

process for new entrants because manufacturers are reluctant to establish a nationwide service and sales network until they have gained customer acceptance and have an established customer base, and customers are reluctant to purchase from a supplier unless it has an established service and sales network. As a result, a new entrant often finds itself in a "Catch 22" problem. For these reasons, new entry into the market would not be timely, likely or sufficient to deter or counteract the anticompetitive effects resulting from the acquisition.

The proposed Order remedies the anticompetitive effects in the heart-lung machine market by requiring SNIA to divest COBE's heart-lung machine business to Baxter Healthcare Corporation, a large manufacturer of medical products, including disposables for heart-lung machines, within ten (10) days after the Commission accepts the Agreement Containing Consent Order for public comment, or to another Commission-approved buyer within one hundred eighty (180) days after the Agreement Containing Consent Order is accepted for public comment. In the event that SNIA fails to divest the heart-lung machine assets, or the acquirer fails to obtain FDA approval and the ability to manufacture and sell heart-lung machines, the Commission may appoint a trustee to divest the COBE heart-lung machine business to a new acquirer. The divestiture trustee will have the authority and power to divest the heart-lung machine assets in a manner that satisfies the requirements of the Order.

The proposed Order requires SNIA to provide assistance to the acquirer so that it can compete effectively in the heart-lung machine business. First, SNIA must contract manufacture a supply of heart-lung machines for a limited time period while the acquirer obtains its own FDA approval and obtains the commercial capability to manufacture and sell heart-lung machines in the United States. Second, SNIA must provide technical assistance and advice to help the acquirer in its efforts to begin manufacturing and

selling heart-lung machines. The proposed Order enables the acquirer to hire former COBE employees associated with the research, development, manufacture, marketing, or sales of heart-lung machines. Finally, the Order requires SNIA to cooperate with the acquirer in any patent dispute in which a third party attempts to challenge any of the patents divested pursuant to the Order and in which the ability of the acquirer to become an effective competitor in the heart-lung machine market could be affected.

In order to facilitate the smooth transfer of assets and ensure that the acquirer will get the assistance necessary to independently manufacture the products, the proposed Order provides for the appointment of an interim trustee. The interim trustee will serve until the acquirer has received all necessary FDA approvals and obtains the commercial capability to manufacture and sell heart-lung machines. The Order also requires SNIA to provide to the Commission a report of compliance with the divestiture provisions of the Order within thirty (30) days following the date the Order becomes final, and every ninety (90) days thereafter until SNIA has completed the divestiture. The Order also requires SNIA to notify the Commission at least thirty (30) days prior to any change in SNIA that may affect compliance obligations arising out of the Order.

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

By direction of the Commission.

Donald S. Clark,
Secretary.

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BILLING CODE 6750-01-M

GENERAL SERVICES ADMINISTRATION

Interagency Committee for Medical Records (ICMR); Automation of Medical Standard Form 93

AGENCY: General Services Administration.

ACTION: Guideline on automating medical standard forms.

BACKGROUND: The Interagency Committee on Medical Records (ICMR) are aware of numerous activities using computer-generated medical forms, many of which are not mirror images of the genuine paper Standard Form. With GSA's approval the 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 data standards and require that activities developing computer-generated versions adhere to the required data elements 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 data elements which are required, those (if any) which are optional, and the required format (if necessary). Activities may not add 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 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.

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

ELECTRONIC ELEMENTS FOR SF 93

Item	Placement *
Text:	
Title: Report of Medical History	Top of form.
Note: This information is for official and medically-confidential use only and will not be released to unauthorized persons.	Top of form.
Form ID: Standard Form 93 (Rev. 6-96)	Bottom right corner of form.

