SANFORD™
LABORATORIES

Medical Necessity

◇ BACKGROUND

The 1965 Social Security Act [under Section 1862 (a) (1) (A)] requires that "*Medicare will cover only those services that are medically necessary. The Medicare program does not cover items and services that are not reasonable and necessary for the diagnosis or treatment of an illness, or injury, or to improve the functioning of a malformed body member.*"

For an item or service to be ***considered medically necessary,*** it must be:

- Consistent with the symptoms or diagnosis of the illness or injury under treatment; ***and***
- Necessary and consistent with generally accepted professional medical standards (i.e., not experimental); ***and***
- Not furnished primarily for the convenience of the patient or provider; ***and***
- Furnished at the most appropriate level considered safe and effective for the patient.

Therefore, Medicare may deny payment for a test the provider believes is appropriate, but which does not meet the Medicare coverage criteria (e.g., done for screening purposes) or where documentation in the patient's medical record does not support that the tests ordered were reasonable and necessary for a given patient. Tests submitted for Medicare reimbursement must meet program requirements or the claim may be denied.

The ordering provider should retain in the patient's medical record the history and physical examination notes documenting evaluation and management of one of the Medicare covered conditions/diagnoses, with relevant clinical signs/symptoms or abnormal laboratory test results, appropriate to one of the covered indications. The patient's medical record should further indicate changes/alterations in medications prescribed for the treatment of the patient's condition. There must be an order for each test documented in the patient's medical record. Documentation must be submitted to Medicare upon request. **The patient's medical record must include documentation to support medical necessity.** If you have any questions regarding this policy or the Sanford Laboratories Patient Fee Disclosure please contact Dr. Kimberlee Bohy, M.D., Clinical Consultant for Sanford Laboratories Clinic Laboratories at 605-333-1730 or Dr. Rachel Starks, M.D., Clinical Consultant for the Sioux Falls and Rapid City Reference Laboratories at 605-312-4601 or 605-404-4364.

◇ MEDICAL RECORD DOCUMENTATION

- Title XVIII of the Social Security Act, section 1833 (e). This section prohibits Medicare payment for any claim lacking the necessary information to process the claim.
- 42CFR410.32. Diagnostic tests may only be ordered by an authorized provider acting within the scope of their license and Medicare requirements

Diagnosis codes and/or signs and symptoms must be documented in the patient's medical record:

- For each CPT code billed, there should be documentation that the service was performed
- Documentation must also substantiate the level of service billed
- Documentation should be written on a timely basis
- The medical records should be annotated by the provider who performed the service

◇ ORGAN AND DISEASE ORIENTED PANELS

Effective January 1, 1997
To assist providers with ordering, the Centers for Medicare and Medicaid (CMS) and the American Medical Association (AMA) worked together to develop the "Organ and Disease-Oriented Panels." The premise behind the development of these panels was to allow the provider to order tests that are medically necessary for a certain condition by ordering the appropriate panel rather than the individual tests. The strategy was to eliminate the old automated multi-channel panels and replace them with more clinically grounded groupings of tests. To use the organ or disease-oriented code, the laboratory must perform each test listed under the panel. The laboratory cannot make changes or substitutions to these panels. It is important to remember that even though CMS views the ordering of an Organ or Disease-Oriented Panel as ordering an individual test, **there must be documentation in the patient's medical record to support the medical necessity for *each* test within the panel.** Sanford Laboratories provides updated and new limited coverage information to clients as it becomes available. All claims are subject to post-payment review. If this occurs, our carrier may require the laboratory to produce documentation from the medical record that would support medical necessity for each test billed to Medicare.

