

from engaging in similar acts and practices in the future.

Part I of the order prohibits claims that LASIK surgery services or any other refractive surgery services: (1) Eliminate the need for glasses and contacts for life; (2) pose significantly less risk to patients' eye health than wearing glasses or contacts; or (3) eliminate the risk of glare and halving, unless the claims are substantiated by competent and reliable scientific evidence. "Refractive surgery services" are defined as any surgical procedure designed to improve the focusing power of the eye by permanently changing the shape of the cornea.

Part II of the order requires that future claims about the benefits, performance, efficacy, or safety of any refractive surgery service be substantiated by competent and reliable scientific evidence.

Part III of the order permits device claims approved by the FDA under any new medical device application.

Parts IV, V, VI, and VII of the order require LCA to keep copies of relevant advertisements and materials substantiating claims made in the advertisements, to provide copies of the order to certain of its personnel, to notify the Commission of changes in corporate structure, and to file compliance reports with the Commission. Part VIII provides that the

order will terminate after twenty (20) years under certain circumstances.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

By direction of the Commission.

**Donald S. Clark,**

*Secretary.*

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**BILLING CODE 6750-01-P**

**GENERAL SERVICES ADMINISTRATION**

**Interagency Committee for Medical Records (ICMR); Automation of Medical Standard Form 88**

**AGENCY:** Office of Communications, GSA.

**ACTION:** Guideline on automating medical standard forms.

**BACKGROUND:** The Interagency Committee on Medical Records (ICMR) is aware of numerous activities using computer-generated medical forms, many of which are not mirror-like images of the genuine paper Standard/Optional form. With GSA's approval to ICMR eliminated the requirement that every electronic version of a medical Standard/Optional form be reviewed

and granted an exception. The committee proposes to set required fields standards and that activities developing computer-generated versions adhere to the required fields but not necessarily to the image. The ICMR plans to review medical Standard/Optional forms which are commonly used and/or commonly computer-generated. We will identify those fields which are required, those (if any) which are optional, and the required format (if necessary). Activities may not add or delete data elements that would change the meaning of the form. This would require written approval from the ICMR. Using the process by which overprints are approved for paper Standard/Optional forms, activities may add other data entry elements to those required by the committee. With this decision, activities at the local or headquarters level should be able to develop electronic versions which meet the committee's requirements. This guideline controls the "image" or required fields but not the actual data entered into the field.

**SUMMARY:** With GSA's approval, the Interagency Committee of Medical Records (ICMR) eliminated the requirement that every electronic version of a medical Standard/Optional form be reviewed and granted any exception. The following fields must appear on the electronic version of the following form:

**ELECTRONIC ELEMENTS FOR SF 88**

Item	Placement*
Report of Medical Examination ..... Standard Form 88 (Rev. 8/2001) (Form ID) .....	Top of form. Bottom right corner of form.
Data Entry Fields: 1. Date of Exam 2. Last Name 2. First Name 2. Middle Name 3. Identification Number 4. Grade of Position 4. Component of Position 5. Home Address (Number, street or RDFD, city or town, state and ZIP code) 6. Emergency Contact (Name) 6. Emergency Contact (address) 7. Date of Birth 8. Age 9. Sex—Female (Checkbox) 9. Sex—Male (Checkbox) 10. Relationship of Contact 11. Place of Birth 12. Agency 13. Organization Unit 14a. Total Years Government Service—Military 14b. Total Years Government Service—Civilian 15. Name of Examining Facility or Examiner 15. Address of Examining Facility or Examiner 16. Rating or Specialty of Examiner 17. Purpose of Examination 18. Clinical Evaluation—Check each item in appropriate columns; enter "NE" if not evaluated a. Head, Face, Neck and Scalp—Normal (Checkbox)	Above below listed items

