportion of people
20 who receive information verbally and in writing for new prescriptions from prescribers or dispensers. The
21 baseline, measured in a survey conducted by FDA, for written information was 14 percent from prescribers
22 and 32 percent from dispensers. Legislation adopted in 1996 called upon the private sector to develop a
23 plan whereby 95 percent of people would receive useful written information with their prescriptions by the
24 year 2006. Guidelines in the Action Plan for the Provision of Useful Prescription Medicine Information¹²
25 were approved by Department of Health and Human Services Secretary Donna Shalala in January 1997.
26

27 **Related Objectives From Other Focus Areas**

28

29 **Educational and Community-Based Programs**

- 30 5 Worksite health promotion programs
 - 31 6 Participation in employer-sponsored health promotion activities
 - 32 7 Patient satisfaction with health care provider communication
 - 33 8 Patient and family education
 - 34 9 Community disease prevention and health promotion activities
 - 35 11 Culturally appropriate community health promotion programs
 - 36 12 Elderly participation in community health promotion
- 37

38 **Environmental Health**

- 39 29 Infectious and parasitic diseases
- 40

41 **Injury/Violence Prevention**

- 42 28 Nonfatal poisoning
- 43

44 **Occupational Safety and Health**

- 45 3 Workplace injury and illness surveillance
- 46 12 Latex allergy
- 47 16 Hepatitis B vaccinations

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Oral Health

- 6 Gingivitis
- 7 Periodontal disease
- 9 Dental sealants
- 11 Topical fluorides

Access to Quality Health Services

- C.4 Time-dependent care for cardiac symptoms

Public Health Infrastructure

- 6 Access to public health information and surveillance data
- 12 Access to laboratory services
- 13 Access to comprehensive epidemiology services
- 16 Collaboration and cooperation in prevention research efforts

Health Communication

- 1 Public access to health information
- 4 Satisfaction with health information
- 7 Health communication/media technology curricula

Arthritis, Osteoporosis, and Chronic Back Conditions

- 8 Early diagnosis and treatment of systemic rheumatic diseases (arthritis)

Cancer

- 8 Sun exposure
- 10 Pap tests
- 11 Colorectal screening examination
- 13 Breast examination and mammogram

Diabetes

- 15 Lipid assessment
- 16 Glycosolated hemoglobin measurement
- 17 Urinary measurement of microalbumin
- 21 Aspirin therapy
- 22 Self-blood glucose monitoring

Disability and Secondary Conditions

- 7 Print size on medicine, patient instructional materials, and syringe markings

Heart Disease and Stroke

- 3 Knowledge of early warning symptoms of heart attack
- 7 Controlled high blood pressure
- 8 Action to help control blood pressure
- 9 Blood pressure monitoring
- 12 Blood cholesterol screening
- 13 Treatment of LDL cholesterol

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HIV

- 3 Condom Use
- 4 Screening for STDs and immunization for hepatitis B
- 9 Compliance with Public Health Service treatment guidelines
- 11 Years of healthy life following HIV diagnosis
- 12 Perinatally acquired HIV infection

Immunization and Infectious Diseases

- 1 Vaccine-preventable diseases
- 2 Impact of influenza vaccinations
- 3 Hepatitis A
- 4 Hepatitis B in infants
- 5 Hepatitis B, under 25
- 6 Hepatitis B in adults
- 13 Hospital-acquired infections from antimicrobial-resistant microorganisms
- 14 Antimicrobial use in intensive care
- 15 Occupational needle-stick exposures
- 16 Bacterial meningitis
- 17 Invasive pneumococcal infections
- 18 Invasive early-onset group B streptococcal disease
- 19 Lyme disease
- 20 Peptic ulcer hospitalizations
- 21 Immunization of children 19-35 months
- 22 States with 90 percent immunization coverage
- 23 Immunization coverage for children in day care, kindergarten, and first grade
- 24 Immunizations among adults
- 25 Curative therapy for tuberculosis
- 26 Preventive therapy among high-risk persons with tuberculosis
- 27 Antibiotics for ear infections
- 28 Antibiotics prescribed for colds
- 29 Inappropriate rabies postexposure prophylaxis
- 30 2-year-olds receiving vaccinations as part of primary care
- 31 Provider measurement of immunization coverage levels
- 32 Immunization registries
- 33 Vaccine-associated adverse reactions
- 34 Febrile seizures caused by pertussis vaccines
- 35 Prevention services for international travelers
- 36 Laboratory confirmation of tuberculosis cases

Mental Health and Mental Disorders

- 3 Unipolar major depression

Respiratory Diseases

- 10 Instruction on peak expiratory flow monitoring (asthma)
- 11 Short-acting inhaled beta agonists (asthma)
- 12 Long-term management (asthma)

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Substance Abuse

- 3 3 Drug-related deaths
- 4 4 Drug abuse-related emergency department visits
- 5 10 Steroid use

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