An Advanced Beneficiary Notice (ABN) is a written notice instructing the subject that Medicare will probably deny payment for that specific service or item; specifies the reason the provider expects Medicare to deny payment, and that the subject will be personally and fully responsible for payment if Medicare denies payment. The ABN provides the subject with the opportunity to refuse to receive the service or item.

For the purposes of clinical research trials, it must be determined if the study is a Medicare Qualifying Study and if a specific subject is a Medicare beneficiary. This flowchart is designed to assist in the determination if an ABN is required.

For further information, go to: CMS website link

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**Flowchart**

Is the subject a Medicare Beneficiary?

- **No**
  - Stop, an ABN is not required.

- **Yes**
  - Is this a Medicare Qualifying Trial?
    - **Yes**
      - Stop, an ABN is not required.
    - **No**
      - Are all research procedures paid by a grant?
        - **No**
          - An ABN may be required if the service is not a covered service, because the subject may be responsible for payment if Medicare denies payment.
        - **Yes**
          - Stop, an ABN is not required.