## ELECTRONIC ELEMENTS FOR SF 88—Continued

Item	Placement*
<ul style="list-style-type: none"> <li>a. Head, Face, Neck and Scalp—Abnormal (Checkbox)</li> <li>b. Ears-General (Internal Canals) (auditory acuity under item 39)—Normal (Checkbox)</li> <li>b. Ears-General (Internal Canals) (auditory acuity under item 28t)—Abnormal (Checkbox)</li> <li>c. Drums (Perforations)—Normal (Checkbox)</li> <li>c. Drums (Perforations)—Abnormal (Checkbox)</li> <li>d. Nose—Normal (Checkbox)</li> <li>d. Nose—Abnormal (Checkbox)</li> <li>e. Sinuses—Normal (Checkbox)</li> <li>e. Sinuses—Abnormal (Checkbox)</li> <li>f. Mouth and Throat—Normal (Checkbox)</li> <li>f. Mouth and Throat—Abnormal (Checkbox)</li> <li>g. Eyes—General (Visual accuity and refraction under item 28li–28s)—Normal (Checkbox)</li> <li>g. Eyes—General (Visual accuity and refraction under item 28li–28s)—Abnormal (Checkbox)</li> <li>h. Ophthalmoscopic—Normal (Checkbox)</li> <li>h. Ophthalmoscopic—Abnormal (Checkbox)</li> <li>i. Pupils (Equality and reaction)—Normal (Checkbox)</li> <li>i. Pupils (Equality and reaction)—Abnormal (Checkbox)</li> <li>j. Ocular Motility (Associated parallel movements nystagmus)—Normal (Checkbox)</li> <li>j. Ocular Motility (Associated parallel movements nystagmus)—Abnormal (Checkbox)</li> <li>k. Lungs and Chest—Normal (Checkbox)</li> <li>k. Lungs and Chest—Abnormal (Checkbox)</li> <li>l. Heart (Thrust, size, rhythm, sounds)—Normal (Checkbox)</li> <li>l. Heart (Thrust, size, rhythm, sounds)—Abnormal (Checkbox)</li> <li>m. Vascular System—Normal (Checkbox)</li> <li>m. Vascular System—Abnormal (Checkbox)</li> <li>n. Abdomen and Viscera (Include hernia)—Normal (Checkbox)</li> <li>n. Abdomen and Viscera (Include hernia)—Abnormal (Checkbox)</li> <li>o. Prostate (Over 40 or clinically indicated)—Normal (Checkbox)</li> <li>o. Prostate (Over 40 or clinically indicated)—Abnormal (Checkbox)</li> <li>p. Testicular—Normal (Checkbox)</li> <li>p. Testicular—Abnormal (Checkbox)</li> <li>q. Anus and Rectum (Hemorrhoids, Fistulae) (Hemocult Results)—Normal (Checkbox)</li> <li>q. Anus and Rectum (Hemorrhoids, Fistulae) (Hemocult Results)—Abnormal (Checkbox)</li> <li>r. Endocrine System—Normal (Checkbox)</li> <li>r. Endocrine System—Abnormal (Checkbox)</li> <li>s. G–U System—Normal (Checkbox)</li> <li>s. G–U System—Abnormal (Checkbox)</li> <li>t. Upper Extremities (Strength, range of motion)—Normal (checkbox)</li> <li>t. Upper Extremities (Strength, range of motion)—Abnormal (Checkbox)</li> <li>u. Feet—Normal (Checkbox)</li> <li>u. Feet—Abnormal (Checkbox)</li> <li>v. Lower Extremities (Except feet) (Strength, range of motion)—Normal (Checkbox)</li> <li>v. Lower Extremities (Except feet) (Strength, range of motion)—Abnormal (Checkbox)</li> <li>w. Spine, Other Musculoskeletal—Normal (Checkbox)</li> <li>w. Spine, Other Musculoskeletal—Abnormal (Checkbox)</li> <li>x. Identifying Body Marks, scars, Tattoos (Explain in Notes)—Normal (Checkbox)</li> <li>x. Identifying Body Marks, scars, Tattoos (Explain in Notes)—Abnormal (Checkbox)</li> <li>y. Skin, Lymphatics—Normal (Checkbox)</li> <li>y. Skin, Lymphatics—Abnormal (Checkbox)</li> <li>z. Neurologic (Equilibrium tests under item 28t)—Normal (Checkbox)</li> <li>z. Neurologic (Equilibrium tests under item 28t)—Abnormal (Checkbox)</li> <li>aa. Psychiatric (Specify any personality deviation)—Normal (Checkbox)</li> <li>aa. Psychiatric (Specify any personality deviation)—Abnormal (Checkbox)</li> <li>bb. Breasts—Normal (Checkbox)</li> <li>bb. Breasts—Abnormal (Checkbox)</li> <li>cc. Pelvic (Females only)—Normal (Checkbox)</li> <li>cc. Pelvic (Females only)—Abnormal (Checkbox)</li> </ul> <p>19. Notes (Describe every abnormality in detail. Enter pertinent item number before each comment. Continue in item 29 and use additional sheets if necessary)</p> <p>20. Dental—Acceptable (Checkbox)</p> <p>20. Dental—Not Acceptable (Checkbox)</p> <p>20. Dental—Not Acceptable (if checked, explain)</p> <p>20. Dental—Dental Examination not done by Dental Officer</p> <p>21. Remarks and Additional Dental Defects and Diseases</p> <p>22. Test Results (Copies of results are preferred as attachments)</p> <ul style="list-style-type: none"> <li>22a. Urinalysis—Specific Gravity</li> <li>22a. Urine Albumin</li> <li>22a. Urine Sugar</li> <li>22b. Syphilis Serology (Specify test used and results)</li> <li>22c. EKG</li> <li>22d. Blood Type and RH Factor</li> </ul>	
	Above below listed items.

