Medicare's Advanced Beneficiary Notice: an ethical analysis

"...in terms of ethics, Medicare's Advance Beneficiary Notice appears an anomaly in today's health services environment where mutual exchanges of information between care providers and patients, shared decision-making, patient autonomy and informed consent are taken seriously and guided by ethical principles."

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An Advanced Beneficiary Notice (ABN) is a notice that must be completed and signed prior to the delivery of services by patients with Medicare health insurance whenever care providers believe that a particular service or treatment will not be covered. The purpose of the ABN is to inform patients that they may be financially liable for payment of such noncovered services. Written notices leading to the implementation of current ABNs have been used since Section 1879 of the Social Security Act was enacted in 1972, requiring written notices to inform beneficiaries that they may be responsible for paying the costs of services not covered by Medicare [1].

The length and content of notices have changed over the decades, but have generally functioned as a means to notify patients that payment might not be made for noncovered services or care that Medicare deemed unreasonable and unnecessary [2]. A procedure, test or service that is not covered by Medicare, and for which the healthcare provider is not reimbursed, will then be billed to the patient. For years, physicians disapproved of the language 'unreasonable and unnecessary' in ABNs due to the implied conclusion that some physicians were ordering unnecessary tests and services for patients. In 2001, the Center for Medicare and Medicaid Services (CMS) introduced a new, one-page general-use ABN that was appreciated for its concise length, improved clarity and physician-friendly language [2]. Notably, the clause informing beneficiaries that Medicare does not cover items identified as unreasonable and unnecessary was removed from the revised ABN and remains absent today, while 'reasonable and necessary' criterion is still disseminated to patients through annually distributed guides such as 'Medicare and You' [3,4].

The use of multiple forms was finally abandoned in September 2008 when the one-page ABN form, CMS-R-131, emerged as a replacement for the general-use form CMS-R-131-G, the physician-order laboratory test form CMS-R-131L and the Notice of Exclusion from Medicare benefits form [1]. Nonetheless, physician organizations such as the American Medical Association have continued to lobby for elimination of ABNs altogether, citing additional conflicts and the imposition they make on the physician–patient relationship [5,6]. Understandably, ABNs are a nuisance for physicians because the job of educating patients about what Medicare may or may not cover is left to them, their patient access representatives, or other healthcare providers [7,8]. The incentive for physicians is, however, identifiable and worthwhile from a practical standpoint: the ABN is a written notice that transfers the risk of nonpayment from providers to patients [8].

Although the ABN contains physician-friendly language, no provisions are made for patients who are illiterate, under-literate, have English as a second language or do not

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understand the language contained in the ABN for other reasons. The healthcare provider who provides the ABN and asks for the patient signature is often not the same provider who has ordered and explained the test for which the ABN is required, because the ABN is the responsibility of the CMS payee rather than the provider who orders the test. If the patient has additional questions about the test after learning that it may not be covered by Medicare, the healthcare provider who is asking for the ABN to be signed may not be able to answer these questions, because that person does not have access to the patient's record [9]. For clinical laboratory testing, patients may be sent to another facility to have blood drawn, and the test is run by a laboratory with which the physician contracts for laboratory services. These providers may receive only a written order from the physician's office, and have no other information about the patient than positive identification prior to venipuncture. With this limited knowledge, the laboratory personnel may be unable to provide the patient with answers to questions about the need to have the test completed, if other covered tests may be suitable, what the test will tell the physician and whether refusing the test will have adverse effects on the patient's health.

Most of the professional literature concerning the history and use of ABNs exists in the form of journalistic accounts of its development. Much has been written about the impact (mostly negative) ABNs have made on the work of physicians and clinical laboratory professionals while essentially nothing has been written about the impact made on patient welfare. Instead, most of the literature concerning the development and use of ABNs has focused on helping physicians and laboratories comply with Medicare's requirements and successfully implement written notices so liability for noncovered tests and services can be avoided and passed to patients. What appears to be missing from the long and ongoing conversation among the professional associations and medical news outlets is an ethical analysis of the dilemma created for patients when ABNs are required and administered.

From a bioethical point of view, ABNs are similar to informed consent documents because patients are not merely agreeing to pay for lab tests, but also being put in a position to determine how vital the test is and how badly they want to have it done. Because patients most often encounter ABNs at the laboratory and not in their doctor's office, they are put in an ethical situation where they must decide whether or not to have a test performed without the benefit of their doctor's immediate counsel. In other words, the ABN process not only shifts financial responsibility to the patient, but the medical responsibility too! In a sense, it seems that ABNs have developed in a bubble apart from the theoretical and practical developments in bioethics that have informed and supported movements such as 'patient-centered care', 'shared decision-making' and the participatory style of medicine that has replaced the paternalistic methods of the past.