ORGAN AND DISEASE-ORIENTED PANELS - as of January 1, 2022

PANEL NAME & CODE	LIST OF TESTS
Acute Hepatitis Panel **CPT 80074**	- Hepatitis A antibody (IgM) (86709) - Hepatitis B core antibody (IgM) (HBcAb) (86705) - Hepatitis B surface antigen (HBsAg) (87340) - Hepatitis C antibody (86803)
Basic Metabolic Panel **CPT 80047**	- Calcium, ionized (82330) - Carbon dioxide (82374) - Chloride (82435) - Creatinine (82565) - Glucose (82947) - Potassium (84132) - Sodium (84295) - Urea Nitrogen (BUN) (84520)
Basic Metabolic Panel **CPT 80048**	- Calcium (82310) - Carbon dioxide (82374) - Chloride (82435) - Creatinine (82565) - Glucose (82947) - Potassium (84132) - Sodium (84295) - Urea Nitrogen (BUN) (84520)
Comprehensive Metabolic Panel **CPT 80053**	- Albumin (82040) - Alkaline Phosphatase (84075) - ALT (SGPT) (84460) - AST (SGOT) (84450) - Bilirubin, total (82247) - Calcium (82310) - Carbon dioxide (82374) - Chloride (82435) - Creatinine (82565) - Glucose (82947) - Potassium (84132) - Sodium (84295) - Total Protein (84155) - Urea Nitrogen (BUN) (84520)
Electrolyte Panel **CPT 80051**	- Carbon dioxide (82374) - Chloride (82435) - Potassium (84132) - Sodium (84295)
Hepatic Function Panel **80076**	- Albumin (82040) - Alkaline Phosphatase (84075) - ALT (SGPT) (84460) - AST (SGOT) (84450) - Bilirubin, Direct (82248) - Bilirubin, Total (82247) - Total Protein (84155)
Lipid Panel **CPT 80061**	- Cholesterol, serum, total (82465) - Triglycerides (84478) - HDL cholesterol, direct measurement (83718)
Obstetric Panel **CPT 80081**	- ABO blood typing (86900) - Rh blood typing (86901) - Antibody screen, RBC (86850) - Complete Blood Count (CBC) and automated differential WBC count (85025 or 85027 and 85004) **OR** Complete Blood Count (CBC), automated (85027) and appropriate manual differential WBC count (85007 or 85009) - Hepatitis B surface antigen (HBsAg) (87340) - HIV-1 antigen(s) and HIV-1 and HIV-2 antibodies (87389) - Rubella antibody (86762) - Syphilis test, qualitative (86592)
Renal Function Panel **CPT 80069**	- Albumin (82040) - Calcium (82310) - Carbon dioxide (82374) - Chloride (82435) - Creatinine (82565) - Glucose (82947) - Phosphorus, inorganic (phosphate) (84100) - Potassium (84132) - Sodium (84295) - Urea Nitrogen (BUN) (84520)

Reference: American Medical Association, Current Procedural Terminology CPT 2022

◇ROUTINE SCREENING

Medicare coverage does not usually include routine screening or experimental diagnostic testing based on the requirements for medical necessity. Screening is defined as examinations and/or diagnostic procedures performed in the absence of signs or symptoms. According to Medicare, **screening excludes** routine physical checkups (including tests performed in the absence of signs or symptoms) from the Medicare program. Screening tests are often performed based on the patient's age and/or family history. **While performance of such examinations and tests may be considered good medical practice, they are not covered services under the Medicare program.** In certain situations, Medicare may through the legislative process, define tests that will be covered if performed as a screening test. To find additional information at Medicare.gov, copy the link under the "Reference" column and paste into the address line of your browser.

Laboratory screening tests which Medicare covers under defined conditions:

