

American Medical Association

Physicians dedicated to the health of America



E. Ratcliffe Anderson, Jr., MD 515 North State Street 312 464-5000
Executive Vice President, CEO Chicago, Illinois 60610 312 464-4184 Fax

11 78 '00 APR 28 10:33

April 27, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane (Room 1061)
Rockville, Maryland 20852

**RE: Status of Useful Written Prescription Drug Information for Patients
[Docket No. 00N-0352]**

The American Medical Association (AMA), representing approximately 300,000 physicians and physicians-in-training, is pleased to comment on the status of useful written prescription information for patients, 65 Fed. Reg. 29, 7022-7023 (February 11, 2000). The AMA has had a longstanding interest in this subject and served on the Keystone Center's Steering Committee that led to the *Action Plan for the Provision of Useful Prescription Drug Information* (Keystone Action Plan).

The AMA has long held the view that physicians have the responsibility to educate and counsel their patients about prescription medicines to encourage adherence (compliance), to help patients identify adverse events associated with drug therapies and, ultimately, to improve health outcomes. In that regard, the AMA has developed *Guidelines for Physicians for Counseling Patients About Prescription Medications in the Ambulatory Setting* (enclosed). These guidelines were prepared to help physicians provide useful oral counseling and, when appropriate, written information about prescription medications they are prescribing for their patients. The AMA has widely disseminated these guidelines.

While the AMA and many national medical specialty societies elected not to support the above-mentioned Keystone Action Plan for a number of reasons, the AMA believes that the provision of useful written information as a supplement to oral counseling by physicians can improve patients' knowledge about prescription medicines. Thus, the AMA generally is supportive of the intent of Section 601 of P.L. 104-180 that individuals receiving new prescriptions should also receive useful written information when the medication is dispensed. Furthermore, as stated many times in the past, the AMA supports a private-sector approach to meeting this objective.

The current issue before us is to identify what is "useful" written prescription drug information for patients. Ideally, this question should be answered through evidence-based studies on the effect of written information on medication adherence and health outcomes. Unfortunately, these data are unavailable. Thus, we must rely on the combined "subjective" wisdom of experts in the field, practicing physicians and other health professionals, and patients/consumers to provide a "best guess" of what is likely to be "useful" written prescription drug information for patients.

The study by Bonnie L. Svarstad, PhD, and Dara C. Bultman, PhD (*Evaluation of Written Prescription Information Provided in Community Pharmacies: An 8-State Study*), that was commissioned by the Food and Drug Administration (FDA) through the National Association of Boards of Pharmacy (NABP) and presented at the FDA's February 29, 2000, public meeting, was well-designed and executed. However, the conclusions of this study as to whether specific written information from sampled pharmacies was

00N-0352

CH

However, the AMA has three specific areas of concern regarding written prescription information for patients. The first concern relates to fair balance in written information. The AMA believes that written information for patients about prescription medicines should serve two primary purposes: (1) to encourage patients to adhere to the medication regimen so as to optimize therapeutic outcomes, and (2) to help patients identify, and report to their physicians, possible contraindications that may have been missed when the drug was prescribed or serious adverse events associated with drug therapy. To achieve these two goals requires that written information be fairly balanced in presenting both benefits and risk information about a particular medicine. In her presentation, Dr. Svarstad expressed a similar view.

Unfortunately, some members of the Keystone Steering Committee and some stakeholders at the public meeting of February 29, 2000, have contended that the chief focus of written information should be on the harm a medication can cause, with essentially no emphasis on promoting adherence. The AMA continues to raise the concern that if written information is so weighted toward the potential harm a prescription medicine presents (i.e., emphasis on warnings, contraindications, adverse reactions, overdose, dependence, etc.), then the written information, itself, may well do more harm than good. Such biased information may frighten many concerned patients to the point of non-adherence with their medications, resulting in poor therapeutic outcomes.

The AMA's second concern relates to how risk information is presented. While the AMA believes that information about warnings, contraindications, and precautions should be included in written information, this information needs to be presented in a way that moves the patient to take appropriate action. In most cases, this will be to call the prescribing physician for advice. For example, the United States Pharmacopeia's (USP) *Patient Education Leaflets* have used the phrase, "Before using this medicine, be sure to tell your doctor if you..." This would be followed by potential or real contraindications for use of the medication (e.g., allergy). The AMA is concerned that if risk information is just listed or only tells the patient to not take the medication, the patient appropriately will not take the medication, but inappropriately will not contact his/her physician for expert advice and, if necessary, an alternative therapeutic regimen.

The AMA's third concern relates to the Keystone Action Plan's recommendation to not allow off-label indications in non-customized written prescription information for patients. The AMA continues to believe this does a great disservice by not promoting disclosure of accepted life saving and essential off-label uses of drugs to patients. Today, in important medical specialties like oncology and pediatrics, more than half of drug treatment of patients are off-label uses. Often, these off-label uses are the standard of care. Denying such valuable information to patients is inappropriate.

