even greater (75%). In the absence of an effective vaccine, behavioral interventions represent one of the few methods for reducing high HIV incidence among African American MSM (AAMSM). Unfortunately, in the third decade of the epidemic, very few of the available HIV-prevention interventions for African American populations have been designed specifically for MSM. In fact, until very recently none of CDC's evidence-based, HIV-prevention interventions had been specifically tested for efficacy in reducing HIV transmission among MSM of color. Given the conspicuous absence of (1) Evidence-based HIV interventions and (2) outcome evaluations of existing AAMSM interventions, our collaborative team intends to address a glaring research gap by implementing a best-practices model of comprehensive program evaluation.

The purpose of this project is to test, in a real world setting, the efficacy of an HIV transmission prevention intervention for reducing sexual risk among African American men who have sex with men in LAC. The project is a 3-session, group-level intervention that will provide participants with the information, motivation, and skills necessary to reduce their risk of transmitting or acquiring HIV. The intervention will be evaluated using baseline, 3 month and 6 month follow-up assessments. This project will also conduct in-depth qualitative interviews with 36 men in order to assess their experiences with the intervention, elicit recommendations for improving the intervention, and to better understand the factors that put African American MSM at risk for HIV.

CDC is requesting a 3-year clearance for data collection. The data collection system involves screenings, limited locator information, contact information, a baseline questionnaire, client satisfaction surveys, a 3-month follow-up questionnaire, a 6-month follow-up questionnaire, and case study interviews. An estimated 700 men will be screened for eligibility in order to enroll 528 men. The baseline and follow up questionnaires contain questions about participants' socio-demographic information, health and healthcare, sexual activity, substance use, and other psychosocial issues. The duration of each baseline, 3-month, and 6-month questionnaires are estimated to be 60 minutes; the 36 Success Case Study interviews 90 minutes; Outreach Recruitment Assessment 5 minutes; limited locator information form 5 minutes; participant contact information form 10 minutes; each client satisfaction survey 5 minutes. There is no cost to participants other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number responses per espondent	Average burden per respondent (in hours)	Total annual urden in hours
AAMSM	Outreach Recruitment Assessment (screener).	700	1	5/60	58
AAMSM	Limited Locator Information	700	1	5/60	58
Enrolled AAMSM	Participant Contact Information Form.	528	1	10/60	88
Enrolled AAMSM	Baseline Questionnaire	528	1	1	528
Enrolled AAMSM	Client Satisfaction Survey	224	3	5/60	56
Enrolled AAMSM	3 month follow up Questionnaire	420	1	1	420
Enrolled AAMSM	6 month follow up Questionnaire	400	1	1	400
Enrolled AAMSM	Success Case Study Interview	36	1	1.5	54
Total					1662

Dated: July 27, 2011.

Daniel Holcomb,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2011–19614 Filed 8–2–11; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3143–NC]

Medicare Program; Evaluation Criteria and Standards for Quality Improvement Program Contracts (10th Statement of Work)

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice with comment period.

SUMMARY: This notice with comment period describes the general criteria we intend to use to evaluate the effectiveness and efficiency of Quality Improvement Organizations (QIOs) that will enter into contracts with CMS under the 10th Statement of Work (SOW) on August 1, 2011. The evaluation of a QIOs' performance related to their SOW will be based on evaluation criteria specified for the aims, drivers, tasks, and subtasks set forth in section J–10 of the QIOs' 10th SOW.

DATES: *Effective Date*: August 1, 2011 to July 31, 2014.

Comment Date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on September 2, 2011.

ADDRESSES: In commenting, please refer to file code CMS–3143–NC. Because of staff and resource limitations, we cannot accept comments by facsimile (Fax) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov*. Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address *only*: Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS–3143–NC, P.O. Box 8010, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address *only*: Centers for Medicare & Medicaid Services, Department of Health and Human Services, *Attention:* CMS–3143–NC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments *only* to the following addresses prior to the close of the comment period:

a. For delivery in Washington, DC: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD: Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244–1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Alfreda Staton, 410–786–4194.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov*. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

Section 1153(h)(2) of the Social Security Act (the Act) requires the Secretary of the Department of Health and Human Services to publish in the **Federal Register** the general criteria and standards that will be used to evaluate the effective and efficient performance of contract obligations by the Quality Improvement Organizations (QIOs), and to provide the opportunity for public comment with respect to these criteria and standards. This notice describes the general criteria that will be used to evaluate QIO performance under the 10th Statement of Work (SOW) contract beginning August 1, 2011.