Many commentators say the final revised ABN form now in use is better than past versions because it provides clearer options for patients [1]. However, the supposed clarified options available to patients merely address the financial risks of the healthcare encounter and categorically neglect concerns for patients' health. Moreover, all three of the options for patients on the ABN involve commitments to take responsibility for the costs of services not covered by Medicare. Understandably, having patients choose one of these options is beneficial for care providers, laboratories and Medicare because in all cases it lets them off the financial hook. Moreover, this set of options has the potential for discouraging Medicare claims submissions, which of course carries the possibility of large savings for the federal government.

In order to understand the ethical insufficiency of the ABN in current use, it must be recognized as a hybrid document (see Figure 1). The top half of the document is analogous to the consent form healthcare institutions require prior to most medical or surgical procedures. The service or diagnostic procedure is identified in Section D and an estimated cost is listed in Section F. The reason why Medicare may not pay for the service or procedure (noncovered item, does not meet medical necessity rules, etc.) is given in Section E. As illustrated in the table below, the 'what you need to do now' section of the document consists of action steps that are meant to lead patients to an opportunity to assert their autonomy and choose an option from those provided. However, the action steps are egregiously inadequate for helping patients arrive at an ethically sound choice. As discussed earlier, patients who have questions may not receive the information they seek at the time the ABN is provided.

For example, the first bullet item (see Box 1) in the section labeled "What you need to do now" is externally inconsistent. In other words, reading the notice cannot help a patient make an informed decision about their care because the notice does not provide the relevant information necessary for making care decisions. Specifically, the notice does not give the patient reasons why the scheduled service was recommended by their doctor. Questions of this nature cannot be appropriately answered by the laboratory personnel who are interacting with the patient, and queries from the patient may put this person in an uncomfortable or inappropriate position. Likewise, the notice does not provide information about alternative tests or services.

A. Notifier:

B. Patient Name: **C. Identification Number:**

Advance Beneficiary Notice of Noncoverage (ABN)

NOTE: If Medicare doesn't pay for **D.** _____ below, you may have to pay. Medicare does not pay for everything, even some care that you or your health care provider have good reason to think you need. We expect Medicare may not pay for the **D.** _____ below.

D.	E. Reason Medicare May Not Pay:	F. Estimated Cost

WHAT YOU NEED TO DO NOW:

- Read this notice, so you can make an informed decision about your care.
- Ask us any questions that you may have after you finish reading.
- Choose an option below about whether to receive the **D.** _____ listed above.

Note: If you choose Option 1 or 2, we may help you to use any other insurance that you might have, but Medicare cannot require us to do this.

G. OPTIONS: Check only one box. We cannot choose a box for you.

☐ **OPTION 1.** I want the **D.** _____ listed above. You may ask to be paid now, but I also want Medicare billed for an official decision on payment, which is sent to me on a Medicare Summary Notice (MSN). I understand that if Medicare doesn't pay, I am responsible for payment, but **I can appeal to Medicare** by following the directions on the MSN. If Medicare does pay, you will refund any payments I made to you, less co-pays or deductibles.

☐ **OPTION 2.** I want the **D.** _____ listed above, but do not bill Medicare. You may ask to be paid now as I am responsible for payment. **I cannot appeal if Medicare is not billed.**

☐ **OPTION 3.** I don't want the **D.** _____ listed above. I understand with this choice I am **not** responsible for payment, and **I cannot appeal to see if Medicare would pay.**

H. Additional Information:

This notice gives our opinion, not an official Medicare decision. If you have other questions on this notice or Medicare billing, call **1-800-MEDICARE** (1-800-633-4227/**TTY:** 1-877-486-2048). Signing below means that you have received and understand this notice. You also receive a copy.

I. Signature:	J. Date:

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0566. The time required to complete this information collection is estimated to average 7 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850.

Form CMS-R-131 (03/11) Form Approved OMB No. 0938-0566

Figure 1. CMS-R-131 Form.

Most importantly, the notice does not inform patients about the health-related benefits and risks of all options. So while the financial consequences of choosing one option over another are explained in Section G, the possible health consequences of not having the test or procedure are conspicuously absent. Therefore, it would be wholly impossible for any patient to make an informed decision about their care given the lack of care-related information.

The second bullet item (see Box 1) appears almost flippant given the serious, clinical environment in which the notice would be administered and how

Box 1. Patient instructions.

What do you need to do now?
- Read this notice, so you can make an informed decision about your care
- Ask us any questions that you may have after you finish reading
- Choose an option below about whether to receive the [test, service, or procedure] listed above

likely barriers to comprehension such as anxiety, sensory or cognitive impairment and uncertainty are to exist. Providing a list of open-ended questions or 'questions commonly asked' might be a more effective approach for facilitating patient engagement. A 'frequently asked questions' addendum would probably be well received, as it is a common feature on websites for healthcare businesses of all types, and is used by insurance and healthcare providers for other purposes.