In conclusion, the AMA believes that physicians have the primary responsibility to educate and counsel their patients about prescription medicines. The AMA generally is supportive of private-sector initiatives for the provision of written prescription medicine information when a medication is dispensed, as an "adjunct" to physician counseling. Furthermore, the AMA generally agrees with the Keystone Action Plan and the interpretation of that Plan by Svarstad and Dura on criteria for and elements of written information. However, the AMA emphasizes that written information must be fairly balanced in presenting both benefits and risk information, that risk information should be presented in a way that moves the patient to call their physician for advice, and that off-label uses should be allowed in non-customized written information. Finally, the AMA emphasizes the lack of "objective," science-based evidence on the effect of written information on adherence and health outcomes. Identification of what

“useful” only reflect an expert panel’s “subjective” views of what useful written information should be, based on criteria from the Keystone Action Plan. Furthermore, no consumers or physicians were represented on the panel.

The AMA urges the FDA to be especially cognizant of this lack of “objective” scientific data on what is “useful” written information as it evaluates what is in the marketplace in the year 2001. While a “one-size-fits-all” approach to “useful” written information may make evaluation easier, the AMA encourages the FDA to be as flexible as possible so that opportunities to “improve” usefulness are not lost. The AMA also believes this was the intent of Congress when it mandated that written patient medication information remain within the private sector.

In Chapter 3 of the Keystone Action Plan, it states that “written prescription information should be (1) scientifically accurate, (2) unbiased in content and tone, (3) sufficiently specific and comprehensive, (4) presented in an understandable and legible format that is readily comprehensible to consumers, (5) timely and up-to-date, and (6) useful.” The AMA generally is supportive of these six criteria and most of them are mentioned in the AMA’s own guidelines (see enclosure). The study by Svarstad and Dura addressed all of these criteria. However, because consumers were not included in the evaluation, this study did not determine if the samples of written information were understandable, legible, and readily comprehensible to the general population of consumers for whom the information was intended. This deficiency should be corrected in any future study.

The Keystone Action Plan defines written prescription medicine information as “sufficiently specific and comprehensive” if certain components of useful information are included, as follows: established name and brand name (if any) of drug; “black box” warnings; indication for use; contraindications; precautions; possible adverse reactions; risk of tolerance or dependence; information on proper use; proper storage instructions; general information (e.g., statement encouraging discussion with health care professional about the prescription medicine); and a disclaimer (e.g., the materials are summaries and do not contain all possible information about the medicine).

Svarstad and Dura appear to have interpreted this section of the Keystone Action Plan to mean that written prescription information is “sufficiently specific and comprehensive” if six general criteria are met. The written information should: (1) identify the drug and its benefits; (2) identify contraindications and what to do; (3) include specific directions about how to take the medication and receive maximum benefit; (4) include specific precautions, their significance, and how to avoid harm; (5) include enough detail for proper ADR monitoring, interpretation, and action; and (6) include storage instructions and general information.

Again, the AMA’s own guidelines (enclosure) generally are consistent with both the Keystone Action Plan and the interpretation of that Plan by Svarstad and Dura. Specifically, the AMA recommends the following elements of written information: (1) name of the medication; (2) use of the medication; (3) patient instructions before using the medication (e.g., contact your physician before taking the medication if certain conditions exist which suggest a contraindication); (4) instructions for proper use of the medication; (5) precautions while using the medication; and (6) side effects of the medication that are serious or occur frequently.

FDA Docket No. 00N-0352

April 27, 2000

Page 4

is "useful" written prescription drug information for patients is highly "subjective." Therefore, the AMA urges the FDA to be as flexible as possible in evaluating written information for "usefulness" in 2001 so that opportunities to "improve" usefulness are not lost.

The AMA appreciates the opportunity to comment on this important issue and would be pleased to discuss its views on useful written prescription drug information for patients more fully with the FDA. Please direct any questions or comments to Margaret Garikes in our Washington Office, at 202-789-7409.

Sincerely,

A handwritten signature in cursive script, appearing to read "E. Ratcliffe Anderson, Jr., MD".

E. Ratcliffe Anderson, Jr., MD

Enclosure

Preamble

Prescription medications are among the most useful and cost-effective treatment options available in the health care system. Care often may be improved when physicians provide useful counseling and information about prescription medications to their patients.

The following guidelines were prepared to help physicians provide useful oral counseling and, when appropriate, written information about prescription medications that are prescribed for their patients in the ambulatory setting. These guidelines are intended to provide suggestions to physicians on the content of information that will likely be most useful to patients that are using prescription medications.

These guidelines are not substitutes for the best professional judgement of physicians in providing high quality care to their patients, and they should not be construed as standards of medical practice. Physicians are encouraged to customize prescription medication counseling and information to best meet the needs of individual patients.

American Medical Association

Physicians dedicated to the health of America



515 North State Street
Chicago, Illinois 60610

American Medical Association

Physicians dedicated to the health of America



Guidelines for Physicians for Counseling Patients About Prescription Medications in the Ambulatory Setting

**Approved by:
Board of Trustees
American Medical Association**

Guidelines for Physicians for Counseling Patients¹ About Prescription Medications in the Ambulatory Setting²

1. Medication Record. As part of the medical record, the physician should attempt to maintain and update, as necessary, a record (chart) of all medications (prescription and nonprescription) that the patient is taking currently.

