

treatment that applies only to the individual who is the subject of the information. Other commenters asserted that treatment should be broadly defined when activities are conducted by health care providers to improve or maintain the health of the patient. A broad interpretation may raise concerns about potential misuse of information, but too limited an interpretation will limit beneficial activities and further contribute to problems in patient compliance and medical errors.

*Response:* We find the commenters' arguments for a broad definition of treatment persuasive. Today, health care providers consult with one another, share information about their experience with particular therapies, seek advice about how to handle unique or challenging cases, and engage in a variety of other discussions that help them maintain and improve the quality of care they provide. Quality of care improves when providers exchange information about treatment successes and failures. These activities require sharing of protected health information. We do not intend this rule to interfere with these important activities. We therefore define treatment broadly and allow use and disclosure of protected health information about one individual for the treatment of another individual.

Under this definition, only health care providers or a health care provider working with a third party can perform treatment activities. In this way, we temper the breadth of the definition by limiting the scope of information sharing. The various codes of professional ethics also help assure that information sharing among providers for treatment purposes will be appropriate.

We note that poison control centers are health care providers for purposes of this rule. We consider the counseling and follow-up consultations provided by poison control centers with individual providers regarding patient outcomes to be treatment. Therefore, poison control centers and other health care providers can share protected health information about the treatment of an individual without a business associate contract.

*Comment:* Many commenters suggested that "treatment" activities should include services provided to both a specific individual and larger patient populations and therefore urged that the definition of treatment specifically allow for such activities, sometimes referred to as "disease management" activities. Some argued that an analysis of an overall population is integral to determining which individuals would benefit from disease management services. Thus, an analysis

of health care claims for enrolled populations enables proactive contact with those identified individuals to notify them of the availability of services. Certain commenters noted that "disease management" services provided to their patient populations, such as reminders about recommended tests based on nationally accepted clinical guidelines, are integral components of quality health care.

*Response:* We do not agree that population based services should be considered treatment activities. The definition of "treatment" is closely linked to the § 160.103 definition of "health care," which describes care, services and procedures related to the health of an individual. The activities described by "treatment," therefore, all involve health care providers supplying health care to a particular patient. While many activities beneficial to patients are offered to entire populations or involve examining health information about entire populations, treatment involves health services provided by a health care provider and tailored to the specific needs of an individual patient. Although a population-wide analysis or intervention may prompt a health care provider to offer specific treatment to an individual, we consider the population-based analyses to improve health care or reduce health care costs to be health care operations (see definition of "health care operations," above).

*Comment:* A number of commenters requested clarification about whether prescription drug compliance management programs would be considered "treatment." One commenter urged HHS to clarify that provision by a pharmacy to a patient of customized prescription drug information about the risks, benefits, and conditions of use of a prescription drug being dispensed is considered a treatment activity. Others asked that the final rule expressly recognize that prescription drug advice provided by a dispensing pharmacist, such as a customized pharmacy letter, is within the scope of treatment.

*Response:* The activities that are part of prescription drug compliance management programs were not fully described by these commenters, so we cannot state a general rule regarding whether such activities constitute treatment. We agree that pharmacists' provision of customized prescription drug information and advice about the prescription drug being dispensed is a treatment activity. Pharmacists' provisions of information and counseling about pharmaceuticals to their customers constitute treatment, and we exclude certain communications

made in the treatment context from the definition of marketing. (See discussion above.)

*Comment:* Some commenters noted the issues and recommendations raised in the Institutes of Medicine report "To Err Is Human" and the critical need to share information about adverse drug and other medical events, evaluation of the information, and its use to prevent future medical errors. They noted that privacy rules should not be so stringent as to prohibit the sharing of patient data needed to reduce errors and optimize health care outcomes. To bolster the notion that other programs associated with the practice of pharmacy must be considered as integral to the definition of health care and treatment, they reference OBRA '90 (42 U.S.C. 1396r-8) and the minimum required activities for dispensing drugs; they also note that virtually every state Board of Pharmacy adopted regulations imposing OBRA '90 requirements on pharmacies for all patients and not just Medicaid recipients.

*Response:* We agree that reducing medical errors is critical, and do not believe that this regulation impairs efforts to reduce medical errors. We define treatment broadly and include quality assessment and improvement activities in the definition of health care operations. Covered pharmacies may conduct such activities, as well as treatment activities appropriate to improve quality and reduce errors. We believe that respect for the privacy rights of individuals and appropriate protection of the confidentiality of their health information are compatible with the goal of reducing medical errors.

*Comment:* Some commenters urged us to clarify that health plans do not perform "treatment" activities; some of these were concerned that a different approach in this regulation could cause conflict with state corporate practice of medicine restrictions. Some commenters believed that the proposed definition of treatment crossed into the area of cost containment, which would seem to pertain more directly to payment. They supported a narrower definition that would eliminate any references to third party payors. One commenter argued that the permissible disclosure of protected health information to carry out treatment is too broad for health plans and that health plans that have no responsibility for treatment or care coordination should have no authority to release health information without authorization for treatment purposes.

*Response:* We do not consider the activities of third party payors, including health plans, to be