

Government of the District of Columbia Department of Health Board of Dietetics and Nutrition

899 NORTH CAPITOL ST. NE – 2ND FLR. WASHINGTON, DC 20002

June 25, 2015

9:30 am - 12:00 pm

MEETING AGENDA



OPEN SESSION: Call to Order

OS-0625-01	SENIOR DEPUTY DIRECTOR'S REPORT	
OS-0625-02	EXECUTIVE DIRECTOR'S REPORT	
OS-0625-03	BOARD ATTORNEY'S REPORT	
OS-0625-04	CHAIRPERSON'S REPORT	
OS-0625-05	OPEN SESSION MINUTES	
	Board Action: To consider the Open Session Minutes of the	
	March 10, 2015 meeting.	
OS-0625-06	SCOPE OF PRACTICE	
	Board Action: To continue the discussion on scope of practice	
	for Dietitians and Nutritionists.	
OS-0625-07	FitDC INITIATIVE	
	Board Action: To discuss the FitDC initiative with	
	representatives and officials of the D.C. Government.	
OS-0625-08	CMS RULE ON ORDERING PRIVILEGES FOR DIETITIANS	
	Board Action: To discuss the Federal Register notice on the rule	
	issued by Center for Medicare and Medicaid Service's (CMS)	
	which loosens ordering privileges for Dietitians. According to	
	the notice, this rule change removes " unnecessary, obsolete,	
	or excessively burdensome" regulations on health care	
	providers and suppliers.	
OS-0625-09	LICENSURE REQUIREMENTS FOR NUTRITION – MUNICIPAL	
	REGULATIONS §4505.2(a)	
	Board Action: To discuss the licensure loophole at §4505.2(a) of	
	the D.C. Municipal Regulations for Nutrition, which states that	
	all applicants for to receive a passing score on the national	
	exam except "[a]n applicant for licensure by endorsement."	
OS-0625-10	ANTITRUST AND OTHER IMPLICATIONS OF RECENT	
	SUPREME COURT RULING	
	Board Action: To discuss a letter to the Board from the Alliance	
	for Natural Health USA interpreting a recent U.S. Supreme	
	Court case on the antitrust limits for state licensing boards.	



TO BE READ BY THE CHAIRPERSON PRIOR TO THE END OF THE PUBLIC SESSION

This concludes the public open session meeting and pursuant to the DC Official Code 2-575B and for the purposes set forth therein, the Board will now move into the closed executive session portion of the meeting.



Government of the District of Columbia Department of Health

BOARD OF DIETETICS/NUTRITION

OPEN SESSION MINUTES

899 NORTH CAPITOL ST. NE ROOM 216 WASHINGTON, DC 20002

March 10, 2015 9:30am-10:30am



Government of the District of Columbia Department of Health BOARD OF DIETETICS/NUTRITION

OPEN SESSION MINUTES MARCH 10, 2015

ATTENDANCE:

BOARD		
MEMBERS:		
	MELISSA MUSIKER, CHAIRPERSON	PRESENT
	EDWARD JOHNSON, CONSUMER MEMBER	PRESENT
	JANET UNONU, MEMBER	PRESENT
STAFF:		
	ROBINS JENKINS, EXECUTIVE DIRECTOR, BOARDS OF	PRESENT
	ALLIED AND BEHAVIORAL HEALTH	
	ERIC YEAGER, ESQ., HEALTH LICENSING	PRESENT
	SPECIALIST	
	LEONARD HOWARD, INVESTIGATOR	PRESENT
	PANRAVEE VONGJAROENRAT, ESQ., BOARD	PRESENT
	ATTORNEY	
VISITORS	JESSICA MCGEE	PRESENT
	ALYSSA SMITH	

The open session MINUTES begin on the next page.