ELECTRONIC ELEMENTS FOR SF 88—Continued

Item	Placement*
22e. Chest X-Ray or PPD (Place, date, film number and result)	
22f. Other Tests	
23. Relationship to Sponsor	
24a. Sponsor's Name—Last	
24b. Sponsor's Name—First	
24c. Sponsor's Name—MI	
24c. Sponsor's ID Number (SSN or Other)	
25. Depart./Service	
26. Hospital or Medical Facility	
27. Records Maintained At	
Last Name—First Name—Middle Name .....	Top of back page.
Identification Number .....	Top of back page.
Number of Sheets Attached .....	Top of back page.
28. Measurements and Other Findings .....	Above below listed items.
28a. Height	
28b. Weight	
28c. Color Hair	
28d. Color Eyes	
28e. Build—Slender (Checkbox)	
28e. Build—Medium (Checkbox)	
28e. Build—Heavy (Checkbox)	
28e. Build—Obese (Checkbox)	
28f. Temperature	
28g(1). Blood Pressure (Arm at heart level)—Sitting—Sys.	
28g(1). Blood Pressure (Arm at heart level)—Sitting—Dias.	
28g(2). Blood Pressure (Arm at heart level)—Recumbent—Sys.	
28g(2). Blood Pressure (Arm at heart level)—Recumbent—Dias.	
28g(3). Blood Pressure (Arm at heart level)—Standing (5 minutes)—Sys.	
28g(3). Blood Pressure (Arm at heart level)—Standing (5 minutes)—Dias.	
28h(1). Pulse (Arm at heart level)—Sitting	
28h(2). Pulse (Arm at heart level)—Recumbent	
28h(3). Pulse (Arm at heart level)—Standing—3 minutes	
28h(4). Pulse (Arm at heart level)—After Exercise	
28h(5). Pulse (Arm at heart level)—2 minutes after exercise	
28i(1). Distant Vision—Right 20/ (number)	
28i(1). Distant Vision—Right—Corrected to 20/ (number)	
28i(2). Distant Vision—Left 20/ (number)	
28i(2). Distant Vision—Left Corrected to 20/ (number)	
28j(1). Refraction—Right—By	
28j(1). Refraction—Right—S	
28j(1). Refraction—Right—CX	
28j(2). Refraction—Left—By	
28j(2). Refraction—Left—S	
28j(2). Refraction—Left—CX	
28k(1). Near Vision—Right (Number)	
28k(1). Near Vision—Right—Corrected To (Number)	
28k(1). Near Vision—Right—By (Number)	
28k(2). Near Vision—Left (Number)	
28k(2). Near Vision—Left—Corrected To (Number)	
28k(2). Near Vision—Left—By (Number)	
28l(1). Heterophoria (Specify Distance)—ESO	
28l(2). Heterophoria (Specify Distance)—EXO	
28l(3). Heterophoria (Specify Distance)—RH	
28l(4). Heterophoria (Specify Distance)—LH	
28l(5). Heterophoria (Specify Distance)—Prism Division	
28l(6). Heterophoria (Specify Distance)—Prism Conv. Ct.	
28l(7). Heterophoria (Specify Distance)—PC	
28l(8). Heterophoria (Specify Distance)—PD	
28m(1). Accommodation—Right	
28m(2). Accommodation—Left	
28n(1). Field of Vision—Right	
28n(2). Field of Vision—Left	
28o. Color Vision (Test used and result)	
28p. Night Vision (Test used and result)	
28q(1). Depth Perception (Test used and score)—Uncorrected	
28q(2). Depth Perception (Test used and score)—Corrected	
28r. Red Lens Test	
28s(1). Intraocular Tension—Right	
28s(2). Intraocular Tension—Left	
28t. Audiometer—Right Ear—500–512	
28t. Audiometer—Right Ear—1000–1024	