II. Provisions of the Notice With Comment Period

Description

Under the 10th SOW, QIOs are responsible for completing the requirements for the following Aims: Beneficiary and Family Centered Care; Improve Individual Care—A Patient Safety Aim with components focused on Healthcare Associated Infections (HAIs), Pressure Ulcers, Physical Restraints, Nursing Home Systemic Improvement, Adverse Drug Events, Quality Reporting and Improvement; Integrate Care for Populations and Communities—A Care Transitions Aim; and Improve Health for Populations and Communities—A Prevention Aim. The ability to achieve the goals for each Aim will be through the following Drivers: Learning and Action Networks, Technical Assistance, and the Care Reinvention through Innovation Spread (CRISP) Model. (Detailed information for each Aim and Driver may be found in sections C.6. through C.10. of the 10th SOW posted at the *http://www.fedbizopps.gov* Web site.)

Beneficiary and Family Centered Care (See Section C.6 of the 10th Statement of Work)

The Beneficiary and Family Centered Care Aim focuses on: QIO statutorily mandated case review activities as well as interventions to promote responsiveness to beneficiary and family needs; providing opportunities for listening to and addressing beneficiary and family concerns; and providing resources for beneficiaries and caregivers in decision making. Beneficiary-generated concerns provide an excellent opportunity to explore root causes, develop alternative approaches to improving care, and improve beneficiary and family experiences with the health care system. Beneficiary and family engagement and activation efforts are needed to produce the best possible outcomes of care. These QIO beneficiary and family centered efforts align with the National Quality Strategy, which encourages patient and family engagement.

Improve Individual Patient Care (Patient Safety) Initiatives (See Section C.7 of the 10th Statement of Work)

The Patient Safety initiatives are designed to help achieve the goals of improving individual patient care by: Reducing Healthcare-Associated Infections (HAIs)—Central Line Bloodstream Infections (CLABSI), Catheter-Associated Urinary Tract Infections (CAUTI), Clostridium Difficile Infections (CDI) and Surgical-Site Infections (SSI); Reducing Healthcare Acquired Conditions in Nursing Homes—Pressure Ulcers and Physical Restraints; Developing a learning and action network to begin to make forward progress toward a safer system of care; reducing Adverse Drug Events (ADEs) and medication-related harm; and providing technical assistance to hospitals to improve their quality of care related to Medicare programs such as the Hospital Inpatient Quality Reporting (IQR) Program and the Hospital Outpatient Quality Reporting (OQR) Program to promote quality improvement and transparency for consumer decision making through publicly reported quality data.

Integrate Care for Populations and Communities (See Section C.8 of the 10th Statement of Work)

The QIO work must improve the quality of care for Medicare beneficiaries who transition among care settings through a comprehensive community effort. These efforts aim to reduce readmissions following hospitalization and to yield sustainable and replicable strategies to achieve high-value health care for sick and disabled Medicare beneficiaries.

Improve Health for Populations and Communities (See Section C.9 of the 10th Statement of Work)

The QIO must improve population and community health through prevention and early diagnosis by: Improving flu immunizations of patients ages 50 and older during the flu season; improving pneumococcal immunization of patients ages 65 and older; improving appropriate low-dose aspirin therapy use in patients with ischemic vascular disease; improving blood pressure control in patients with hypertension; improving low-density lipoprotein-cholesterol (LDL–C) control among adults with ischemic vascular disease; improving tobacco cessation

intervention among adult patients who smoke (screening and cessation counseling); improving colorectal cancer screening in patients ages 50 through 75; improving breast cancer screening in women ages 40 through 69; improving participation in the Physician Quality Reporting System (PQRS); improving the use of Electronic Health Records (EHRs) for care management; and integrating health information technology to achieve meaningful use and improve care coordination and prevention goals.