OPEN SESSION MINUTES MARCH 10, 2015



Government of the District of Columbia Department of Health

BOARD OF DIETETICS/NUTRITION

00	MINILITEC	
OS-0310-01	MINUTES	
	Board Action : The Board approved the December 9, 2014 Open	
	Session meeting minutes.	
OS-0310-02	EXECUTIVE DIRECTOR'S REPORT	
	The Executive Director announced that there would be training	
	held for board members on March 26, 2015 at the DOH building	
	between 8:30 a.m. and 5:00 p.m. She noted that this training will	
	focus on regulatory processes.	
OS-0310-03	BOARD ATTORNEY'S REPORT	
	Board Action: The Board Attorney reported that the U.S.	
	Supreme Court ruled on the North Carolina Board of Dentistry	
	and updated the board on the possible impact of the decision.	
OS-0310-04	BOARD CHAIRPERSON'S REPORT	
	Board Action: The Board Chair announced that she will be guest	
	speaker at the upcoming District of Columbia Metro Academy of	
	Dietetics and Nutrition (DCMADA) annual meeting on April 10,	
	2015. The meeting will be held between 8:30 a.m. and 4:30 p.m. at	
	the National Society of Homebuilders office located at 1201 15 th	
	Street, N.W., Washington, D.C. 20005.	
	Finally, the Board Chair thanked Board Member Edward Johnson	
	, · ·	
	for his dedicated service on the Board, noting that his term had	
	ended	
OS-0310-05	SCOPE OF PRACTICE DISCUSSION	
	Board Action : As the Board plans to consider law and regulation	
	updates to clarify the definitions and scope of practice for each	
	profession (Dietitians and Nutritionists), the Board continued its	
	conversation with members of the public. The Board plans	
	additional discussions on this topic at future meetings.	



WELCOME TO FITDC

FitDC is a new, fresh health and wellness initiative conceived by N Muriel Bowser to encourage all District of Columbia residents from 1 to Ward 8 to get out, move more and adopt a healthier, more a lifestyle. If you're excited about health and wellness, then get on bo

you want to get healthier and make better lifestyle choices but nee of help or encouragement getting started, there's support for you! are lots of resources and programs in D.C. that help empower resi to improve their health and wellness.



TO GET THINGS STARTED!

Beginning this summer, FitDC is launching the FitDC Billion Steps
Challenge. We want to inspire and motivate D.C. residents from acre
the city to participate in the challenge and join with their communit
walk: One Billion Steps! We know that's a lot of steps, but by workin
together with initiative partners, community groups, neighbors and

FitDC Page 4 of 5

coaches, it can be done. Let's take up this fitness challenge and see long it takes D.C. to walk one billion steps!

FitDC is a joint initiative by the D.C. Department of Health and the D.C. Department of Parks and Recreation.

What Do Our FitDC Coaches Say About FitDC?

.

I want to be a FitDC coach because it allows the community to come together as one and be happy while being healthy.



Nate Green
Youth Coach

FitDC Events

Ward 1 Walk

Starts: 9:00 am

Ends: June 13, 2015 - 11:00 am

Location: Columbia Heights Community Center, 1480 Girard Street Northwest Washington, DC 20009, United States

Back

□ LET'S FIND YOUR FITDC COACH!

FitDC – Nutrition Page 1 of 6

NUTRITION

A Fresh Start to Healthy Eating

NUTRITION IS KEY







Nutrition is a key part of leading a healthy lifestyle. Eating properly will help you maintain a healthy weight, reduce your risk of illness, and aid in your overall health and wellness. Eating healthy can be fun — and your body will thank you!

Nutrition Facts

FitDC – Nutrition Page 2 of 6



3.7 liters

Recommended Daily Water Intake



2.7 liters

Recommended Daily Water Intake



25 minutes

Pace Yourself, Don't eat until you are full

NUTRITION TIPS

READ THE LABELS

Make it a habit to read nutrition labels when you're grocery shopping. If you need help, consult your healthcare provider.

AVOID (NON) SUGARY SWEET

Artificial sweeteners slow down your metabolism, so avoid them as well as diet drinks and other "sugar-free" foods.

PACE YOURSELF

Don't eat until you're full – eat until you're no longer hungry.

Avoid overeating by waiting 20 to 30 minutes before getting a second serving. By that time, your cravings will be gone.

FAIL TO PREPARE, PREPARE TO FAIL

Preparing meals in advance will help ensure that you stay on track with your fitness goals and avoid missing meals throughout the day.

EAT FRESH

When grocery shopping, stay along the perimeter of the store, where you'll find fruits, vegetables, lean meats and beans. Avoid purchasing processed foods containing ingredients that do not occur naturally.

DAILY DOSES OF H20

Hydration helps your body perform necessary functions like digestion and it gives you energy and keeps your skin clear. The Institute of Medicine recommends that women consume 91 ounces of water from food and drink daily and men consume 125 ounces.

