Dear Sir,

This email is to collect all my comments on the 7.28.2 proposal.

Having the original in hand, and comparing it to the proposal, a number of problems are apparent, which call proceeding to Hearing into question.

As changes to meet those requirements seem beyond the scope of the proposal, perhaps a new Public Hearing would be a better course.

1) 7.28.2.7.M is inconsistent with 7.28.2.33 and was apparently overlooked.

M. Definitions beginning with “M”: “Medically directed services” means in-home services that are provided in accordance with a patient/client’s plan or level of care which is reviewed and approved by a physician at least annually.

2) 7.28.2.33 has changes throughout the section, although, the description provided includes only A.(2) and (3). The list of providers is inconsistent within the section as "physician, physician assistant, nurse practitioner or clinical nurse specialist", "physician, or physician assistants, nurse practitioners and clinical nurse specialists", "physician, or physician assistant, nurse practitioner or clinical nurse specialist". Creativity is nice, but the meanings are different, so the language should be consistent.

3) 7.28.2.14.E is incorrect as presented. There should be a period after (D), with (E) treated separately.

4) 7.28.2.26 is rather garbled and needs to be rewritten. The changes made, mostly replacing periods with semi-colons, made things worse and factually incorrect. Eliminate the changes, or better yet, rewrite the garble.

5) 7.8.2.2 has garble at line 3, as "Tbe" means nothing.

I suggest that the proposed text needs to be examined carefully for punctuation, as I likely missed many errors.

Beyond the items listed above, the overall, and more serious, question is that the changes seem non-compliant with CMS regulations, as noted in my earlier email. The "solution" would appear to be supplying definitions compliant with the CFR, within this document, and that seems beyond the scope of the proposal.

Please contact me for any questions or clarifications.

Regards,
§ 410.75 Nurse practitioners' services.

(a) **Definition.** As used in this section, the term “physician” means a doctor of medicine or osteopathy, as set forth in section 1861(r)(1) of the Act.

(b) **Qualifications.** For Medicare Part B coverage of his or her services, a nurse practitioner must be a registered professional nurse who is authorized by the State in which the services are furnished to practice as a nurse practitioner in accordance with State law, and must meet one of the following:

(1) Obtained Medicare billing privileges as a nurse practitioner for the first time on or after January 1, 2003, and meets the following requirements:

   (i) Be certified as a nurse practitioner by a recognized national certifying body that has established standards for nurse practitioners.

   (ii) Possess a master's degree in nursing or a Doctor of Nursing Practice (DNP) doctoral degree.

(2) Obtained Medicare billing privileges as a nurse practitioner for the first time before January 1, 2003, and meets the standards in paragraph (b)(1)(i) of this section.

(3) Obtained Medicare billing privileges as a nurse practitioner for the first time before January 1, 2001.

(c) **Services.** Medicare Part B covers nurse practitioners' services in all settings in both rural and urban areas, only if the services would be covered if furnished by a physician and the nurse practitioner -

(1) Is legally authorized to perform them in the State in which they are performed;
(2) Is not performing services that are otherwise excluded from coverage because of one of the statutory exclusions; and

(3) Performs them while working in collaboration with a physician.

(i) Collaboration is a process in which a nurse practitioner works with one or more physicians to deliver health care services within the scope of the practitioner’s expertise, with medical direction and appropriate supervision as provided for in jointly developed guidelines or other mechanisms as provided by the law of the State in which the services are performed.

(ii) In the absence of State law governing collaboration, collaboration is a process in which a nurse practitioner has a relationship with one or more physicians to deliver health care services. Such collaboration is to be evidenced by nurse practitioners documenting the nurse practitioners' scope of practice and indicating the relationships that they have with physicians to deal with issues outside their scope of practice. Nurse practitioners must document this collaborative process with physicians.

(iii) The collaborating physician does not need to be present with the nurse practitioner when the services are furnished or to make an independent evaluation of each patient who is seen by the nurse practitioner.

(d) Services and supplies incident to a nurse practitioners' services.
Medicare Part B covers services and supplies incident to the services of a nurse practitioner if the requirements of § 410.26 are met.

(e) Professional services. Nurse practitioners can be paid for professional services only when the services have been personally performed by them and no facility or other provider charges, or is paid, any amount for the furnishing of the professional services.