Drivers—Learning and Action Networks, Technical Assistance, and Care Reinvention Through Innovation Spread (CRISP) Model (See Section C.10 of the 10th Statement of Work)

Learning and Action Networks are mechanisms by which large scale improvement around a given aim is fostered, studied, adapted, and rapidly spread regardless of the change methodology, tools, or time-bounded initiative that is used to achieve the aim. Learning Action Networks collaborate with the Regional Extension Centers with respect to quality improvement and health IT/data related issues. Learning and Action Networks consciously manage knowledge as a valuable resource. They engage leaders around an action based agenda. The network creates opportunities for in-depth learning and problem solving, it accepts all offers of support seeking to catalyze interested parties, and it is transparent, flexible, interchangeable, and purposeful.

It is expected that the QIO will develop and facilitate sustainable Learning and Action Networks within their respective State, as well as participate in CMS supported and facilitated Learning and Action Networks, which will function to support QIO activities at the local level. The QIO must develop a team(s) (number and composition to be determined by the QIO) that is responsible for supporting and facilitating the Learning and Action Networks for their respective State. This team is responsible for creating interest and active participation in the Learning and Action Networks from vested parties within the State around a specific aim(s).

The QIO must provide technical assistance to providers, facilities, and partners. The QIO must offer direct assistance related to quality improvement questions and needs to support local providers in making changes by connecting the requestor with quality improvement knowledge, providing follow-up available at the local and national level. The QIO must rely on their own internal resources, those of the community, those availed by Federal agencies, and those of the National Coordinating Centers. The QIO must provide technical assistance to individual providers, provider groups or health care systems upon their request as well as upon the direction of CMS.

In general, technical assistance is more focused, limited, and directed than activities of the Learning and Action Networks although it could be a component of these activities. Some activities include the following:

- The QIO is expected to develop and spread a sustainable infrastructure by facilitating the adoption of change from the QIO to a provider, provider group or health care system.
- The QIO will ensure that each initiative includes a sustainability plan and the QIO will work to achieve consensus among participants so that the quality improvement efforts will continue as the need continues.
- The QIO will identify pertinent data resources available to support the local provider community. This includes claims data, data organized by other contractors, data available from the Centers for Disease Control, National Institutes of Health, World Health Organization, the Census Bureau, the community information available through the coordinating center, the Center for Medicare and Medicaid Innovation, and the Agency for Healthcare Research and Quality. The QIO must conduct data analysis and develop meaningful data reports to be used by the local provider community, Learning and Action Networks and breakthrough initiatives.

The Care Reinvention through Innovation Spread (CRISP) Model is the framework for supporting the communications and outreach activities required to complete all Aims of the 10th SOW successfully. The CRISP Model is designed to minimize internal fragmentation, siloing, and duplication or conflict of messages across individual QIOs and the QIO Program as a whole. The Model is used through all activities of the 10th SOW so that all QIO operations are stakeholder-centric and focus on at least one of the three phases of communicating with stakeholders about quality improvement work: (1) Initiation and ''will building''; (2) engagement and maintenance; and (3) retention and sustainment throughout the life of the QIO task. The goal of the model is to give access to the right information and services, in the right form, at the right time, to the right people in the right place. The model does this by focusing the QIO's energies such that each policy, action, and decision is made with an educated and strategic consideration of the impacts they may have on stakeholders.

Under the CRISP Model, the QIO must ensure that Innovation Spread Advisors (ISAs) are identified for their State or territory. This individual(s) would bring knowledge to every QIO Aim (or project) team within the enterprise by: Helping the Aim teams determine who the stakeholders are and what they need; ensuring beneficiary input; facilitating the appropriate mechanisms for stakeholder communication; and determining if activities are successful. The ISA(s) from each QIO must attend CMS-sponsored training sessions and serve as brand ambassadors with branding responsibilities as indicated in section C.10.3.