MAKE YOUR PLATE COLORFUL

Fruits and vegetables are chock-full of nutrients and antioxidants that can help prevent heart disease and cancer. So, fill your plate with a rainbow of fruits and veggies: dark, leafy greens (spinach, kale, collard greens, broccoli, chard); berries (raspberries, blackberries, blueberries); citrus (oranges and grapefruits); root vegetables (carrots, beets); apples; celery; and red, yellow and green bell peppers.

NUTRITION RESOURCES IN DC

CACFP



The Child and Adult Care Food Program (CACFP) provides a monthly financial subsidy, training and technical assistance, nutrition education, and food safety information to child development centers, adult day care centers, afterschool programs, and emergency shelters that serve meals to eligible D.C. residents.

Learn More

Healthy Schools



D.C.'s public schools are working hard to ensure that children receive the best in-school nutrition possible. Initiatives such as the Fresh Fruit and Vegetable Program, School Breakfast Programs, the After School Snack Program, and other schoolcentered nutrition assistance help D.C. children make healthier choices.

Learn More

Farmers Markets



Farmers Markers Wants landing residents and Cumin-Spiced Chicken with Children) provide smiles with assistance in offer matching edollars deathed to maintain Chunky Tomato Sauce Supplemental Nutrition

Assistance Program (SNAP) and Special Supplemental Nutrition Program for Women, Infants and Children (WIC). These matching programs, which match up to a certain amount of benefits spent at the market, exist to ensure that fresh fruits and vegetables are available to everyone. There are numerous farmers markets in the District that are accessible to most neighborhoods.

FRESHFARM Markets

Community Foodworks

Healthy Recipes



- Chicken Vegetable Skillet
- Mango Salsa
- ✓ Green Herb Chicken Salad
- ✓ 5 Ingredient Sweet Potato Casserole
- ✓ Sautéed Tilapia Tacos with Grilled Peppers and Onion
- ✓ Refried Bean Poblanos with Cheese



DC Free Summer Meals Program

The U.S. Department of Agriculture (USDA) Summer Food Service Program (SFSP) - known here as the D.C. Free Summer Meals Program (FSMP) – provides reimbursement for free, nutritious meals and snacks served to children 18 and younger. These meals help children in low-income parts of the city access the nutrition they need during the summer months, when they're not in school.

Learn More



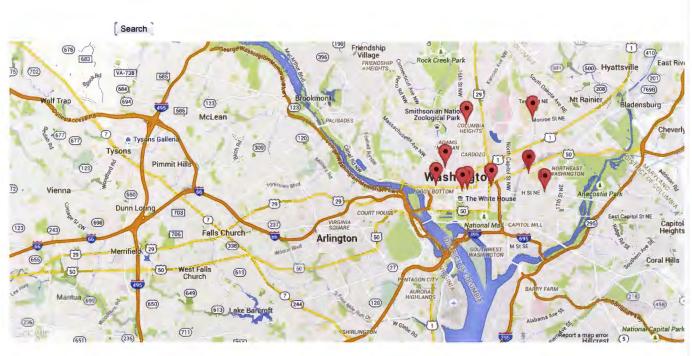
Community Gardens

Currently, the District has 26 community gardens with plots available for D.C. residents to grow their own fresh produce.

Learn More

FitDC – Nutrition Page 4 of 6

Ward Nutrition Resource Map



Default View

What's your nutrition mantra?

Consume in moderation and train your palate.



FitDC Events

Ward 1 Walk

Starts: 9:00 am
Ends: June 13, 2015 - 11:00 am
Location: Columbia Heights
Community Center, 1480 Girard
Street Northwest, Washington, DC
20009, United States

Back

Next

□ LET'S TALK ABOUT WORKING OUT!