(1) Supervision of other nonphysician staff by a nurse practitioner does not constitute personal performance of a professional service by a nurse practitioner.

(2) The services are provided on an assignment-related basis, and a nurse practitioner may not charge a beneficiary for a service not payable under this provision. If a beneficiary has made payment for a service, the nurse practitioner must make the appropriate refund to the beneficiary.

(f) Medical record documentation. For nurse practitioners' services, the nurse practitioner may review and verify (sign and date), rather than re-document, notes in a patient's medical record made by physicians; residents; nurses; medical, physician assistant, and advanced practice registered nurse
students; or other members of the medical team, including, as applicable, notes documenting the nurse practitioner's presence and participation in the service.

§ 484.2 Definitions.
As used in subparts A, B, and C, of this part -

Allowed practitioner means a physician assistant, nurse practitioner, or clinical nurse specialist as defined at this part.

Branch office means an approved location or site from which a home health agency provides services within a portion of the total geographic area served by the parent agency. The parent home health agency must provide supervision and administrative control of any branch office. It is unnecessary for the branch office to independently meet the conditions of participation as a home health agency.

Clinical note means a notation of a contact with a patient that is written, timed, and dated, and which describes signs and symptoms, treatment, drugs administered and the patient's reaction or response, and any changes in physical or emotional condition during a given period of time.

Clinical nurse specialist means an individual as defined at § 410.76(a) and (b) of this chapter, and who is working in collaboration with the physician as defined at § 410.76(c)(3) of this chapter.

In advance means that HHA staff must complete the task prior to performing any hands-on care or any patient education.

Nurse practitioner means an individual as defined at § 410.75(a) and (b) of this chapter, and who is working in collaboration with the physician as defined at § 410.75(c)(3) of this chapter.

Parent home health agency means the agency that provides direct support and administrative control of a branch.
Physician is a doctor of medicine, osteopathy, or podiatric medicine, and who is not precluded from performing this function under paragraph (d) of this section. (A doctor of podiatric medicine may perform only plan of treatment functions that are consistent with the functions he or she is authorized to perform under State law.)

Physician assistant means an individual as defined at § 410.74(a) and (c) of this chapter.

Primary home health agency means the HHA which accepts the initial referral of a patient, and which provides services directly to the patient or via another health care provider under arrangements (as applicable).

Proprietary agency means a private, for-profit agency.

Pseudo-patient means a person trained to participate in a role-play situation, or a computer-based mannequin device. A pseudo-patient must be capable of responding to and interacting with the home health aide trainee, and must demonstrate the general characteristics of the primary patient population served by the HHA in key areas such as age, frailty, functional status, and cognitive status.

Public agency means an agency operated by a state or local government.

Quality indicator means a specific, valid, and reliable measure of access, care outcomes, or satisfaction, or a measure of a process of care.

Representative means the patient's legal representative, such as a guardian, who makes health-care decisions on the patient's behalf, or a patient-selected representative who participates in making decisions related to the patient's care or well-being, including but not limited to, a family member or an advocate for the patient. The patient determines the role of the representative, to the extent possible.

Simulation means a training and assessment technique that mimics the reality of the homecare environment, including environmental distractions and constraints that evoke or replicate substantial aspects of the real world in a fully interactive fashion, in order to teach and assess proficiency in performing skills, and to promote decision making and critical thinking.

Subdivision means a component of a multi-function health agency, such as the home care department of a hospital or the nursing division of a health department, which independently meets the conditions of participation for HHAs. A subdivision that has branch offices is considered a parent agency.
Summary report means the compilation of the pertinent factors of a patient's clinical notes that is submitted to the patient's physician, physician assistant, nurse practitioner, or clinical nurse specialist.

Supervised practical training means training in a practicum laboratory or other setting in which the trainee demonstrates knowledge while providing covered services to an individual under the direct supervision of either a registered nurse or a licensed practical nurse who is under the supervision of a registered nurse.

Verbal order means a physician, physician assistant, nurse practitioner, or clinical nurse specialist order that is spoken to appropriate personnel and later put in writing for the purposes of documenting as well as establishing or revising the patient's plan of care.
