Medicare
State Operations Manual
Provider Certification

Department of Health and Human Services (DHHS)
HEALTH CARE FINANCING ADMINISTRATION (HCFA)

Transmittal 20 **Date: SEPTEMBER 7, 2000**

HEADER SECTION NUMBERS	PAGES TO INSERT	PAGES TO DELETE
Appendix PP	PP-43 - PP-47.2 (8 pp.)	PP-43 - PP-48 (6 pp.)
	PP-82.1 - PP-82.2 (2 pp.)	PP-82.1 - PP-82.2 (2 pp.)
	PP-103 - PP-104 (2 pp.)	PP-103 - PP-104 (2 pp.)

NEW/REVISED MATERIAL--*EFFECTIVE DATE: OCTOBER 10, 2000*

Appendix PP: Guidance to Surveyors - Long Term Care Facilities, is revised at F221, F222, F223, F280, and F323 to update information about restraint use in nursing homes. Most of the text is redlined because not only was information added and deleted, but the text was also reorganized to make the information more reader-friendly to surveyors. This text was sent out for comments three times, and all changes have been carefully considered.

DISCLAIMER: The revision date and transmittal number only apply to the redlined material. All other material was previously published in the manual and is only being reprinted.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F208 (Cont.)	(i) A nursing facility may charge a resident who is eligible for Medicaid for items and services the resident has requested and received, and that are not specified in the State plan as included in the term "nursing facility services" so long as the facility gives proper notice of the availability and cost of these services to residents and does not condition the resident's admission or continued stay on the request for and receipt of such additional services; and (ii) A nursing facility may solicit, accept, or receive a charitable, religious, or philanthropic contribution from an organization or from a person unrelated to a Medicaid eligible resident or potential resident, but only to the extent that the contribution is not a condition of admission, expedited admission, or continued stay in the facility for a Medicaid eligible resident. (4) States or political subdivisions may apply stricter admissions standards under State or local laws than are specified in this section, to prohibit discrimination against individuals entitled to Medicaid.	A nursing facility may charge a Medicaid beneficiary for a service the beneficiary has requested and received, only if: o That service is not defined in the State plan as a "nursing facility" service; o The facility informs the resident and the resident's representative in advance that this is not a covered service to allow them to make an informed choice regarding the fee; and o The resident's admission or continued stay is not conditioned on the resident's requesting and receiving that service. Procedures: §483.12(d)(3) Review State covered services. Compare with the list of items for which the facility charges to determine if the facility is charging for covered services. Determine if the facility requires deposits from residents. If you identify potential problems with discrimination, review the files of one or more residents selected for a focused or comprehensive review to determine if the facility requires residents to submit deposits as a precondition of admission besides what may be paid under the State plan. If interviews with residents suggest that the facility may have required deposits from Medicaid recipients at admission, except those admitted when Medicaid eligibility is pending, corroborate by, for example, reviewing the facility's admissions documents or interviewing family members.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F221* F222**	§483.13 Resident Behavior and Facility Practices a) Restraints. The resident has the right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident's medical symptoms. * Use tag #F221 for deficiencies concerning physical restraints. ** Use tag #F222 for deficiencies concerning chemical restraints	Intent: §483.13(a) The intent of this requirement is for each person to attain and maintain his/her highest practicable well-being in an environment that prohibits the use of restraints for discipline or convenience and limits restraint use to circumstances in which the resident has medical symptoms that warrant the use of restraints. Guidelines: §483.13(a) Definitions of Terms "Physical Restraints" are defined as any manual method or physical or mechanical device, material, or equipment attached or adjacent to the resident's body that the individual cannot remove easily which restricts freedom of movement or normal access to one's body. "Chemical Restraints" is defined as any drug that is used for discipline or convenience and not required to treat medical