Columbia Heights Farmers Market

Services: Bonus Bucks Program, Nutrition Education, Fruit & Vegetable Prescription Program

Hours: Every Saturday, 9:00am - 12:00pm

Get Directions

Historic Brookland Farmers Market

Services: Bonus Bucks Program, Nutrition Education, Fruit & Vegetable Prescription Program

Hours: Every Saturday, 9:00am - 12:00pm

Get Directions

White House FreshFarm Market

Services: Matching for EBT, WIC, Senior Farmers Market Nutrition Coupon Match

Hours: Thursdays 11 to 2 PM **Season:**April 9 to Nov 19 2015

Get Directions

CityCenterDC FreshFarm Markets

Located: Between 10th and 11th Street

Services: Matching for EBT, WIC, Senior Farmers Market Nutrition Coupon

Hours: Tuesdays, 11 AM - 2 PM **Season:**May 5 to Oct 27 2015

Get Directions

Dupont Circle FreshFarm Market

Services: Matching for EBT, WIC, Senior Farmers Market Nutrition Coupon Match

Hours: Sundays, 9:30 AM to 1 PM **Season:** Jan to March 2015 **Hours:** Sundays, 8:30 AM to 1:30 PM

Season: April to December 2015

Get Directions

Foggy Bottom FreshFarm Market

Services: Matching for EBT, WIC, Senior Farmers Market Nutrition Coupon

Hours: Wednesdays, 3 PM to 7 PM **Season:** April 1 to Nov 25 2015

Get Directions

H Street NE FreshFarms Market

Services: Matching for EBT, WIC, Senior Farmers Market Nutrition Coupon

Hours: Saturdays, 9 AM to Noon **Season:** April 18 to Dec 19 2015

Get Directions

Mount Vernon Triangle FreshFarm Market

Services: Matching for EBT, WIC, Senior Farmers Market Nutrition Coupon

Hours: Saturdays, 10 AM to 1 PM **Season:** May 16 to Oct 31 2105

Get Directions

Union Market FreshFarms Market

Services: Matching for EBT, WIC, Senior Farmers Market Nutrition Coupon

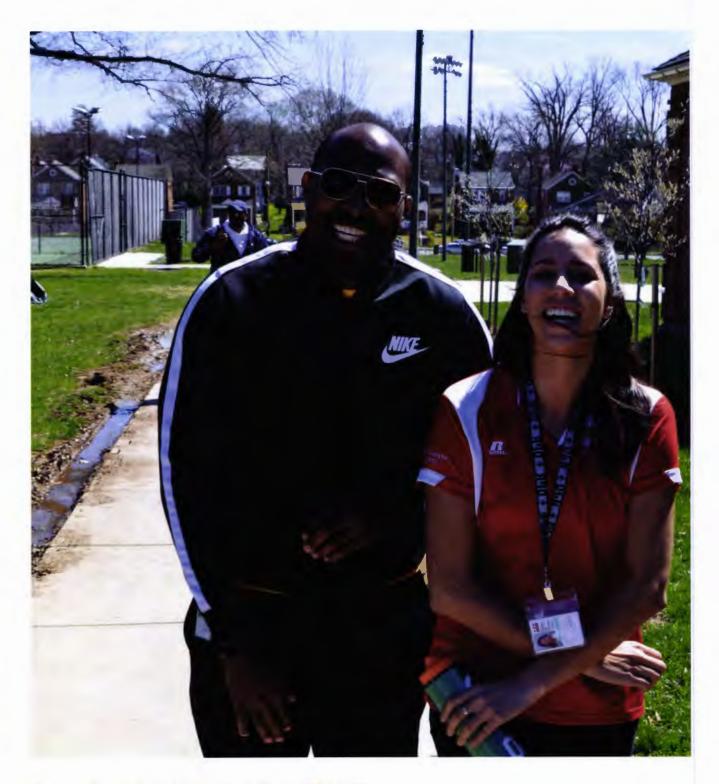
Hours: Sundays, 11 AM to 2 PM

Season: May 17 to TBD

Get Directions

FITDC COACHES

Let's Get Motivated!



ROLE OF FITDC COACHES

FITDC COACHES



PHILIP **THOMAS**

Ward 3 Coach



NATE GREEN



Youth Coach



ELENA LITTLES





CHRIS DOENLEN

Ward 6 Coaci



CHARLES TAYLOR

Ward 8 Coach



CARRYE **BROWN**

Ward 4 Coach



DARRYL GARRETT

Senior Coach



CHRISTIN ALEXANDE

Ward 7 Coaci



AIMEE **STOLTZ**

Ward 2 Coach



MARITA GUMBS

Ward 1 Coach

FitDC – Coaches Page 3 of 5

FitDC coaches motivate D.C. residents to get out, move more, and n healthy choices. They participate in – and lead – monthly "Ward Wal that encourage residents to incorporate more exercise into their life while working towards reaching this goal: One. Billion. Steps.