2. Treatment Plan. Decisions regarding the use of prescription medications are best accomplished out of a collaboration between the physician and the patient. This requires that

the patient be aware of relevant information regarding the prescribed medication, as well as available alternatives. Therefore, the physician should discuss with the patient expectations of treatment and appropriate information regarding risks, benefits and appropriate alternatives of all medications that may be prescribed, prior to deciding on a treatment plan.

3. Oral Counseling. Physicians should counsel patients on their medications, emphasizing what is medically significant. Such information may include:

- The name of the medication and what it is supposed to do.
- How and when to take the medication and for how long.
- Appropriate foods, drinks, other prescription or nonprescription medications, or activities that the patient should avoid while taking this medication.
- The relevant side effects that should be reported to the physician if they occur.
- If applicable, whether anything is unusual about the use of the medication being prescribed (eg, for an off-label indication; prescribing larger than the usual dose).
- Whether the prescription can be refilled and how often.
- What written information the patient can take with them (if available) or instructions to obtain written information from their pharmacist.

After counseling the patient, the physician should encourage the patient to ask questions and should ask the patient whether he or she has any concerns about obtaining the medication or about using it in the way it was prescribed.

4. Written Information. It may be helpful for physicians to provide patients with written information about their medications. This information should include the elements outlined below.

5. Followup. During subsequent office visits, the physician should question the patient about compliance and any beneficial or adverse effects of the medication.

Elements of Written Information

- Name of the medication
- Use of the medication
- Patient instructions before using the medication
- Instructions for proper use of the medication
- Precautions while using the medication
- Side effects of the medication that are serious or occur frequently

It is important that written information be scientifically accurate and nonpromotional for a particular product. It should provide sufficient information so the patient can use the medication properly, be legible, and written in understandable language.

¹ The term *patient*, ie, the person for whom the medication was prescribed and dispensed, is used throughout these guidelines. However, for some patients, other individuals (eg, parents, guardians, caregivers) may also receive the counseling and information.

² These guidelines are not substitutes for the best professional judgment of physicians in providing high quality care to their patients, and they should not be construed as standards of medical practice.

Federal Expre

FedEx

PRIORITY OVERNIGHT

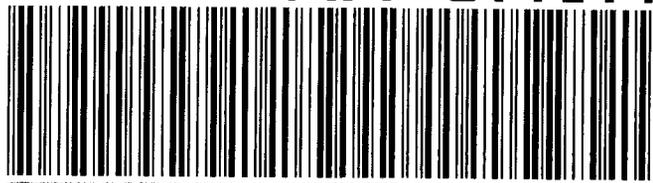
emp# 317690 27APR00

Deliver 28APR

TRK# 8139 9940 7567 FORM 0215

20852 -MD-US

IAD XA GAIA



Form 13 No. 0215

4a Express Package Service
FedEx Priority Overnight
FedEx Standard Overnight
FedEx First Overnight

4b Express Freight Service
FedEx 1Day Freight*
FedEx 2Day Freight
FedEx 3Day Freight

5 Packaging
FedEx Letter*
FedEx Pak*
Other Pkg.

6 Special Handling
Saturday Delivery
Sunday Delivery
HOLD Weekday at FedEx Location
HOLD Saturday at FedEx Location

Does this shipment contain dangerous goods?
No
Yes As per attached Shipper's Declaration
Yes Shipper's Declaration not required
Dry Ice
Cargo Aircraft Only

7 Payment Bill to:
Sender Acct. No. in Section 1 will be billed
Recipient
Third Party
Credit Card
Cash/CI

Total Packages
Total Weight
Total Chan

8 Release Signature
Sign to authorize delivery without obtaining signature.

By signing you authorize us to deliver this shipment without obtaining a signature and agree to indemnify and hold us harmless from any resulting claims.
Questions? Call 1-800-Go-FedEx (800-463-3339)
Visit our Web site at www.fedex.com
Rev. Date 11/98-Pat #154813G-1/99 98 FedEx-PRINTED IN U.S.A. GBFE 7/99

FedEx USA AIRMAIL FedEx Tracking Number 813999407567

1 From This portion can be removed for Recipient's records.
Date 4/27/00 FedEx Tracking Number 813999407567

Sender's Name E. Ratchliffe Anderson, Jr., MD Phone 312 464-5000

Company AMERICAN MEDICAL ASSOCIATION

Address 515 N STATE ST FL 15 Dept./Floor/Suite/Room

City CHICAGO State IL ZIP 60610

2 Your Internal Billing Reference

3 To Recipient's Name Dockets Management Phone

Company Food & Drug Administration

Address 5630 Fishers Lane Rm 1061 Dept./Floor/Suite/Room

To "HOLD" at FedEx location, print FedEx address here.

City Rockville State MD ZIP 20852



0114111362

359

187 1000

RECIPIENT: PEEL HERE