symptoms. "Discipline" is defined as any action taken by the facility for the purpose of punishing or penalizing residents. "Convenience" is defined as any action taken by the facility to control a resident's behavior or manage a resident's behavior with a lesser amount of effort by the facility and not in the resident's best interest. "Medical Symptom" is defined as an indication or characteristic of a physical or psychological condition. _____ Convenience is defined as any action taken by the facility to control a resident's behavior or manage a resident's behavior with a lesser amount of effort by the facility and not in the resident's best interest. Restraints may not be used for staff convenience. However, if the resident needs emergency care, restraints may be used for brief periods to permit medical treatment to proceed unless the facility has a notice indicating that the resident has previously made a valid refusal of the treatment in question. If a resident's unanticipated violent or aggressive behavior places him/her or others in imminent danger, the resident does not have the right to refuse the use of restraints. In this situation, the use of restraints is a measure of last resort to protect the safety of the resident or others and must not extend beyond the immediate episode. The resident's right to participate in care planning and the right to refuse treatment are addressed at §§483.20(k)(2)(ii) and 483.10(b)(4), respectively, and include the right to accept or refuse restraints.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F221 F222 (Cont.)		Physical Restraints are defined as any manual method or physical or mechanical device, material, or equipment attached or adjacent to the resident's body that the individual cannot remove easily which restricts freedom of movement or normal access to one's body. "Physical restraints" include, but are not limited to, leg restraints, arm restraints, hand mitts, soft ties or vests, lap cushions, and lap trays the resident cannot remove easily. Also included as restraints are facility practices that meet the definition of a restraint, such as: o Using side rails that keep a resident from voluntarily getting out of bed; o Tucking in or using velcro to hold a sheet, fabric, or clothing tightly so that a resident's movement is restricted; o Using devices in conjunction with a chair, such as trays, tables, bars or belts, that the resident can not remove easily, that prevent the resident from rising; o Placing a resident in a chair that prevents a resident from rising; and o Placing a chair or bed so close to a wall that the wall prevents the resident from rising out of the chair or voluntarily getting out of bed. Side rails sometimes restrain residents. The use of side rails as restraints is prohibited unless they are necessary to treat a resident's medical symptoms. Residents who attempt to exit a bed through, between, over or around side rails are at risk of injury or death. The potential for serious injury is more likely from a fall from a bed with raised side rails than from a fall from a bed where side rails are not used. They also potentially increase the likelihood that the resident will spend more time in bed and fall when attempting to transfer from the bed. As with other restraints, for residents who are restrained by side rails, it is expected that the process facilities employ to reduce the use of side rails as restraints is systematic and gradual to ensure the resident's safety while treating the resident's medical symptom. The same device may have the effect of restraining one individual but not another, depending on the individual resident's condition and circumstances. For example, partial rails may assist one resident to enter and exit the bed independently while acting as a restraint for another. Orthotic body devices may be used solely for therapeutic purposes to improve the overall functional capacity of the resident. Medical Symptom is defined as an indication or characteristic of a physical or psychological condition. The resident's medical symptoms should not be viewed in isolation, rather the symptoms should be viewed in the context of the resident's condition, circumstances and environment. Objective findings derived from clinical evaluation and the resident's subjective symptoms should be considered to determine the presence of the medical symptom. The resident's subjective symptoms may not be used as the sole basis for using a restraint. Before a resident is restrained, the facility must determine the presence of a speciic medical symptom that would require the use of restraints, and how the use of