The third bullet item instructs patients to make a choice from section G of the Notice (see Box 2). This portion of the document is considered a noteworthy improvement because it provides clearer options for patients and acknowledges a patient's right to appeal when coverage is denied [8]. Ultimately, these improvements mean little because they only address the financial aspects of the healthcare encounter and completely deny the real impact any particular option may have on patient outcomes. If the ABN document was genuinely developed for the purpose of respecting patients' preferences and patient autonomy, it would include education about the possible risks and benefits of choosing one option over another and provide a means by which the patient could exercise that option [10]. Additionally, an ethically sufficient ABN form should include a fourth option in section G (see Box 2) with language to the effect of, "Because Medicare will likely not cover the service my doctor has ordered, I want to postpone my choice about whether or not to have the test, procedure, etc. until my doctor and I have discussed the benefits and risks associated with my options and any alternatives that may be available to me."

The need for a fourth option (and perhaps more) along with other criticisms raised thus far depict several particular problem areas within the ABN, but raise further questions about the general ethical status of the ABN process and whether or not it reflects the ethical norms of medicine, health care and science. Indeed, it appears that the ABN does not accord well with basic bioethical principles such as beneficence, a principle that instructs care providers to positively assist patients and do only what is beneficial for them. In its present, concise form, the ABN has the potential to become a barrier to care and can in no way be interpreted as benefiting patients. In fact, it is not uncommon for patients to react to the ABN with confusion, suspicion and a refusal to sign the form [4]. Patients may decide, after returning home, that they do not wish to have the test if payment will not be made by Medicare, and wish to rescind their acceptance of the potential financial liability. This is impossible, and once a signed ABN is received by the provider, that document is considered binding and the patient may be billed for the test or service [9].

Evaluated in terms of the bioethical principle of nonmaleficence, which instructs care providers to do no harm, the ABN does not fare any better. 'Harm' can of course occur in many forms, and in health care harm often means physical harm. But harm as negligence can be just as impactful, even when it involves protocols involving support information in lieu of protocols involving physiological contact. Medicare's Advanced Beneficiary Notice is an example of harm as negligence because its design and use are grounded in mere procedural ethics that apply only generally to universal circumstances, and not the particular circumstances known to older adult patients or persons with intellectual or language challenges. As a document unable to accommodate a manifold of particular circumstances, the beneficiary notice exhibits an unfortunate probability for doing harm to patients by

Box 2. Patient options.

Options: check only one box. We cannot choose a box for you
- Option 1: I want the _____ listed above. You may ask to be paid now, but I also want Medicare billed for an official decision on payment, which is sent to me on a Medicare Summary Notice (MSN). I understand that if Medicare does not pay, I am responsible for payment, but I can appeal to Medicare by following the directions on the MSN. If Medicare does pay, you will refund any payments I made to you, less co-pays or deductibles.
- Option 2: I want the _____ listed above, but do not bill Medicare. You may ask to be paid now, as I am responsible for payment. I cannot appeal if Medicare is not billed.
- Option 3: I do not want the _____ listed above. I understand with this choice I am not responsible for payment, and I cannot appeal to see if Medicare would pay.

undermining opportunities for diagnostic assessment and subsequent treatments and cures.

Some might argue that the comments in Section H of the ABN (see Figure 1), which state, "This notice gives our opinion, not an official Medicare decision. If you have other questions on this notice or Medicare billing, call 1-800-MEDICARE (1-800-633-4227/TTY: 1-877-486-2048)" are sufficient for covering the plurality of circumstances presented by patients, but that would be a mistake. Undoubtedly, many older adults, especially those with mild-to-moderate cognitive impairment or visual impairment would find Section H disconcerting. Likewise, it is difficult to see how the ABN assists patients and doctors in building strong therapeutic alliances. In other words, it is easy to imagine patients becoming distrustful of doctors who order noncovered tests and services. It is also possible that patients may react in a negative or hostile manner to the healthcare provider who must provide the ABN and ask for a signature prior to services being rendered, especially if this person is unable to answer questions which the patient has about the services or the ABN. Referring patients to the contact information in Section H is not likely to resolve such problems.

Finally, it is conceivable that doctors could develop a distrust or suspicion of patients who react negatively to the ABN and refuse noncovered procedures. Therefore, in terms of ethics, Medicare's Advance Beneficiary Notice appears an anomaly in today's health services environment where mutual exchanges of information between care providers and patients, shared decision-making, patient autonomy and informed consent are taken seriously and guided by ethical principles.

Based on this brief and initial analysis of the ABN, it is recommended that further investigation, especially empirical research, be done at the clinical level to determine if and how Advanced Beneficiary Notices can ethically assist and support patients with Medicare insurance.

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