III. Evaluation of the Aims and Drivers (See Section J–10 and Section C.5 of the 10th Statement of Work)

A qualitative and quantitative evaluation will be conducted at the 18th (intermediate evaluation) and 27th months (final evaluation) of the contract with monitoring and measuring for improvement conducted throughout the 3 year contract cycle. The evaluations will be based on the most recent data available to us. The performance results of the evaluation at both time periods (that is, 18 months and 27 months) will be used, in addition to ongoing monitoring activities, to determine the performance on the overall contract. Using lean and rapid techniques, QIOs will be monitored and measured for improvement on an ongoing basis using self-assessment and Contracting Officer Technical Representative (COTR) review. The COTR will complete assessment and review of qualitative and quantitative contract evaluation objectives.

The following categories will serve as the basis for the qualitative evaluation of the Technical Assistance Drivers as specified on Table 1 of section J–10 in the 10th Statement of Work:

- Rapid Cycle Improvement in Quality Improvement Activities and Outputs.
- Customer Focus and Value of the Quality Improvement Activities to Beneficiaries, Participants and CMS.
- Ability To Prepare the Field To Sustain the Improvements.
- Value Innovation.
- Commitment to ''boundarilessness.''
- Unconditional Teamwork.

The quantitative evaluation of the QIOs will be based on the number of commitments secured, participants

engaged, and the results in achievement of the goals as specified on Tables 2 and 3 in section J–10 of the 10th Statement of Work.

The ''Aims Tasks'' the QIO will be evaluated on are as follows:

C.6 Beneficiary and Family Centered Care:

- Case Review;
- Patient and Family Engagement Campaign.

C.7 Improving Individual Patient Care:

- Reduction of Healthcare Associated Infections (CLABSI, CAUTI, CDI, and SSI);
- Reduction of Healthcare Acquired Conditions in Nursing Homes (Pressure Ulcers and the Use of Physical Restraints);
- Reduction of Adverse Drug Events;
- Hospital Inpatient and Outpatient Quality Reporting and Improvement.

C.8 Integrating Care for Populations and Communities:

- Reduction of Hospital Readmissions Through a Comprehensive Community Effort by Improving the Quality of Care for Medicare Beneficiaries Who Transition Among Care Settings.

C.9 Improving Health for Populations and Communities:

- Promotion of Immunizations, Colorectal, and Breast Cancer Screenings;
- Cardiovascular Health Campaign;
- Improving Participation in the Physician Quality Reporting System (PQRS);
- Improving the Use of Electronic Health Records (EHRs) for Care Management;
- Integrating Health Information Technology to Improve Care Coordination, Achieve Meaningful Use, and Achieve Prevention Goals.

The ''Driver Tasks'' the QIO will be evaluated on are as follows:

C.10.1 Supporting and Convening Learning and Action Networks.

C.10.2 Technical Assistance;

C.10.3 Care Reinvention Through Innovation Spread (CRISP) Model.

If a QIO is not tasked to work on a specific area under an ''Aim'' and/or ''Driver,'' the QIO will not be evaluated under that particular area. Any Special Innovation Project that the QIO may carry out will be evaluated separately and will not be considered in the overall evaluation criteria.

In addition to the qualitative and quantitative evaluation in the 18th and 27th months of the contract, we will conduct monitoring activities throughout the course of the contract and will act upon findings as necessary. The performance results of the evaluation at both time periods (that is, 18 months and 27 months) will be used, in addition to ongoing monitoring activities, to determine the overall performance on the contract.

18th Month Contract Evaluation

The 18th month contract evaluation will determine if the QIO has met the performance evaluation criteria as specified in J–10 of this Statement of Work. The achievement within each of the ''Aims'' and ''Drivers'' will be evaluated on an individual basis for appropriate contract action. Though, in general, evaluation of each ''Aim'' and/or ''Driver'' will relate only to that area, we reserve the right to take appropriate contract action in the event of failure in multiple ''Aims'' and/or ''Drivers''.

18th Month Evaluation Criteria:

- Pass: Criteria met for the ''Aim'' and/or ''Driver'' as specified in the evaluation section of the ''Aim'' and/or ''Driver.''
- Fail: Criteria not met for the ''Aim'' and/or ''Driver'' as specified in the evaluation section of the ''Aim'' and/or ''Driver.''