ELECTRONIC ELEMENTS FOR SF 93—Continued

Item	Placement *
<p>I certify that I have reviewed the foregoing information supplies by me and that it is true and complete to the best of my knowledge. I authorize any of the doctors, hospitals, or clinics mentioned above to furnish the Government a complete transcript of my medical record for purposes of processing my application for this employment or service. I understand that falsification of information on Government forms is punishable by fine and/or imprisonment.</p> <p>Note: Hand to the doctor or nurse, or if mailed mark envelope "TO BE OPENED BY MEDICAL OFFICER ONLY".</p> <p>Data Entry Fields:</p> <p>No. of Attached Sheets.</p> <p>Date of Exam.</p> <p>Name of Patient (Last, first, middle).</p> <p>Identification Number.</p> <p>Grade.</p> <p>Home Street Address (Street or RFD; City or Town; State; and ZIP Code).</p> <p>Examining Facility.</p> <p>Purpose of Examination.</p> <p>Statement of Patient's Present Health and Medications Currently Used.</p> <p>Present Health.</p> <p>Current Medication.</p> <p>Regular or Interm.</p> <p>Allergies (include insect bites/stings and common foods).</p> <p>Height.</p> <p>Weight.</p> <p>Patient's Occupation.</p> <p>Are you (check one).</p> <p>Right Handed.</p> <p>Left Handed.</p> <p>Past/Current Medical History (response is either Yes, No, or Don't know).</p> <p>Household contact with anyone with tuberculosis.</p> <p>Tuberculosis or positive TB test.</p> <p>Blood in sputum or when coughing.</p> <p>Excessive bleeding after injury or dental work.</p> <p>Suicide attempt or plans.</p> <p>Sleepwalking.</p> <p>Wear corrective lenses.</p> <p>Eye surgery to correct vision.</p> <p>Lack vision in either eye.</p> <p>Wear a hearing aid.</p> <p>Sutter or stammer.</p> <p>Wear a brace or back support.</p> <p>Scarlet fever.</p> <p>Rheumatic fever.</p> <p>Swollen or painful joints.</p> <p>Frequent or severe headaches.</p> <p>Dizziness or fainting spells.</p> <p>Eye trouble.</p> <p>Hearing loss.</p> <p>Recurrent ear infections.</p> <p>Chronic or frequent colds.</p> <p>Severe tooth or gum trouble.</p> <p>Sinusitis.</p> <p>Hay fever or allergic rhinitis.</p> <p>Head injury.</p> <p>Asthma.</p> <p>Shortness of breath.</p> <p>Pain or pressure in chest.</p> <p>Chronic cough.</p> <p>Palpitation or pounding heart.</p> <p>Heart trouble.</p> <p>High or low blood pressure.</p> <p>Cramps in your legs.</p> <p>Frequent indigestion.</p> <p>Stomach, liver or intestinal.</p> <p>Gall bladder trouble or gallstones.</p> <p>Jaundice or hepatitis.</p> <p>Broken bones.</p> <p>Adverse reaction to medication.</p> <p>Skin diseases.</p> <p>Tumor, growth, cyst, cancer.</p> <p>Hernia.</p> <p>Hemorrhoids or rectal disease.</p> <p>Frequent or painful urination.</p>	<p>Before signature of examinee.</p>

ELECTRONIC ELEMENTS FOR SF 93—Continued

Item	Placement *
<p> Bed wetting since age 12. Kidney stone or blood in urine. Sugar or albumin in urine. Sexually transmitted diseases. Recent gain or loss of weight. Eating disorder (anorexia, bulimia, etc.). Arthritis, Rheumatism, or Bursitis. Thyroid trouble or goiter. Bone, joint or other deformity. Loss of finger or toe. Painful or "trick" shoulder or elbow. Recurrent back pain or any back injury. "Trick" or locked knee. Foot trouble. Nerve injury. Paralysis (including infantile). Epilepsy or seizure. Car, train, sea or air sickness. Frequent trouble sleeping. Depression or excessive worry. Loss of memory or amnesia. Nervous trouble of any sort. Periods of unconsciousness. Parent/sibling with diabetes, cancer, stroke or heart disease. X-ray or other radiation therapy. Chemotherapy. Asbestos or toxic chemical exposure. Plate, pin or rod in any bone. Easy fatigability. Been told to cut down or criticized for alcohol use. Use illegal substances. Use tobacco. Females Only—Treated for a female disorder—Yes (Check box). Females Only—Treated for a female disorder—No (Check box). Females Only—Treated for a female disorder—Don't know (Check box). Females Only—Change in menstrual pattern—Yes (Check box). Females Only—Change in menstrual pattern—No (Check box). Females Only—Change in menstrual pattern—Don't know (Check box). Females Only—Date of Last Menstrual Period. Females Only—Date of Last Pap Smear. Females Only—Date of Last Mammogram. Have you been refused employment or been unable to hold a job or stay in school because of: Sensitivity to chemicals, dust, sunlight, etc.—Yes (Check box). Have you been refused employment or been unable to hold a job or stay in school because of: Sensitivity to chemicals, dust, sunlight, etc.—No (Check box). Have you been refused employment or been unable to hold a job or stay in school because of: Inability to perform certain motions—Yes (Check box). Have you been refused employment or been unable to hold a job or stay in school because of: Inability to perform certain motions—No (Check box). Have you been refused employment or been unable to hold a job or stay in school because of: Inability to assume certain positions—Yes (Check box). Have you been refused employment or been unable to hold a job or stay in school because of: Inability to assume certain positions—No (Check box). Have you been refused employment or been unable to hold a job or stay in school because of: Inability to assume certain positions—Other medical reasons (If yes, give reasons.)—Yes (Check box). Have you been refused employment or been unable to hold a job or stay in school because of: Inability to assume certain positions—Other medical reasons (If yes, give reasons.)—No (Check box). Have you ever been treated for a mental condition? (If yes, specify when, where, and give details)—Yes (Check box). Have you ever been treated for a mental condition? (If yes, specify when, where, and give details)—No (Check box). Have you ever been denied life insurance? (If yes, state reason and give details)—Yes (Check box). Have you ever been denied life insurance? (If yes, state reason and give details)—No (Check box). Have you had, or have you been advised to have, any operation? (If yes, describe and give age at which occurred.)—Yes (Check box). Have you had, or have you been advised to have, any operation. (If yes, describe and give age at which occurred.)—No (Check box). Have you ever been a patient in any type of hospital? (If yes, specify when, where, why, and name of doctor and complete address of hospital)—Yes (Check box). Have you ever been a patient in any type of hospital? (If yes, specify when, where, why, and name of doctor and complete address of hospital)—No (Check box). </p>	