Type	ICD-10	Test(s) Performed	CPT/HCPCS Codes Associated	Frequency *if* covered by Medicare Part B	Reference
Cardiovascular Screening	Z13.6	Lipid Panel, Cholesterol, Lipoprotein & Triglycerides	80061 - Lipid Panel 82465 - Cholesterol, Total, serum 83718 - Lipoprotein, direct measurement, HDL cholesterol 84478 - Triglycerides	> 5 years after last covered screening test (Patients diagnosed with prior cardiovascular disease are not eligible for this benefit)	https://www.medicare.gov/coverage/cardiovascular-disease-screenings.html
Colorectal Cancer Screening NCD 210.3	Z86.004 For multitarget stool DNA (MT-sDNA) and blood-based biomarker tests, use Z12.11 or Z12.12	FOBT or FIT Stool DNA Test and blood-based biomarker tests	82270 - Blood, occult, by peroxidase activity (e.g., guaiac), qualitative, feces, consecutive collected specimens with single determination, for colorectal neoplasm screening (i.e., patient was provided 3 cards or a single triple card for consecutive collections) G0327 - Colorectal cancer screening, blood-based biomarker G0328 - Colorectal cancer screening; fecal occult blood test, immunoassay, 1-3 simultaneous determinations 81528 - Oncology (colorectal) screening, quantitative real-time target and signal amplification of 10 DNA markers (*KRAS* mutations, promoter methylation of *NDRG4* and *BMP3*) and fecal hemoglobin, utilizing stool, algorithm reported as a positive or negative result	> A screening fecal occult blood test (FOBT) **or** fecal immunochemical test (FIT) are covered once every 12 months if you are 50 or older > A stool DNA test and blood-based biomarker test is covered once every 3 years for individuals who meet **all** these conditions: • Age 50 – 85 • No symptoms of colorectal disease including: ○ Lower GI pain ○ Blood in stool ○ Positive guaiac FOBT or FIT test • At average risk for developing colorectal cancer meaning: ○ No personal history of adenomatous polyps, colorectal cancer, inflammatory bowel disease, including Crohn's Disease and ulcerative colitis. ○ No family history of colorectal cancers or adenomatous polyps, familial adenomatous polyposis, or hereditary nonpolyposis colorectal cancer.	https://www.medicare.gov/coverage/screening-fecal-occult-blood-tests https://www.medicare.gov/coverage/multi-target-stool-dna-tests
Diabetes Screening	Z13.1	Glucose	82947 – Glucose, quantitative, blood (except reagent strip) 82950 – Glucose, post glucose dose (includes glucose) 82951 - Glucose; tolerance test (GTT), 3 specimens (includes glucose)	> One time every 12 months for individuals not diagnosed with pre-diabetes or never tested. > Medicare Part B covers two times per year for patients with any of the following risk factors: • High blood pressure • History of abnormal cholesterol and triglyceride levels • Obesity • History of high blood sugar > Medicare Part B also covers if two or more of these apply to the patient: • Age 65 or older • Overweight • Family history of diabetes • History of gestational diabetes or delivery of a baby weighing more than 9 pounds	https://www.medicare.gov/coverage/diabetes-screenings.html

Type	ICD-10	Test(s) Performed	CPT/HCPCS Codes Associated	Frequency *if* covered by Medicare Part B	Reference
Hepatitis B Virus (HBV) Screening NCD 210.6	For persons with End Stage Renal Disease: Z11.59 **and** N18.6 For asymptomatic, non-pregnant adolescents and high-risk adults: Z11.59 **and** Z72.89 For asymptomatic, non-pregnant adolescents and adults, subsequent visits: Z11.59 **and one** of the following: F11.10, F11.11, F11.13, F13.10, F13.11, F13.130, F13.131, F13.132, F14.10, F14.11, F14.13, F14.93, F15.10, F15.11, F15.13, Z20.2, Z20.5, Z72.52, Z72.53 For pregnant women: Z11.59 **and one** of the following: Z34.00, Z34.80, Z34.90 O09.90 For high-risk pregnant women: Z11.59 **and** Z72.89 **and one** of the following: Z34.00, Z34.01, Z34.02, Z34.03, Z34.80, Z34.81, Z34.82, Z34.83, Z34.90, Z34.91, Z34.92, Z34.93, O09.90, O09.91, O09.92, O09.93	Hepatitis B Surface Antigen (HBsAg) Hepatitis B Core Antibody (HBcAb); Total Hepatitis B Surface Antibody (HBsAb) Hepatitis B Surface Antibody (HBsAG) neutralization	**For Asymptomatic, Non-pregnant adolescents and high-risk adults***:* G0499 – Hepatitis B screening in non-pregnant, high-risk individual includes HBsAg followed by a neutralizing confirmatory test for initially reactive results, and HBsAB and HBcAB **For Pregnant Women:** 86704 – HBcAb; Total 86706 – HBsAb 87340 – HBsAg 87341 – HBsAG neutralization	> One asymptomatic screening for non-pregnant adolescents and adults who meet high-risk definition > Annually for those with continued high risk who don't get HBV > One screening for pregnant women at first prenatal visit for each pregnancy, and rescreening at delivery for those with new or continued risk factors Notes: This includes screening during the first prenatal visit for future pregnancies, even if the patient previously got the HBV shot or had a negative hepatitis B surface antigen screening result	https://www.medicare.gov/coverage/hepatitis-b-virus-infection-screenings
Hepatitis C Virus (HCV) Screening NCD 210.13	Z72.89 and F19.20 For Medicare beneficiaries born between 1945 and 1965 who are not considered high risk use Z11.59	Hepatitis C Virus Antibody	G0472 – Hepatitis C antibody screening, for individual at high risk and other covered indication(s)	> Once for patients born between 1945 and 1965 who are not considered high risk > An initial patient screening, regardless of birth year, for high-risk patients (patients who had a blood transfusion before 1992 and patients with current or history of illicit injection drug use) > Annually only for high-risk patients with continued illicit injection drug use since the prior negative HCV screening test	https://www.medicare.gov/coverage/hepatitis-c-screening-test.html
Human Papillomavirus (HPV) Screening for Cervical Cancer NCD 210.2.1	Z11.51 **and either** Z01.411 or Z01.419	HPV	G0476 - Infectious agent detection by nucleic acid (DNA or RNA); HPV, high-risk types (e.g., 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68)	> Asymptomatic Medicare Part B female patients aged 30 – 65 Frequency – Once every 5 years	https://www.medicare.gov/coverage/cervical-vaginal-cancer-screenings.html