27th Month Contract Evaluation

The 27th month contract evaluation will determine if the QIO has met the performance evaluation criteria as specified in each of the ''Aims'' and ''Drivers'' areas of the 10th SOW. The achievement within the ''Drivers'' and ''Aims'' will be evaluated on an individual basis for appropriate contract action.

27th Month Evaluation Criteria:

- Pass: Criteria met for the ''Aim'' and/or ''Driver'' as specified in the evaluation section of the ''Aim'' and/or ''Driver.''
- Fail: Criteria not met for the ''Aim'' and/or ''Driver'' as specified in the evaluation section of the ''Aim'' and/or ''Driver.''

Overall Contract Evaluation

The results of the 18th and 27th month evaluation periods, in addition to ongoing monitoring activities, will be used to determine how the contractor performed on the overall contract.

If we choose, we may notify the QIO of our intention not to renew the QIO contract and inform the QIO of their rights under the current statute.

Any failure at the 18th or 27th month evaluation for any ''Aim or Driver'' may result in that QIO receiving an adverse past performance evaluation. Further, failure may impact on the QIO's ability to continue similar work in or eligibility for award of the 11th SOW.

The list of measures and performance criteria for each QIO will be recorded on the CMS Dashboard, which will be available on QIOnet (*http://qionet.sdps.org*), the standard information system that supports the QIO Program. We will also post these measures on the publicly accessible CMS Web site (*http://www.cms.gov*).

We will monitor the QIO's performance on the ''Aims'' and ''Drivers'' against established criteria on at least a quarterly basis, and may take appropriate contract action (for example, providing warning for the need for adjustment, instituting a formal correction plan, terminating an activity, or recommending early termination of a contract because of failure to meet contract timelines as specified in sections C.6 through C.10.).

We reserve the right at any point, prior to the notification of our intention not to continue the option for an ''Aim'' and/or ''Driver'' and/or to renew the contract, to revise measures or adjust the expected minimum thresholds for satisfactory performance or remove criteria from an ''Aim'' and/or ''Driver'' evaluation protocol for any reason, including, but not limited to, data gathered based on experience with the amount of improvement achieved during the contract cycle or in pilot projects currently in progress, information gathered through evaluation of the QIO Program overall, or any unforeseen circumstances. Further, in accordance with standard contract procedures, we reserve the right at any time to discontinue an ''Aim'' and/or ''Driver'' or any other part of this contract regardless of QIO performance on the ''Aim'' and/or ''Driver''.

IV. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Regulatory Impact Statement

In accordance with the provisions of Executive Order 12866, this notice was

not reviewed by the Office of Management and Budget.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 15, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2011–19650 Filed 7–29–11; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0554]

Agency Information Collection Activities; Proposed Collection; Comment Request; Veterinary Feed Directive

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting and recordkeeping requirements for distribution and use of Veterinary Feed Directive (VFD) drugs and animal feeds containing VFD drugs.

DATES: Submit either electronic or written comments on the collection of information by October 3, 2011.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7651, *Juanmanuel.vilela@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Veterinary Feed Directive—21 CFR Part 558 (OMB Control Number 0910–0363)—Extension

With the passage of the Animal Drug Availability Act of 1996 (Pub. L. 104–250), the Congress enacted legislation establishing a new class of restricted feed use drugs, VFD drugs, which may be distributed without involving State pharmacy laws. Although controls on the distribution and use of VFD drugs are similar to those for prescription drugs regulated under section 503(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(f)), the implementing VFD regulation (21 CFR 558.6) is tailored to the unique circumstances relating to the distribution of medicated feeds. The content of the VFD is spelled out in the regulation. All distributors of medicated feed containing VFD drugs must notify FDA of their intent to distribute, and records must be maintained of the distribution of all medicated feeds containing VFD drugs. The VFD regulation ensures the protection of public health while enabling animal producers to obtain and use needed drugs as efficiently and cost effectively as possible.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
558.6(a)(3) through (a)(5)	15,000	25	375,000	.25	93,750
558.6(d)(1)(i) through (d)(1)(iii)	300	1	300	.25	75
558.6(d)(1)(iv)	20	1	20	.25	5
558.6(d)(2)	1,000	5	5,000	.25	1,250
514.1(b)(9)	1	1	1	3.00	3
Total					95,083

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.