Take the FitDC Billion Steps Challenge



This site displays a prototype of a "Web 2.0" version of the daily Federal Register. It is not an official legal edition of the Federal Register, and does not replace the official print version or the official electronic version on GPO's Federal Digital System (FDsys.gov).

The documents posted on this site are XML renditions of published Federal Register documents. Each document posted on the site includes a link to the corresponding official PDF file on FDsys.gov. This prototype edition of the daily Federal Register on FederalRegister.gov will remain an unofficial informational resource until the Administrative Committee of the Federal Register (ACFR) issues a regulation granting it official legal status. For complete information about, and access to, our official publications and services, go to the OFR.gov website.

The OFR/GPO partnership is committed to presenting accurate and reliable regulatory information on FederalRegister.gov with the objective of establishing the XML-based Federal Register as an ACFR-sanctioned publication in the future. While every effort has been made to ensure that the material on FederalRegister.gov is accurately displayed, consistent with the official SGML-based PDF version on FDsys.gov, those relying on it for legal research should verify their results against an official edition of the Federal Register. Until the ACFR grants it official status, the XML rendition of the daily Federal Register on FederalRegister.gov does not provide legal notice to the public or judicial notice to the courts.

The Federal Register

The Daily Journal of the United States Government

Rule

Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Part II

A Rule by the Centers for Medicare & Medicaid Services on 05/12/2014

Action

Final Rule.

Summary

This final rule reforms Medicare regulations that CMS has identified as unnecessary, obsolete, or excessively burdensome on health care providers and suppliers, as well as certain regulations under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). This final rule also increases the ability of health care professionals to devote resources to improving patient care, by eliminating or reducing requirements that impede quality patient care or that divert resources away from providing high quality patient care. We are issuing this rule to achieve regulatory reforms under **Executive Order 13563** on improving regulation and regulatory review and the Department's plan for retrospective review of existing rules. This is the latest in a series of rules developed by CMS over the last 5 years to reform

4/20/2015 Federal Register | Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Part II existing rules to reduce unnecessary costs and increase flexibility for health care providers.

Table of Contents

- DATES:
- FOR FURTHER INFORMATION CONTACT:
- **SUPPLEMENTARY INFORMATION:**
- Table of Contents
- I. Summary and Background
- A. Executive Summary of This Final Rule
- 1. Purpose
- 2. Summary of the Major Provisions
- 3. Summary of Costs and Benefits
- a. Overall Impact
- b. Section-by-Section Economic Impact Estimates
- B. Legislative and Regulatory History
- II. Provisions of the Proposed Rule and Analysis and Response to Public Comments
- A. Ambulatory Surgical Centers
- B. Intermediate Care Facilities for Individuals With Intellectual Disabilities
- C. Hospitals
- 1. Governing Body (§ 482.12)
- 2. Medical Staff (§ 482.22)
- 3. Food and Dietetic Services (§ 482.28)
- 4. Nuclear Medicine Services (§ 482.53)
- 5. Outpatient Services (§ 482.54)
- 6. Special Requirements for Hospital Providers of Long-Term Care Services ("Swing-Beds") (§ 482.66)
- D. Transplant Centers and Organ Procurement Organizations
- 1. Reports to CMS (§ 482.74)
- 2. Transplant Outcome Review (§ 482.80(c) and § 482.82(c))
- 3. Volume and Clinical Experience Requirements (§§ 482.80(c)(2) and 482.82(c)(2))
- 4. Transplant Center Re-Approval Process
- 5. Technical Corrections
- E. Long-Term Care Facilities
- F. Rural Health and Primary Care
- 1. CAH Provision of Services (§ 485.635(a))
- 2. CAH and RHC/FQHC Physician Responsibilities (§§ 485.631(b)(1)(v), 485.631(b)(2), and 491.8(b)(2))
- 3. RHC/FQHC Definitions: Physician (§ 491.2)