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F221 F222 (Cont.)		restraints would treat the medical symptom, protect the resident's safety, and assist the resident in attaining or maintaining his or her highest practicable level of physical and psychosocial well-being. Medical symptoms that warrant the use of restraints must be documented in the resident's medical record, ongoing assessments, and care plans. While there must be a physician's order reflecting the presence of a medical symptom, HCFA will hold the facility ultimately accountable for the appropriateness of that determination. The physician's order alone is not sufficient to warrant the use of the restraint. It is further expected, for those residents whose care plans indicate the need for restraints, that the facility engage in a systematic and gradual process toward reducing restraints (e.g., gradually increasing the time for ambulation and muscle strengthening activities). This systematic process would also apply to recently admitted residents for whom restraints were used in the previous setting. Consideration of Treatment Plan In order for the resident to be fully informed, the facility must explain, in the context of the individual resident's condition and circumstances, the potential risks and benefits of all options under consideration including using a restraint, not using a restraint, and alternatives to restraint use. Whenever restraint use is considered, the facility must explain to the resident how the use of restraints would treat the resident's medical symptoms and assist the resident in attaining or maintaining his/her highest practicable level of physical or psychological well-being. In addition, the facility must also explain the potential negative outcomes of restraint use which include, but are not limited to, declines in the resident's physical functioning (e.g., ability to ambulate) and muscle condition, contractures, increased incidence of infections and development of pressure sores/ulcers, delirium, agitation, and incontinence. Moreover, restraint use may constitute an accident hazard. Restraints have been found in some cases to increase the incidence of falls or head trauma due to falls and other accidents (e.g., strangulation, entrapment). Finally, residents who are restrained may face a loss of autonomy, dignity and self respect, and may show symptoms of withdrawal, depression, or reduced social contact. In effect, restraint use can reduce independence, functional capacity, and quality of life. Alternatives to restraint use should be considered and discussed with the resident. Alternatives to restraint use might include modifying the resident's environment and/or routine. In the case of a resident who is incapable of making a decision, the legal surrogate or representative may exercise this right based on the same information that would have been provided to the resident. (See §483.10(a)(3) and (4).) However, the legal surrogate or representative cannot give permission to use restraints for the sake of discipline or staff convenience or when the restraint is

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F221 F222 (Cont.)		not necessary to treat the resident's medical symptoms. That is, the facility may not use restraints in violation of the regulation solely based on a legal surrogate or representative's request or approval. Assessment and Care Planning for Restraint Use There are instances where, after assessment and care planning, a least restrictive restraint may be deemed appropriate for an individual resident to attain or maintain his or her highest practicable physical and psychosocial well-being. This does not alter the facility's responsibility to assess and care plan restraint use on an ongoing basis. Before using a device for mobility or transfer, assessment should include a review of the resident's: o Bed mobility (e.g., would the use of a device assist the resident to turn from side to side? Is the resident totally immobile and unable to change position without assistance?); and o Ability to transfer between positions, to and from bed or chair, to stand and toilet (e.g., does the raised side rail add risk to the resident's ability to transfer?). The facility must design its interventions not only to minimize or eliminate the medical symptom, but also to identify and address any underlying problems causing the medical symptom. Interventions that the facility might incorporate in care planning include: o Providing restorative care to enhance abilities to stand, transfer, and walk safely; o Providing a device such as a trapeze to increase a resident's mobility in bed; o Placing the bed lower to the floor and surrounding the bed with a soft mat; o Equipping the resident with a device that monitors his/her attempts to arise; o Providing frequent monitoring by staff with periodic assisted toileting for residents who attempt to arise to use the bathroom; o Furnishing visual and verbal reminders to use the call bell for residents who are able to comprehend this information and are able to use the call bell device; and/or o Providing exercise and therapeutic interventions, based on individual assessment and care planning, that may assist the resident in achieving proper body position, balance and alignment, without the potential negative effects associated with restraint use. Procedures: §483.13(a) Determine if the facility follows a systematic process of evaluation and care planning prior to using restraints. Since continued restraint use is associated with a potential for a decline in functioning if the risk is not addressed, determine if the interdisciplinary team addressed the risk of decline at the time restraint use was initiated and that the care plan reflected measures to minimize a decline. Also determine if the plan of care was consistently implemented. Determine whether the decline can be attributed to a disease progression or inappropriate use of restraints.

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F221 F222 (Cont.)		For sampled residents observed as physically restrained during the survey or whose clinical records show the use of physical restraints within 30 days of the survey, determine whether the facility used the restraint for convenience or discipline, or a therapeutic intervention for specific periods to attain and maintain the resident's highest practicable physical, mental, or psychosocial well-being. Probes: §483.13(a) This systematic approach should answer these questions: 1. What are the medical symptoms that led to the consideration of the use of restraints? 2. Are these symptoms caused by failure to: a. Meet individual needs in accordance with the resident assessments including, but not limited to, section III of the MDS, Customary Daily Routines (MDS version 2.0 section AC), in the context of relevant information in sections I and II of the MDS (MDS version 2.0 sections AA and AB)? b. Use rehabilitative/restorative care? c. Provide meaningful activities? d. Manipulate the resident's environment, including seating? 3. Can the cause(s) of the medical symptoms be eliminated or reduced? 4. If the cause(s) cannot be eliminated or reduced, then has the facility attempted to use alternatives in order to avoid a decline in physical functioning associated with restraint use? (See Physical Restraints Resident Assessment Protocol (RAP), paragraph I). 5. If alternatives have been tried and deemed unsuccessful, does the facility use the least restrictive restraint for the least amount of time? Does the facility monitor and adjust care to reduce the potential for negative outcomes while continually trying to find and use less restrictive alternatives? 6. Did the resident or legal surrogate make an informed choice about the use of restraints? Were risks, benefits, and alternatives explained? 7. Does the facility use the Physical Restraints RAP to evaluate the appropriateness of restraint use? 8. Has the facility re-evaluated the need for the restraint, made efforts to eliminate its use and maintained residents' strength and mobility?

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F223	(b) Abuse. The resident has the right to be free from verbal, sexual, physical, and mental abuse, corporal punishment, and involuntary seclusion.	Intent: §483.13(b) Each resident has the right to be free from abuse, corporal punishment, and involuntary seclusion. Residents must not be subjected to abuse by anyone, including, but not limited to, facility staff, other residents, consultants or volunteers, staff of other agencies serving the resident, family members or legal guardians, friends, or other individuals. Guidelines: §483.13(b) and (c) "Abuse" means the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish." (42 CFR 488.301) This also includes the deprivation by an individual, including a caretaker, of goods or services that are necessary to attain or maintain physical, mental, and psychosocial well-being. This presumes that instances of abuse of all residents, even those in a coma, cause physical harm, or pain or mental anguish. "Verbal abuse" is defined as the use of oral, written or gestured language that willfully includes disparaging and derogatory terms to residents or their families, or within their hearing distance, regardless of their age, ability to comprehend, or disability. Examples of verbal abuse include, but are not limited to: threats of harm; saying things to frighten a resident, such as telling a resident that he/she will never be able to see his/her family again. "Sexual abuse" includes, but is not limited to, sexual harassment, sexual coercion, or sexual assault. "Physical abuse" includes hitting, slapping, pinching and kicking. It also includes controlling behavior through corporal punishment. "Mental abuse" includes, but is not limited to, humiliation, harassment, threats of punishment or deprivation.

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	(i) The services that are to be furnished to attain or maintain the resident's highest practicable physical, mental, and psychosocial well-being as required under §483.25; and (ii) Any services that would otherwise be required under §483.25 but are not provided due to the resident's exercise of rights under §483.10, including the right to refuse treatment under §483.10(b)(4).	The care plan must reflect intermediate steps for each outcome objective if identification of those steps will enhance the resident's ability to meet his/her objectives. Facility staff will use these objectives to monitor resident progress. Facilities may, for some residents, need to prioritize their care plan interventions. This should be noted in the clinical record or on the plan of care. The requirements reflect the facility's responsibilities to provide necessary care and services to attain or maintain the highest practicable physical, mental and psychosocial well-being, in accordance with the comprehensive assessment and plan of care. However, in some cases, a resident may wish to refuse certain services or treatments that professional staff believe may be indicated to assist the resident in reaching his or her highest practicable level of well-being. Desires of the resident should be documented in the clinical record (see guidelines at §483.10(b)(4) for additional guidance concerning refusal of treatment). §483.20(k)(1) Probes: o Does the care plan address the needs, strengths and preferences identified in the comprehensive resident assessment? o Is the care plan oriented toward preventing avoidable declines in functioning or functional levels? How does the care plan attempt to manage risk factors? Does the care plan build on resident strengths? o Does the care plan reflect standards of current professional practice? o Do treatment objectives have measurable outcomes? o Corroborate information regarding the resident's goals and wishes for treatment in the plan of care by interviewing residents, especially those identified as refusing treatment. o Determine whether the facility has provided adequate information to the resident so that the resident was able to make an informed choice regarding treatment. o If the resident has refused treatment, does the care plan reflect the facility's efforts to find alternative means to address the problem? For implementation of care plan, see §483.20(k)(3).