Type	ICD-10	Test(s) Performed	CPT/HCPCS Codes Associated	Frequency *if* covered by Medicare Part B	Reference
Human Immunodeficiency (HIV) Screening NCD 210.7	Increased risk factors not reported: Z11.4 Increased risk factors reported: Z11.4 and Z72.51, Z72.52, Z72.53 or Z72.89 Pregnant patients: Z11.4 and Z34.00, Z34.01, Z34.02, Z34.03, Z34.80, Z34.81, Z34.82, Z34.83. Z34.90, Z34.91, Z34.92, Z34.93, O09.90, O09.91, O09.92, or O09.93	HIV-1 and / or HIV-2 by EIA, ELISA, or Rapid antibody test	G0432 - Infectious agent antibody detection by EIA technique, HIV-1 and/or HIV-2 screening G0433 - Infectious agent antibody detection by ELISA technique, HIV-1 and/or HIV-2 screening G0435 - Infectious agent antibody detection by rapid antibody test, HIV-1 and/or HIV-2, screening G0475 - HIV antigen/ antibody, combination assay, screening 80081 – Obstetric panel (includes HIV testing)	> Annually for patients ages of 15-65 without regard to perceived risk > Annually for patients younger than 15 and adults older than 65 at increased HIV risk > For pregnant patients, 3 times per pregnancy • When diagnosed as pregnant • During 3rd trimester • At labor, if clinician orders it	https://www.medicare.gov/coverage/hiv-screening.html
Prostate Cancer Screening NCD 210.1	Z12.5	Prostate Specific Antigen (PSA)	G0103 – Prostate Cancer Screening; Prostate Specific Antigen Test (PSA)	> Annually for male patients aged 50 or older with Medicare Part B (coverage begins day after 50th birthday)	https://www.medicare.gov/coverage/prostate-cancer-screenings.html
Screening for Sexually Transmitted Infections (STIs) NCD 210.10	Z11.3, Z11.59, Z72.89, Z72.51, Z72.52, Z72.53, Z34.00, Z34.01, Z34.02, Z34.03, Z34.80, Z34.81, Z34.82, Z34.83. Z34.90, Z34.91, Z34.92, Z34.93, O09.90, 09.91, O09.92, or O09.93	Screening tests for Chlamydia, gonorrhea, syphilis and hepatitis	**Chlamydia** 86631 - Chlamydia Ab 86632 - Chlamydia Ab, IgM 87110 - Chlamydia culture, any source 87270 – Infectious agent antigen detection by IF technique; *Chlamydia trachomatis* 87320 – Infectious agent antigen detection by immunoassay technique, (e.g., EIA, ELISA, IMCA), qualitative or semi-quantitative, multiple-step method. *Chlamydia trachomatis* 87490 – Infectious agent detection by nucleic acid (DNA or RNA), *Chlamydia trachomatis,* direct probe technique 87491 – infectious agent detection by nucleic acid (DNA or RNA), *Chlamydia trachomatis,* amplified probe technique 87810 – infectious agent antigen detection by immunoassay with direct optical observation, *Chlamydia trachomatis* 87800 – Infectious agent detection by nucleic acid (DNA or RNA), multiple organisms; direct probe technique **Gonorrhea** 87590 – Infectious agent antigen detection by nucleic acid (DNA or RNA), Neisseria gonorrhoeae, direct probe technique 87591 – Infectious agent antigen detection by nucleic acid (DNA or RNA), Neisseria gonorrhoeae, amplified probe technique 87850 – Infectious agent antigen detection by immunoassay with direct optical observation, Neisseria gonorrhoeae	> One screening a year for chlamydia, gonorrhea, and syphilis in women at increased risk but not pregnant > Up to 2 screenings for chlamydia and gonorrhea per pregnancy for women at increased STI risk and continued increased risk for the second screening > One screening a year for syphilis in men at increased risk > One syphilis screening per pregnancy for pregnant women • Up to two additional screenings in the third trimester and at delivery if at continued increased risk for STIs > One screening per pregnancy for Hepatitis B in pregnant women: • One additional screening at delivery if at continued increased STI risk	https://www.medicare.gov/coverage/sexually-transmitted-infections-screening-and-counseling.html