- 4. Technical Correction
- 5. Comments Beyond the Scope of This Rulemaking
- G. Solicitation of Comment on Reducing Barriers to Services in Rural Health Clinics (RHCs)
- 1. Telehealth
- 2. Hospice
- 3. Home Health
- 4. Other Services
- 5. Comments Outside the Scope
- H. Clinical Laboratory Improvement Amendments of 1988 (CLIA)
- III. Collection of Information Requirements
- IV. Waiver of Delayed Effective Date for Revisions to 42 CFR Part 483
- V. Regulatory Impact Analysis
- A. Statement of Need
- B. Overall Impact
- C. Anticipated Effects
- 1. Effects on Ambulatory Surgical Centers
- 2. Effects on Intermediate Care Facilities for Individuals Who Are Intellectually Disabled
- 3. Effects on Hospitals
- Ordering Privileges for Registered Dietitians (RDs) (Food and Dietetic Services § 482.28)
- Nuclear Medicine Services (§ 482.53)
- 4. Effects on Transplant Centers and Organ Procurement Organizations
- 5. Effects on Long Term Care Facilities
- 6. Effects on Rural Health and Primary Care Providers and Suppliers
- CAH and RHC/FQHC Physician Responsibilities (§§ 485.631(b)(2) and 491.8(b)(2))
- Provision of Services (§ 485.635(a))
- RHC/FQHC Definition of a Physician (§ 491.2)
- 7. Effects on Laboratories
- 8. Effects on Small Entities
- D. Alternatives Considered
- E. Uncertainty
- F. Accounting Statement and Table
- List of Subjects
- PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; OPTIONAL PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES
- PART 416—AMBULATORY SURGICAL SERVICES
- PART 440—SERVICES: GENERAL PROVISIONS
- PART 442—STANDARDS FOR PAYMENT TO NURSING FACILITIES AND INTERMEDIATE CARE FACILITIES FOR INDIVIDUALS WITH INTELLECTUAL DISABILITIES

4/20/2015 Federal Register | Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Part II staff has mechanisms in place to ensure that issues localized to particular hospitals are duly considered and addressed.

Finally, we note that some commenters argued in support of a unified medical staff by pointing to our previous position permitting a single governing body for hospitals within a system. We believe that the CoPs pertaining to the governing body and medical staff are unique in their focus on governance processes. We are taking this opportunity to emphasize that permitting use of a system governing body or medical staff must not be construed as implying that compliance with any other hospital CoPs may also be demonstrated at the system (multi-hospital) level. Each separately participating hospital is required to demonstrate its compliance with all other hospital CoPs in order to participate in Medicare. Although there can be system approaches in many of these areas (such as infection control or quality assessment/performance improvement programs), each individual hospital must demonstrate that it fulfills the applicable CoP requirements.

3. Food and Dietetic Services (§ 482.28)

We proposed to revise the hospital requirements at § 482.28(b), "Food and Dietetic Services," which currently requires that a therapeutic diet must be prescribed only by the practitioner or practitioners responsible for the care of the patient.

The Interpretive Guidelines (IGs) for this requirement, which are contained in the State Operations Manual (SOM) for surveyors, further state that "[in] accordance with State law and hospital policy, a dietitian may assess a patient's nutritional needs and provide recommendations or consultations for patients, but the patient's diet must be prescribed by the practitioner responsible for the patient's care." State survey agencies have applied this requirement to mean that registered dietitians or other clinically qualified nutrition professionals (RDs) cannot be granted privileges by the hospital to order patient diets (or to order necessary laboratory tests to monitor the effectiveness of dietary plans and orders, or to make subsequent modifications to those diets based on the laboratory tests) since these practitioners have never been considered to be among those in the hospital who are "responsible for the care of the patient." The responsibility for the care of the patient, and the attendant hospital privileges that accompany this responsibility, have traditionally and exclusively been the provenance of the physician, more specifically the MD and DO, and, to a lesser extent, the APRN and PA. Understanding the regulatory language and its interpretation, most hospitals have taken a very conservative approach toward the granting of privileges, especially ordering privileges, to other types of non-physician practitioners, including RDs. Consequently, most hospitals have withheld ordering privileges from RDs absent a clear signal from CMS and the subsequent and necessary changes to the CoPs that would allow them to do so.

