requirements. The changes to § 431.107(b)(4) do not require that States issue new provider agreements. States frequently use provider agreements that are general in nature but that bind the provider to adhere to the provider requirements stipulated in the State's regulations or manuals. It is not our intention to change, by this regulation, the mechanics by which States impose requirements upon their Medicaid providers.

States have flexibility to prescribe procedures for complying with additional Federal requirements relating to its provider agreement. A determination should be made by each State regarding whether revisions or new provider agreements are necessary, or whether the agreement is all-inclusive, that is, the provider agrees to comply with all additional Federal requirements, and no revisions are needed.

Enforcement Procedures

Comment: Some commenters requested further instructions on the statement in the preamble of the interim final rule that hospitals and hospices must inform HCFA in writing of the ''date they achieve compliance'' (57 FR 8195), while another believes this requirement is unnecessary. One commenter suggested that §§ 417.436(d) and 483.10 be amended to include an address and telephone number at which HCFA will receive non-compliance complaints.

Response: The process for hospitals and hospices to inform HCFA of the day they achieved compliance was set forth through instructions issued by HCFA in October, 1992. The reporting process is now complete. The purpose of this process was to provide us with evidence that hospitals and hospices were maintaining policies that would provide written information to adult individuals of their rights to accept or refuse medical or surgical treatment and to formulate an advance directive. These rights are subsequently referred to as the ''advance directive requirements''. This mechanism was designed so we would not need to conduct immediate on-site inspections of the nearly 8,000 hospitals and hospices to determine compliance with the advance directive requirements.

In addition, we note that to ensure that HHAs, SNFs and NFs are complying with the advance directives requirements, these entities will be assessed for compliance during the next routine on-site survey. The advance directive requirements are part of the resident rights requirements at § 483.10(b)(8) for SNFs and NFs and the patient rights condition of participation at § 484.10(c)(2)(ii) for HHAs.

Concerning where an individual can file a complaint for non-compliance, we have decided to follow the usual procedure and delegate the responsibility to receive complaints and initiate investigations to the State survey and certification agency under the authority of Regional Administrators. We have added new provisions at §§ 417.436(d)(3) and 489.102(a)(4) to require that providers and HMOs and CMPs must inform individuals that complaints concerning non-compliance with the advance directive requirements may be filed with the State survey and certification agency. This may be accomplished, for example, by posting a statement of an individual's rights under the advance directives requirements of the law and the name, address and telephone number of the State survey and certification agency to which the individual should file his or her complaint. In addition, we are amending § 483.10(b)(7)(iv) to require a facility to include in its written description of a resident's legal right a statement that the resident may file a complaint with the survey and certification agency concerning noncompliance with the advance directives requirements. Section 484.10(f) of the HHA patient rights condition of participation also has been amended to specify that the patient also has the right to use the home health hotline to lodge complaints concerning the implementation of the advance directive requirements. In addition, the Medicare Hotline (1–800–638–6833) is another avenue to register complaints.

Comment: One commenter asked how soon after a hospital adds a new unit or service would it have to report to HCFA regarding achieving compliance with the advance directive requirements.

Response: We are not requiring hospitals to notify HCFA concerning compliance with the advance directive requirements each time a new unit or service is added. However, any new unit or service that is added to a hospital would be expected to meet the advance directive requirements for all new admissions as soon as it began operation and would be monitored in accordance with the normal enforcement procedures, as outlined above.

Comment: One commenter suggested that we grant hospitals that are accredited by the Joint Committee on the Accreditation of Hospitals (JCAHO) deemed status for advance directive requirements now that the JCAHO has incorporated advance directives requirements into its standards. Another commenter questioned if HCFA will ask State departments of health to monitor compliance with the advance directive requirements within the context of the Medicare validation survey process.

Response: National organizations that have been granted recognition of their accrediting programs are required to provide reasonable assurance to HCFA that the providers that they accredit meet the Medicare conditions of participation. However, since the advance directives requirements are not part of the Medicare conditions of participation for hospitals, accredited hospitals are not deemed to meet this requirement based on an accreditation survey.

Instead, each hospital and hospice must comply with the advance directive requirements as part of its provider agreement with HCFA. As discussed above, each hospital (including any accredited by JCAHO or AOA) was required to inform HCFA, in writing, of the date that it achieved compliance with the advance directive requirements. As part of the compliance process, each hospital submitted an attestation statement signed and dated by its hospital administrator that informed HCFA of compliance. Compliance with the advance directive requirements is verified as part of the next routine on-site survey for hospices and non-accredited hospitals. For accredited hospitals, compliance is verified during any complaint investigation and at the time of validation surveys. This verification is a one-time event for both hospitals and hospices, unless a specific complaint is received about advance directives. All complaints about advance directives are investigated; failure to comply with the advance directives requirements is a cause for termination of a hospice's or hospital's provider agreement.

Comment: Two commenters suggested we extend the time period for the State agency to conduct an investigation to determine if a facility is in compliance with the advance directives provisions to the date when the provider agreement with HCFA is terminated. Currently, the time period for written notification of deficiencies is 15 days from the initial visit and the commenters are requesting that this be changed to 30 days. The commenters believe that 15 days is not sufficient time to permit adequate communication with all entities involved in many health care systems, particularly when providers are members of hospital chains, where information needs to be exchanged between corporate headquarters, attorneys, and the particular facility cited.