## ELECTRONIC ELEMENTS FOR SF 88—Continued

Item	Placement*
28t. Audiometer—Right Ear—2000–2048 28t. Audiometer—Right Ear—3000–3096 28t. Audiometer—Right Ear—4000–4096 28t. Audiometer—Right Ear—6000–6144 28t. Audiometer—Left Ear—500–512 28t. Audiometer—Left Ear—100–1024 28t. Audiometer—Left Ear—2000–2048 28t. Audiometer—Left Ear—3000–3096 28t. Audiometer—Left Ear—4000–4096 28t. Audiometer—Left Ear—6000–6144 28u. Psychological and Psychomotor (Tests used and score) 29. Notes (Continued) and Significant or Interval History 30. Summary of Defects and Diagnoses (List diagnoses with item numbers) 31. Recommendations—Further Specialist Examinations Indicated (Specify) 32. Physical Profile—P 32. Physical Profile—U 32. Physical Profile—L 32. Physical Profile—H 32. Physical Profile—E 32. Physical Profile—S 33. Examinee—Is Qualified for (Checkbox) 33. Examinee—Is Qualified for Explanation 33. Examinee—Is Not Qualified for (Checkbox) 33. Examinee—Is Not Qualified for Explanation 34. Physical Category—A 34. Physical Category—B 34. Physical Category—C 34. Physical Category—E 35. If Not Qualified, List Disqualifying Defects by Item Number 36. Typed or Printed Name of Physician 36. Signature of Physician 37. Typed or Printed Name of Physician 37. Signature of Physician 38. Typed or Printed Name of Dentist or Physician (Indicate which) 38. Signature of Dentist or Physician 39. Typed or Printed Name of Reviewing Officer or Approving Authority 39. Signature of Reviewing Officer or Approving Authority	

\*If no specific placement, data element may be in any order.

**FOR FURTHER INFORMATION CONTACT:** CDR Katherine Ciacco Palatianos, Indian Health Service, Department of Health and Human Services, Rockville, MD 20857 or e-mail at [kciacco@hqe.ihs.gov](mailto:kciacco@hqe.ihs.gov).

Dated: March 21, 2003.

**Katherine Ciacco Palatianos,**  
*Chairperson, Interagency Committee on Medical Records.*

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**BILLING CODE 6820–34–M**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**[Docket No. 02N–0354]**

**Agency Information Collection Activities; Submission for OMB Review; Comment Request; The Evaluation of Long-Term Antibiotic Drug Therapy for Persons Involved in Anthrax Remediation Activities**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the information collection provisions by May 2, 2003.

**ADDRESSES:** OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be electronically mailed to [sshapiro@omb.eop.gov](mailto:sshapiro@omb.eop.gov) or faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Stuart Shapiro, Desk Officer for FDA, FAX: 202–395–6974.

**FOR FURTHER INFORMATION CONTACT:** Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.