ELECTRONIC ELEMENTS FOR SF 93—Continued

Item	Placement *
<p>Have you consulted or been treated by clinics, physicians, healers, or other practitioners within the past 5 years for other than minor illnesses? (If yes, give complete address of doctor, hospital, clinic, and details)—Yes (Check box).</p> <p>Have you consulted or been treated by clinics, physicians, healers, or other practitioners within the past 5 years for other than minor illnesses? (If yes, give complete address of doctor, hospital, clinic, and give details)—No (Check box).</p> <p>Have you ever been rejected for military service because of physical, mental, or other reasons? (If yes, give date and reason for rejection)—Yes (Check box).</p> <p>Have you ever been rejected for military service because of physical, mental, or other reasons? (If yes, give date and reason for rejection)—No (Check box).</p> <p>Have you ever been discharged from military service because of physical, mental, or other reasons? (If yes, give date, reason, and type of discharge; whether honorable, other than honorable, for unfitness or unsuitability.)—Yes (Check box).</p> <p>Have you ever been discharged from military service because of physical, mental, or other reasons? (If yes, give date, reason, and type of discharge; whether honorable, other than honorable, for unfitness or unsuitability.)—No (Check box).</p> <p>Have you ever received, is there pending or have you ever applied for pension or compensation for existing disability? (If yes, specify what kind, granted by whom, and what amount, when.)—Yes (Check box).</p> <p>Have you ever received, is there pending or have you ever applied for pension or compensation for existing disability? (If yes, specify what kind, granted by whom, and what amount, when.)—No (Check box).</p> <p>Have you ever been arrested or convicted of a crime, other than minor traffic violations (If yes, provide details.)—Yes (Check box).</p> <p>Have you ever been arrested or convicted of a crime, other than minor traffic violations (If yes, provide details.)—No (Check box).</p> <p>Have you ever been diagnosed with a learning disability? (If yes, give type, where, and how diagnosed.)—Yes (Check box).</p> <p>Have you ever been diagnosed with a learning disability? (If yes, give type, where, and how diagnosed.)—No (Check box).</p> <p>List All Immunizations Received.</p> <p>Typed or Printed Name of Examinee.</p> <p>Signature of Examinee.</p> <p>Date of Signature.</p> <p>Physician's Summary and Elaboration of All Pertinent Data. (Physician shall comment on all positive answers in items 7 through 11. Physicians may develop by interview any additional medical history deemed important, and record any significant findings here.)</p> <p>Typed or Printed Name of Physician or Examiner.</p> <p>Signature of Physician or Examiner.</p> <p>Date of Signature.</p>	

* If no placement indicated, items can appear anywhere on the form.

FOR FURTHER INFORMATION CONTACT: CDR Steven S. Kerrick, USN National Naval Medical Center, Department of Ophthalmology, Bethesda, MD 20889-5000 or E-Mail at StevenK966@aol.com.

Dated: May 12, 1999.

Steven S. Kerrick,

Chairperson, Interagency Committee on Medical Records.

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GENERAL SERVICES ADMINISTRATION

Interagency Committee for Medical Records (ICMR); Automation of Medical Standard Form 509

AGENCY: General Services
Administration.

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 the 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 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 on Medical Records (ICMR) eliminated the requirement that every electronic version of a medical Standard/Optional form be reviewed and granted an exception. The following fields must appear on the electronic version of the following form: