Medicare
State Operations Manual
Provider Certification

Department of Health and Human Services (DHHS)

HEALTH CARE FINANCING ADMINISTRATION (HCFA)

Transmittal 15 **Date: APRIL 2000**

HEADER SECTION NUMBERS	PAGES TO INSERT	PAGES TO DELETE
List of Exhibits	9-v - 9vi (2 pp.)	9-v - 9vi (2 pp.)
	9-xiii - 9-xiv (2 pp.)	9-xiii - 9-xiv (2 pp.)
Exhibit 85 (Cont.) - Exhibit 87	9-191 **AND** 9-198 (2 pp.)	9-191 - 9-198 (8 pp.)
Exhibit 90	--- ---	9-203 - 9-206 (4 pp.)
Exhibit 266	9-753 - 9-754.1 (3 pp.)	9-753 - 9-754 (2 pp.)
Appendix P	P-17 - P-18 (2 pp.)	P-17 - P-18 (2 pp.)
Appendix PP	PP-121 - PP-123.1 (4 pp.)	PP-121 - PP-123.1 (4 pp.)
	PP-123.4 - PP-123.5 (2 pp.)	PP-123.4 - PP-123.5 (2 pp.)
	PP-163.8 - PP-164 (2 pp.)	PP-163.8 - PP-164 (2 pp.)

NEW/REVISED MATERIAL--EFFECTIVE DATE: April 21, 2000

List of Exhibits is revised to delete Exhibit 86 (Resident Census and Conditions of Residents, HCFA-672 (7/95) and Exhibit 90 (Roster/Sample Matrix, HCFA-802).

Exhibit 86, Resident Census and Conditions of Residents, Form HCFA-672 (7/95), is **DELETED** and was previously replaced with the revised Form HCFA-672 (10/98) Transmittal #8.

Exhibit 90, Roster/Sample Matrix, HCFA-802, is **DELETED** and was replaced by Exhibits 265; Form HCFA-802 (7/99) the Roster/Sample Matrix, Exhibit 266; Form HCFA-802P (7/99) the Roster/Sample Matrix Provider Instructions, and Exhibit 267; Form HCFA-802S (7/99) the Roster/Sample Matrix Instructions for Surveyors.

Exhibit 266, Roster/Sample Matrix Provider Instructions (7/99), is revised to add a crosswalk to the Minimum Data Set.

Appendix P: Survey Procedures for Long Term Care Facilities, is revised to delete an incorrect sentence in the Objectives of Task 4, Sample Selection.

Appendix PP: Guidance to Surveyors - Long Term Care Facilities, is revised at F329 to delete antipsychotic drugs no longer used, to remove confusing guidance about behavior charts, revises the antidepressant drug list to reflect antidepressants currently in use, to correct typographical errors in quoted text, and to restore interpretive guidance at F430 that was inadvertently deleted.

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.

LIST OF EXHIBITS (Cont.)

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N O T E

THE FOLOWING EXHIBITS ARE IN PRINTED COPY ONLY:

EXHIBIT 85 (CONT.) (PAGE 9-191)

EXHIBIT 87 (PAGE 9-198)

AND EXHIBIT 266 (PAGES 9-753 - 9-754.1)

8. Pressure sores, old scars from pressure sores or evidence of surgical repair of pressure sores;

9. Amputation;

10. Significant weight loss;

11. Feeding tubes and/or improper positioning while feeding is infusing; and

12. Ventilators, oxygen, or intravenous therapies.

o Impact of the facility environment and safety issues.--

1. Infection control practices (such as handwashing, glove use, and isolation procedures);

2. Functional and clean equipment, including kitchen equipment;

3. Presentation and maintenance of a homelike and clean environment; and

4. Availability, use and maintenance of assistive devices.

NOTE: If the initial tour is being conducted during a mealtime, include an initial brief observation of the dining areas. Note if there are any concerns with meal service, quality of life, positioning, sufficient space, etc.

TASK 4 - SAMPLE SELECTION

A. General Objective.--The objective of this task is to select a case-mix stratified sample (see Special Factors to Consider in Sample Selection below for further information) of facility residents based on QIs and other offsite and onsite sources of information in order to assess compliance with the resident-centered long term care requirements.

B. General Procedures.--

o The Phase 1 sample is preselected during Task 1, Offsite Survey Preparation, based on QIs and other areas of concern. The preselected sample is reviewed during the sample selection meeting and residents are retained for the sample unless they are discharged, or the survey team has another reason to substitute (e.g., to select interviewable residents). Each team member is assigned to review a certain number of residents, completing all facets of review that have been selected including any quality of life assessment protocols selected for these residents.

o The Phase 2 sample is selected onsite, part way through the survey when surveyors have collected enough information to determine the focus of the remainder of the survey. The Phase 2 sample residents are selected to represent new concerns and/or to continue further investigation of Phase 1 concerns when Phase 1 reviews proved inconclusive or when necessary to determine scope of a problem. It is statutorily required that the sample in each facility be case-mix stratified in order to capture both interviewable and non-interviewable residents, and residents from both heavy and light care categories.

NOTE: If the team is conducting sample selection during a meal time, delay or interrupt this task to conduct brief observations of the dining areas. Note if there are any concerns with meal service, quality of life, positioning, sufficient space, etc.

C. Definitions.--

o Interviewable Resident.--This is a resident who has sufficient memory and comprehension to be able to answer coherently the majority of questions contained in the Resident Interview. These residents can make day-to-day decisions in a fairly consistent and organized manner.

o Comprehensive Review.--For Task 5C, Resident Review, this includes observations, interviews, and record reviews for all care areas for the sampled residents as applicable.

o Focused Review.--For Task 5C, Resident Review, this includes the following:

- For Phase 1: Observations, interviews and record reviews concerning all highlighted areas of concern and all unhighlighted areas pertinent to the resident;

- For Phase 2: Observations, interviews and record review for all highlighted areas of concern pertinent to the resident.

o Closed Record Review.--For Task 5C, Resident Review, this includes a record review of residents' care issues and transfer and discharge.

o Roster/Sample Matrix.--This worksheet, (Exhibit 265, Form HCFA-802), is used by the survey team during Offsite Survey Preparation, and at the Phase 1 and Phase 2 Sample Selection meetings to note areas of concern for the survey, and to select residents for the sample. There are separate sets of instructions for the use of this form by the survey team and the facility. (See these instructions at Exhibits 266 and 267.

D. Protocol.--

1. Phase 1 - Sample Selection.--The Phase 1 sample is preselected during Task 1, Offsite Survey Preparation, based on the facility's QIs of concern. (See Task 1 for further information.) Final phase 1 sample selection occurs after the tour is completed and the facility has provided the completed Roster/Sample Matrix (Form HCFA-802, Exhibit 265), or to provide this information in some other format (e.g., computer-generated list). However, do not delay Phase 1 sample selection if the facility's Roster/Sample Matrix has not arrived. The team will complete the sample selection for Phase 1 by performing the following tasks:

NOTE: For facilities with a population of "short-stay" residents, the team may not have been able to preselect concerns or potential sampled residents. In that instance Phase 1 sample selection will occur during this task.

o First determine if any preselected concerns should be dropped due to the QI data not representing the conditions of current residents. For example, there was a preselected QI concern with residents with tube feedings, but the tour has verified there are no residents in the facility who are receiving tube feedings. Note new concerns and determine if some preselected residents can be evaluated for the new concerns, as well as those originally selected.

o Review the Roster/Sample Matrix provided by the facility and compare it to the findings from the tour to determine if there is a reason to substitute another resident for any of the residents from the Offsite sample. A preselected resident who is no longer in the facility can be considered for the closed record review. The team may substitute other residents for those preselected, if necessary. They can select either from the QI reports, the tour, or the facility's Roster/Sample Matrix.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F329 (Cont.)		ANTIPSYCHOTIC DRUGS

GENERIC	BRAND	DAILY ANTIPSYCHOTIC ORAL DOSAGE FOR RESIDENTS WITH ORGANIC MENTAL SYNDROMES MG/DAY
Chlorpromazine	(Thorazine)	75
Promazine	(Sparine)	150
Trifluprom azine	(Vesprin)	20
Thioridazine	(Mellaril)	75
Mesoridazine	(Serentil)	25
Acetophenazine	(Tindal)	20
Perphenazine	(Trilafon)	8
Fluphenazine	(Prolixin, Permitil)	4
Trifluoperazine	(Stelazine)	8
Chlorprothixene	(Taractan)	75
Thiothixene	(Navane)	7
Haloperidol	(Haldol)	4
Molindone	(Moban)	10
Loxapine	(Loxitane)	10
Clozapine	(Clozaril)	50
Prochlorperazine	(Compazine)	10
Risperidone	(Risperdal)	2
Olanzapine	(Zyprexa)	10
Quetiapine	(Seroquel)	200

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F329 Cont.		1. The doses listed are daily doses (usually administered in divided doses) for residents with organic mental syndromes (now called "Delirium, Dementia, and Amnestic and other cognitive disorders by DSM-IV). The facility is encouraged to initiate therapy with lower doses and when necessary only gradually increase doses. The facility may exceed these doses if it provides evidence (see Survey Procedures and Probes) to show why it is necessary for the maintenance or improvement in the resident's functional status. 2. The "specific conditions" for use of antipsychotic drugs are listed under the Guideline for §§483.25(l)(1) and (2). 3. The dose of prochlorperazine may be exceeded for short term (seven day) treatment of nausea and vomiting. Residents with nausea and vomiting secondary to cancer or cancer chemotherapy can also be treated with higher doses for longer periods of time. 4. When antipsychotic drugs are used outside these Guidelines without valid reasons for the higher dose, they may be deemed unnecessary drugs as a result of excessive dose. F. Monitoring for Antipsychotic Drug Side Effects The facility assures that residents who are undergoing antipsychotic drug therapy receive adequate monitoring for significant side effects of such therapy with emphasis on the following: o Tardive dyskinesia; o Postural (orthostatic) hypotension; o Cognitive/behavior impairment; o Akathisia; and o Parkinsonism. NOTES: For a more detailed description of these side effects, see the RAP: Psychotropic Drug Use, pg. F-72, Resident Assessment Instrument Training Manual and Resource Guide, 1990 edition.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F329 Cont.		When antipsychotic drugs are used without monitoring for these side effects, they may be unnecessary drugs because of inadequate monitoring. G. Antidepressant Drugs The under diagnosis and under treatment of depression in nursing homes has been documented in a Journal of the American Medical Association paper entitled "Depression and Mortality in the Nursing Home" (JAMA, February 27, l991-vol. 265, No. 8). HCFA continues to support the accurate identification and treatment of depression in nursing homes. The following is a list of commonly used antidepressant drugs: Antidepressant Drugs Generic Name — Brand Name Amitriptyline* (Elavil) Amoxapine (Asendin) Desipramine (Norpramin, Pertofrane) Doxepin* (Sinequan) Imipramine* (Tofranil) Maprotiline (Ludiomil) Nortriptyline (Aventyl, Pamelor) Protriptyline (Vivactil) Trimipramine* (Surmontil) Fluoxetine (Prozac) Sertraline (Zoloft)

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F329 Cont.		Antidepressant Drugs (Cont.) Generic Name — Brand Name Trazodone (Desyrel) Clomipramine* (Anafranil) Paroxetine (Paxil) Bupropion (Wellbutrin) Isocarboxazid* (Marplan) Phenelzine* (Nardil) Tranylcypromine* (Parnate) Venlafaxine (Effexor) Nefazodone (Serzone) Fluvoxamine (Luvox) * These are not necessarily drugs of choice for depression in the elderly. They are listed here only in the event of their potential use. Procedures: §483.25(l)(1) Consider drug therapy "unnecessary" only after determining that the facility's use of the drug is: o In excessive dose (including duplicate drug therapy); o For excessive duration; o Without adequate monitoring; o Without adequate indications of use; o In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or o Any combination of the reasons above. Allow the facility the opportunity to provide a rationale for the use of drugs prescribed outside the preceding Guidelines. The facility may not justify the use of a drug prescribed outside the proceeding Guidelines solely on the basis of "the doctor ordered it." This justification would render the regulation meaningless. The rationale must be based on sound risk-benefit analysis of the resident's symptoms and potential adverse effects of the drug.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F329 (Cont.)		LIST OF DRUGS WITH HIGH POTENTIAL FOR SEVERE ADVERSE OUTCOMES 1. Pentazocine (Talwin) Risk: **"Pentazocine is a narcotic analgesic that causes more central nervous system side effects, including confusion and hallucinations, more commonly than other narcotic drugs."** Dizziness, lightheadedness, euphoria, and sedation are also common side effects of pentazocine. 2. Long-Acting Benzodiazepines NOTE: Surveyor guidance for unnecessary drugs (483.25(l)(1) (F329) already has guidelines for Long Acting Benzodiazepine Drugs. The Surveyor should use that guideline. This guideline is repeated here to give emphasis to potential side effects of these drugs. Risk: **"These benzodiazepine drugs have an extremely long half-life in the elderly (often days), producing prolonged sedation and increased incidence of falls and fractures."** Other common side effects of benzodiazepine drugs include drowsiness, ataxia, fatigue, confusion, weakness, dizziness, vertigo, syncope, and psychological changes. 3. Amitriptyline (Elavil) Also include combination products such as: Amitriptyline and chlordiazepoxide (Limbitrol) Amitriptyline and Perphenazine (Triavil). Risk: **"Because of its strong anticholinergic and sedating properties, amitriptyline is rarely the antidepressant of choice in the elderly."** Anticholinergic side effects are indicated by symptoms such as dry mouth, blurred vision, urinary retention, constipation, confusion, and sometimes, delirium or hallucinations. Amitriptyline can also cause cardiac arrhythmias and orthostatic hypotension. Exception: Surveyor review is not required if: o The resident is being treated for neurogenic pain (that is trigeminal neuralgia, peripheral neuropathy); o There is evidence in the record that the resident has experienced this type of pain; and o That a risk/benefit has been considered, including alternative pain therapies that may have fewer side effects in the individual.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F329 (Cont.)		4. Doxepin (Sinequan) Risk: **"Because of its strong anticholinergic and sedating properties, doxepin is rarely the antidepressant of choice in the elderly."** Anticholinergic side effects are indicated by symptoms such as dry mouth, blurred vision, urinary retention, constipation, confusion, and sometimes delirium or hallucinations. Doxepin may also cause cardiac arrhythmias. 5. Meprobamate (Miltown), (Equanil) NOTE: Surveyor guidance for unnecessary drugs (483.25(l)(1) (F329)) already has guidelines for this drug under "D. Miscellaneous Hypnotic/Sedative/Anxiolytic Drugs." This guideline is provided here to further emphasize the risk of using this drug. Risk: **"Meprobamate is a highly addictive and sedating anxiolytic (i.e., antianxiety drug). Avoid in elderly patients. Those using memprobamate for prolonged periods may be addicted and may need to be withdrawn slowly."** The most frequent side effects of meprobamate are drowsiness and ataxia. 6. Disopyramide (Norpace), (Norpace CR) Risk: **"Disopyramide, of all antiarrhythmic drugs, is the most potent negative inotrope (decreased force of heart contraction) and therefore may induce heart failure in the elderly. It is also strongly anticholinergic."** Anticholinergic side effects are indicated by symptoms such as dry mouth, blurred vision, urinary retention, constipation, confusion, and sometimes delirium or hallucinations. In addition to the anticholinergic side effects, disopyramide has the following cardiovascular side effects: edema, weight gain, chest pain, dyspnea, syncope and hypotension. 7. Digoxin (Lanoxin) Risk: **Because of decreased renal clearance of digoxin, doses in the elderly should rarely exceed 0.125 mg daily, except when treating atrial arrhythmias.** (NOTE: the panelists' review of the literature has revealed countless studies showing that low dose digoxin is effective, but higher dose digoxin adds risks without improving outcomes.) Side effects may include anorexia, nausea and vomiting are the common early signs of digoxin toxicity. Nervous system symptoms include headache, fatigue, malaise, drowsiness, depression, and generalized muscle weakness. Visual disturbances also occur, including blurred vision, yellow or green vision, diplopia, photophobia, and flashing lights.

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F429 (Cont.)		**Narcotic Drugs** such as Codeine (Empirin with Codeine, Tylenol with Codeine), Meperidine (Demerol), Fentanyl (Duragesic), Hydromorphone (Dilaudid), Morphine (many brands), Oxycodone (Percocet, Roxicodone, etc.), Propoxyphen (Darvon, Darvon Comp-65, Darvon-N, Darvocet-N, etc.). Exception: Review by the surveyor is not necessary if these drugs are used periodically (once every three months) for a short duration (not over seven days) for symptoms of an acute, self-limiting illness. 6. Insomnia Drugs: o Decongestants such as Phenylephrine (Duo-Medihaler), Phenylpropanolamine (Genex), Pseudoephedrine (Novafed, Sudafed, Triaminic AM, Efidac/24); o Theophylline (Elixophyllin Bronkodyl, Theo-Dur, Slo-Bid); o Desipramine (Pertofrane, Norpramin); o Selective Serotonin Reuptake Inhibitors such as Fluoxetine (Prozac), Paroxetine (Paxil), Sertraline (Zoloft); o Methylphenidate (Ritalin); o Monamine Oxidase Inhibitors (MAOIs) such as Phenelzine (Nardil), Tranylcypromine (Parnate); and o Beta Agonists such as Isoproterenol (Isuprel), Albuterol (Proventil), Bitolterol (Tornalate), Terbutaline (Brethine). Risk: **"May cause or worsen insomnia."** (The surveyor should consider that insomnia is often a symptom of untreated depression and Chronic Obstructive Pulmonary Disease (COPD.))

TAG NUMBER	REGULATION	GUIDANCE TO SURVEYORS
F430	these reports must be acted upon.	Guidelines: §483.60(c)(2) The director of nursing and the attending physicians are not required to agree with the pharmacist's report, nor are they required to provide a rationale for their "acceptance" or "rejection" of the report. They must, however, act upon the report. This may be accomplished by indicating acceptance or rejection of the report and signing their names. The facility is encouraged to provide the medical director with a copy of drug regimen review reports and to involve the medical director in reports that have not been acted upon.
F431	(d) Labeling of drugs and biologicals. Drugs and biologicals used in the facility must be labeled in accordance with currently accepted professional principles, and include the appropriate accessory and cautionary instructions, and the expiration date when applicable.	Guidelines: §483.60(d) This section imposes currently accepted labeling requirements on facilities, even though the pharmacies will be immediately responsible for accomplishing the task. The critical elements of the drug label in a long-term care facility are the name of the drug and its strength. The names of the resident and the physician do not have to be on the label of the package, but they must be identified with the package in such a manner as to assure that the drug is administered to the right patient. All drugs approved by the Food and Drug Administration must have expiration dates on the manufacturer's container. "When applicable" means that expiration dates must be on the labels of drugs used in long term care facilities unless State law stipulates otherwise.
F432	(e) Storage of drugs and biologicals. (1) In accordance with State and Federal laws, the facility must store all drugs and biologicals in locked compartments under proper temperature controls, and permit only authorized personnel to have access to the keys.	Guidelines: §483.60(e) Compartments in the context of these regulations include but are not limited to drawers, cabinets, rooms, refrigerators, carts, and boxes. The provisions for authorized personnel to have access to keys must be determined by the facility management in accordance with Federal, State, and local laws and facility practices. "Separately locked" means that the key to the separately locked Schedule II drugs is not the same key that is used to gain access to the non-Schedule II drugs. Probes: §483.60(e) Are all drugs and biologicals stored properly, locked and at proper temperature?