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F280	(2) A comprehensive care plan must be-- (i) Developed within 7 days after the completion of the comprehensive assessment; (ii) Prepared by an interdisciplinary team, that includes the attending physician, a registered nurse with responsibility for the resident, and other appropriate staff in disciplines as determined by the resident's needs, and, to the extent practicable, the participation of the resident, the resident's family or the resident's legal representative; and (iii) Periodically reviewed and revised by a team of qualified persons after each assessment.	§483.20(k)(2) Guidelines: As used in this requirement, "Interdisciplinary" means that professional disciplines, as appropriate, will work together to provide the greatest benefit to the resident. It does not mean that every goal must have an interdisciplinary approach. The mechanics of how the interdisciplinary team meets its responsibilities in developing an interdisciplinary care plan (e.g., a face-to-face meeting, tele-conference, written communication) is at the discretion of the facility. The physician must participate as part of the interdisciplinary team, and may arrange with the facility for alternative methods, other than attendance at care planning conferences, of providing his/her input, such as one-on-one discussions and conference calls. The resident's right to participate in choosing treatment options, decisions in care planning and the right to refuse treatment are addressed at §483.20(k)(2)(ii) and 483.10(b)(4), respectively, and include the right to accept or refuse treatment. The facility has a responsibility to assist residents to participate, e.g., helping residents, and families, legal surrogates or representatives understand the assessment and care planning process; when feasible, holding care planning meetings at the time of day when a resident is functioning best; planning enough time for information exchange and decision making; encouraging a resident's advocate to attend (e.g. family member, friend) if desired by a resident. The resident has the right to refuse specific treatments and to select among treatment options before the care plan is instituted. (See §483.20(k)(2)(ii) and 483.10(b)(4).) The facility should encourage residents, legal surrogates and representatives to participate in care planning, including attending care planning conferences if they so desire. While Federal regulations affirm the resident's right to participate in care planning and to refuse treatment, the regulations do not create the right for a resident, legal surrogate or representative to demand that the facility use specific medical intervention or treatment that the facility deems inappropriate. Statutory requirements hold the facility ultimately accountable for the resident's care and safety, including clinical decisions. §483.20(k)(2) Probes: 1. Was interdisciplinary expertise utilized to develop a plan to improve the resident's functional abilities? a. For example, did an occupational therapist design needed adaptive equipment or a speech therapist provide techniques to improve swallowing ability? b. Do the dietitian and speech therapist determine, for example, the optimum textures and consistency for the resident's food that provide both a nutritionally adequate diet and effectively use oropharyngeal capabilities of the resident? c. Is there evidence of physician involvement in development of the care plan (e.g., presence at care plan meetings, conversations with team members concerning the care plan, conference calls)? 2. In what ways do staff involve residents and families, surrogates, and/or representatives in care planning?