			87800 - Infectious agent detection by nucleic acid (DNA or RNA), multiple organisms, direct probe(s) technique *** Use 87800 when performing combined chlamydia and gonorrhea testing** **Hepatitis B** 87340 – Infectious agent antigen detection by immunoassay technique, (e.g., EIA, ELISA, IMCA) qualitative or semi-quantitative, multiple-step method, Hepatitis B Surface Antigen (HbsAg) 87341 – Infectious agent antigen detection by immunoassay technique, (e.g., EIA, ELISA, IMCA) qualitative or semi-quantitative, multiple step method, Hepatitis B surface antigen (HbsAg) neutralization **Syphilis** 86592 - Syphilis test, non-treponemal antibody, qualitative (e.g., VDRL, RPR, ART) 86593 - Syphilis test, non-treponemal antibody, quantitative 86780 – Antibody, Treponema pallidum		

Tests ordered in the absence of symptoms, physician/provider findings, or other evidence of disease or injury, are considered screening tests and therefore a **non-covered** service under Medicare. In such cases, the provider providing the non-covered service can bill the Medicare beneficiary directly without submitting a claim to Medicare. Submitting claims to Medicare for services that the provider knows do not fall within Medicare coverage guidelines is a fraudulent act. The provider may submit charges to Medicare in situations where the beneficiary wishes to have them submitted to obtain a denial from Medicare so the service can be submitted to a supplemental insurance company. This process must be documented on the Medicare submission claim.

◇LIMITED COVERAGE

Each Carrier (Part B coverage for physician's office or independent laboratory) and fiscal Intermediary (Part A coverage for hospital and skilled nursing home facilities) develops policies to define under which signs, symptoms, or diagnoses the service will be covered based on review of test utilization. These policies are **Local Coverage Determinations (LCDs) and Local Coverage Articles (LCAs)**. Local Coverage Articles contain coding and other guidelines that complement an LCD. Medicare contractors post articles on the Medicare Coverage Database (MCD). Because test utilization patterns vary in different regions of the country and in different states, LCDs and LCAs differ from the carrier in one state to the carrier in another state. Since utilization in hospitals and nursing homes is different from those in the physician's office and independent laboratory, there may be different LCDs and LCAs in the same state for the carrier and intermediary. **The Medicare Administrative Contractor (MAC) to which the laboratory bills the test service determines which LCDs and LCAs apply to any given patient, regardless of the address of the patient and/or ordering physician or other authorized ordering provider.**

National Coverage Determinations (NCDs) are policies developed by CMS at the national level. They are binding on all MACs and cannot be revised by local contractors. Local contractors can add frequency limits and may supplement a NCD where the NCD is silent on an issue. **National Coverage Determinations apply to all clinical laboratories throughout the United States.**

National Coverage Determinations, Local Coverage Determinations and Local Coverage Articles are available on the Sanford Laboratories website at www.sanfordhealth.org/medical-services/laboratories. Click on "Compliance" on right side of page and scroll down and click on "National Coverage Determinations", "Local Coverage Determinations" or "Local Coverage Articles" as needed. A copy of the Medical Necessity policy can be located by clicking on the "Advanced Beneficiary Notice of Noncoverage" link.

Please be aware that it is not enough to link the procedure code to a correct payable ICD10-CM diagnosis code. The diagnosis must be present for the procedure(s) to be paid, but in addition, the procedure(s) must be reasonable and necessary for that diagnosis. Documentation in the Medicare beneficiary's medical record must support the necessity for the test(s) provided.

◇ADVANCE BENEFICIARY NOTICE OF NONCOVERAGE FORM

When a test with limited coverage (NCD, LCD or LCA) is ordered, the laboratory is allowed to submit the test to Medicare for payment. If payment is denied, the laboratory will be able to bill the beneficiary if an Advance Beneficiary Notice of Noncoverage (ABN) form was completed. The form regulations apply to participating and non-participating provider services that may be determined as not medically necessary. Under federal law, ***providers must inform Medicare beneficiaries in writing before providing a service that Medicare may consider not medically necessary.*** The ABN form allows the beneficiary to make an informed decision about receiving the service and involves them in their health care treatment decisions. The Advance Beneficiary Notice of Noncoverage forms also protect the provider's right to collect payment from the beneficiary when claims are denied by Medicare as "not reasonable and necessary."

Office of Management and Business (OMB) Approved Advance Beneficiary Notice of Noncoverage Form
The ABN form that is acceptable for use is Form CMS-R-131 (Exp. 06/30/2023) / Form Approved OMB No. 0938-0566. A copy of the Advance Beneficiary Notice of Noncoverage form is available on the Sanford Laboratories website at www.sanfordhealth.org/medical-services/laboratories. Click on "Compliance" on right side of page and scroll down. Click on "Advance Beneficiary Notice of Noncoverage" to locate the "Printable ABN Form".

THE ADVANCE BENEFICIARY NOTICE OF NONCOVERAGE FORM MUST:

- Be obtained prior to collecting the specimen from the beneficiary or prior to the beneficiary receiving the service (procedure/test) that are the subject of the notice.
- Be verbally reviewed with the beneficiary or his/her representative. Any questions raised during the review process must be answered prior to the beneficiary signing the ABN.
- If the patient demands the service and refuses to sign the ABN, have a second employee in your lab or office witness the attempted administration of the ABN and the beneficiary's refusal to sign. Both employees should sign an annotation on the form attesting to having witnessed the attempted administration and the refusal of the beneficiary to sign the ABN. If there is only one person available, the second witness may be contacted by telephone to witness the beneficiary's refusal to sign the ABN by telephone and may sign the form at a later time.
- The unused patient signature line on the form may be used for the annotation and signatures. Writing in the margins of the form is also permissible. In this case, the patient may be billed for the services if Medicare denies the claim.
- Be administered to beneficiaries enrolled in the Medicare FFS program. It is not used for services provided under the Medicare Advantage (MA) Program.

INSTRUCTIONS FOR COMPLETINGE THE ADVANCE BENEFICIARY OF NONCOVERAGE FORM

Form CMS-R-131 (Exp. 06/30/2023) / Form Approved OMB No. 0938-0566

1. Use black or blue ink and make sure each copy is legible and readable.

2. Determine if the test(s) ordered have a NCD or LCD/LCA. This information is available on the Sanford Laboratories website at www.sanfordhealth.org/medical-services/laboratories. Click on "Compliance" on right side of page and scroll down to the "Printable Compliance Forms" section of the page. Click on the appropriate link i.e., "Advance Beneficiary Notice of Noncoverage", "National Coverage Determinations", "Local Coverage Determinations" or "Local Coverage Articles" to print an ABN form or view appropriate documents.

3. **"Notifier"** Box – *REQUIRED* – Write the name, address and phone number of the entity administering the ABN. If the ABN form used does not have the notifier information pre-populated in the upper left-hand corner of the document, the administrator of the ABN must provide this information. The notifier requirements include:
    I. Lab/Clinic Name
    II. Lab/Clinic Address
    III. Lab/Clinic Phone Number

4. **"Patient Name"** Box - *REQUIRED* - Print the name of the beneficiary (patient) as it appears on their Medicare card.

5. **"Identification Number"** Box – *REQUIRED by Sanford Laboratories* – Enter a unique patient identification number for the Medicare beneficiary. Do not use their Medicare ID number or Social Security number.