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F321 (Cont.)	naso-gastric tube was unavoidable; and	Complications in tube feeding are not necessarily the result of improper care, but assessment for the potential for complications and care and treatment are provided to prevent complications in tube feeding by the facility.
F322	(2) A resident who is fed by a naso-gastric or gastrostomy tube receives the appropriate treatment and services to prevent aspiration pneumonia, diarrhea, vomiting, dehydration, metabolic abnormalities, and nasal-pharyngeal ulcers and to restore, if possible, normal eating skills.	Clinical conditions demonstrating that nourishment via an naso-gastric tube is unavoidable include: o The inability to swallow without choking or aspiration, i.e., in cases of Parkinson's disease, pseudobulbar palsy, or esophageal diverticulum; o Lack of sufficient alertness for oral nutrition (e.g., resident comatose); and o Malnutrition not attributable to a single cause or causes that can be isolated and reversed. There is documented evidence that the facility has not been able to maintain or improve the resident's nutritional status through oral intake. <u>Probes: §483.25(g)</u> For sampled residents who, upon admission to the facility, were not tube fed and now have a feeding tube, was tube feeding unavoidable? To determine if the tube feeding was unavoidable, assess the following: o Did the facility identify the resident at risk for malnutrition? o What did the facility do to maintain oral feeding, prior to inserting a feeding tube? Did staff provide enough assistance in eating? Did staff cue resident as needed, assist with the use of assistive devices, or feed the resident, if necessary? o Is the resident receiving therapy to improve or enhance swallowing skills, as need, is identified in the comprehensive assessment? o Was an assessment done to determine the cause of decreased oral intake/weight loss or malnutrition? o If there was a dietitian consultation, were recommendations followed? For all sampled residents who are tube fed: o Is the NG tube properly placed? o Are staff responsibilities for providing enteral feedings clearly assigned (i.e., who administers the feeding, formula, amount, feeding intervals, flow rate)? o Do staff monitor feeding complications (e.g., diarrhea, gastric distension, aspiration) and administer corrective actions to allay complications (e.g., changing rate of formula administration)? o Are there negative consequences of tube use (e.g., agitation, depression, self-extubation, infections, aspiration and restraint use without a medical reason for the restraint)? o When long term use is anticipated, is G tube placement considered? Is the potential for complications from feedings minimized by: o Use of a small bore, flexible naso-gastric tube, unless contraindicated; o Securely attached the tube to the nose/face;

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F322 (Cont.)		o Checking for correct tube placement prior to beginning a feeding or administering medications and after episodes of vomiting or suctioning; o Checking a resident with a newly inserted gastric tube for gastric residual volume every 2-4 hours until the resident has demonstrated an ability to empty his/her stomach; o Properly elevating the resident's head; o Providing the type, rate and volume of the feeding as ordered; o Using universal precautions and clean technique and as per facility/manufacturer's directions when stopping, starting, flushing, and giving medications through the tube; o Using hang time recommendations by the manufacturer to prevent excessive microbial growth; o Implement the procedures to ensure cleanliness of supplies, e.g. irrigating syringes changed on a regular bases as per facility policy. It is not necessary to change the irrigating syringe each time it is used; o Using a pump equipped with a functional alarm (if pump used); o The facility's criteria for determining that a resident may be able to return to eating by mouth (e.g., a resident whose Parkinson's symptoms have been controlled); o There are sampled residents meet these criteria; o If so, the facility has assisted them in returning to normal eating; and o Identify if resident triggers RAPs for feeding tubes, nutritional status, and dehydration/fluid maintenance. Consider whether the RAPs were used to assess causal factors for decline, potential for decline and lack of improvement.
F323	(h) Accidents The facility must ensure that – (1) The resident environment remains as free of accident hazards as is possibled; and	Intent: §483.25(h)(1) The intent of this provision is that the facility prevents accidents by providing an environment that is free from hazards over which the facility has control. Guidelines: §483.25(h)(1) This corresponds to MDS, section K2, MDS version 2.0 section J, when specified for use by the State. "Accident hazards" are defined as physical features in the NF environment that can endanger a resident's safety, including but not limited to: o Physical restraints (see physical restraints §483.13); o Equipment or devices that are defective, poorly maintained, or not used in accordance with manufacturer's specifications (e.g., wheelchairs or geri-chairs with nonworking brakes, and loose nuts and bolts on walkers); o Bathing facilities that do not have nonslip surfaces; o Hazards (e.g., electrical appliances with frayed wires, cleaning supplies easily accessible to cognitively impaired residents, wet floors that are not obviously labeled and to which access is not blocked); o Defective or improperly latched side rails or spaces within side rails, between upper and lower rails, between rails and the mattress, between side rails and the bed frame, or spaces between side rails and the head or foot board of the bed that can entrap limbs, neck or thorax, and can cause injury or death;