6. **"Lab Test(s)"** Box – *REQUIRED* – Write the name of the test(s) ordered (in line-item fashion) that may not be

covered by Medicare. A list of applicable NCDs, LCDs and LCAs is available on the Sanford Laboratories website at www.sanfordhealth.org/medical-services/laboratories. Click on “Compliance” on right side of page and scroll down to “Printable Compliance Forms” section of the page. Click on the appropriate link i.e., “National Coverage Determinations”, “Local Coverage Determinations” or “Local Coverage Articles” to view appropriate documents.

7. **"Reason Medicare May Not Pay"** Box - *REQUIRED* – Place an **"X"** in the box with the appropriate reason you believe Medicare may not pay for the **"Lab Test(s)"** ordered. The reasons are listed below:
    - *Medicare does not pay for these tests for your condition.*
      Example: A diagnosis code is provided but does not meet medical necessity for the test ordered.
    - *Medicare does not pay for these tests as often as this (denied as too frequent).*
      Example: A PSA screen is ordered more frequently than once per year
    - *Medicare does not pay for experimental research tests.*
      Example: The test ordered is considered experimental or for research only.

8. **"Estimated Cost"** Box - *REQUIRED* – Record cost of the test(s) that may not be covered by Medicare. The cost for most tests are available on the Sanford Laboratories website at www.sanfordhealth.org/medical-services/laboratories. Click on “Compliance” on right side of page and scroll down to the “Printable Compliance Forms” section of the page. The “Patient Fees to Use with ABNs” document is located under the “Advance Beneficiary Notice of Noncoverage” section and contains the most current pricing information. If the cost for the test(s) ordered are not provided on this fee schedule, contact the Sanford Laboratories Accounts Receivable department at 605-328-5485 to obtain the cost for the test(s).

9. **"Options"** Box - *REQUIRED* – The beneficiary or the beneficiary's representative must choose only ***one*** of the three options by placing an "X" in front of the appropriate option. You (the notifier) cannot choose an option for them.
    - If the beneficiary or his/her representative wishes to receive some, but not all, of the services on the ABN, the notifier can accommodate this request by completing a new ABN form listing the items/services the beneficiary wishes to receive with the corresponding option selected.

10. **"Additional Information"** Box – *OPTIONAL* - You can enter any additional insurance information or any information that may be useful to the beneficiary in this box.

11. **"Signature"** Box - *REQUIRED* - The beneficiary or the beneficiary's representative must sign the form.

12. **"Date"** Box - *REQUIRED* - The beneficiary or the beneficiary's representative must date the form.

FINALIZATION OF ADMINISTRATION OF THE ADVANCE BENEFICIARY NOTICE OF NONCOVERAGE PROCESS:

If filling out the Sanford Laboratories 2-part ABN form, always give a copy of the completed form (yellow copy) to the patient. The original ABN form (white copy) will be scanned into the patient’s medical record. If using a copy of the ABN form available on the Sanford Laboratories website, give the patient a photocopy of the ABN form after they sign, date and all the required items are complete as indicated above in the ABN Instructions section.

Medicare beneficiaries are aware that they are responsible for payment of routine or screening tests. Advance Beneficiary Notice of Noncoverage forms are not required for "routine or screening tests" as they are not covered services under Medicare; however, Medicare does cover a selection of screening tests if ordered following specific frequency criteria. For a list of the screening tests covered by Medicare, please see pages 3-6 for test details and screening frequencies.

When requesting that Sanford Laboratories bill Medicare, a valid ABN must accompany the sample and request. The laboratory submitting the claim to Medicare must have the form on file.

EXAMPLES OF UNACCEPTABLE ADVANCE BENEFICIARY NOTICE OF NONCOVERAGE FORM PRACTICES ARE:

- Administering ABN forms for all claims and services (blanket forms)
- Failure to state on the ABN form the services which Medicare will likely deny
- Failure to complete the ABN form prior to providing the service (performing the test)
- Failure to provide the estimated cost information on the ABN form
- Administering an ABN form to a patient in a medical emergency or to a patient who is under great duress

Clients and Providers who collect samples and order tests that may not be covered by Medicare will be held responsible for the testing charges if a valid Advanced Beneficiary Notice of Non-Coverage is not collected from the beneficiary.