After the publication of the October 24, 2011 proposed rule (76 FR 65891) and the May 16, 2012 final rule (77 FR 29034), "Medicare and Medicaid Programs; Reform of Hospital and Critical Access Hospital Conditions of Participation," it came to our attention that the regulatory language and the IGs for § 482.28(b) were too restrictive and lacked reasonable flexibility to allow hospitals to extend these

specific privileges to RDs in accordance with State laws. We believe that RDs are the professionals who are best qualified to assess a patient's nutritional status and to design and implement a nutritional treatment plan in consultation with the patient's interdisciplinary care team. In order for patients to receive timely nutritional care, the RD must be viewed as an integral member of the hospital interdisciplinary care team, one who, as the team's clinical nutrition expert, is responsible for a patient's nutritional diagnosis and treatment in light of the patient's medical diagnosis. In the February 7, 2013 proposed rule, we provided research evidence that supports the changes we have proposed (78 FR 9222). Without the proposed regulatory changes allowing hospitals to grant appropriate ordering privileges to RDs, hospitals would not be able to effectively realize improved patient outcomes and overall cost savings that we believe would be possible with such changes.

It should be noted, because a few States elect not to use the regulatory term "registered" and choose instead to use the term "licensed" (or no modifying term at all), or because some States also recognize other nutrition professionals with equal or possibly more extensive qualifications, we proposed to use the term "qualified dietitian." In those instances where we have used the most common abbreviation for dietitians, "RD," throughout this preamble, our intention is to include all qualified dietitians and any other clinically qualified nutrition professionals, regardless of the modifying term (or lack thereof), as long as each qualified dietitian or clinically qualified nutrition professional meets the requirements of his or her respective State laws, regulations, or other appropriate professional standards.

In order for patients to have access to the timely nutritional care that can be provided by RDs, a hospital must have the regulatory flexibility either to appoint RDs to the medical staff and grant them specific nutritional ordering privileges or to authorize the ordering privileges without appointment to the medical staff, all through the hospital's appropriate medical staff rules, regulations, and bylaws. In either instance, medical staff oversight of RDs and their ordering privileges would be ensured. Therefore, we proposed revisions to § 482.28(b)(1) and (2) that would require that individual patient nutritional needs be met in accordance with recognized dietary practices. We would make further revisions that would allow for flexibility in this area by requiring that all patient diets, including therapeutic diets, must be ordered by a practitioner responsible for the care of the patient, or by a qualified dietitian or other clinically qualified nutrition professional as authorized by the medical staff and in accordance with State law. We believe that hospitals that choose to grant these specific ordering privileges to RDs may achieve a higher quality of care for their patients by allowing these professionals to fully and efficiently function as important members of the hospital patient care team in the role for which they were trained. In the proposed rule, we stated that we believe hospitals would realize significant cost savings in many of the areas affected by nutritional care.

We received over 100 comments on our proposed changes to § 482.28 from professional organizations, accreditation organizations, hospitals and hospital systems, and individuals. Overall, the majority of commenters were supportive of the proposed changes, though there were a large number of commenters who were opposed to the exclusive use of the terms "registered dietitian," "qualified dietitian," or "RD" for varied reasons. Here we respond to specific comments:

Comment: As stated above, the majority of commenters were very supportive of the proposed changes with many citing improved patient care, greater efficiency in delivering dietary services, and significant cost savings as benefits that would be realized if the proposed changes were to be finalized. A few commenters provided references (to the same published studies that we cited) that offer evidence of the benefits that might be derived by hospitals if dietitians were granted ordering privileges as well as to guidelines, best practices, professional standards, and recommendations for the ordering of enteral and parenteral nutrition. Other commenters provided detailed information on the recognized training, education, and other qualifications that dietitians and nutrition professionals must meet in order to practice in their respective professions.

Response: We appreciate the commenters' support of our proposed changes as well as the references to the research provided. We agree that these changes will benefit patients as well as the practitioners caring for them, and will allow hospitals to achieve greater efficiency and cost savings in the delivery of food and dietetic services to patients.

We also appreciate the information on the professional standards and guidelines for enteral and parenteral nutrition therapy provided as well that provided on the qualifications for the various dietetics and nutrition professions.

Comment: One commenter, while agreeing with the intent of the proposed changes and many of the statements made in the preamble in support of these changes, did not agree with the use of the term "qualified dietitian" in the regulatory text. The commenter stated that "the terminology 'registered dietitian' or 'RD' is the nationally accepted designation for a professional who has met the minimum educational standards, [and] taken a registration exam complete with mandatory continuing professional education." Similar to this commenter, a few individuals and one professional organization asked for CMS to use the term "registered dietitian" instead of "qualified dietitian," or to clarify that the definition of qualified dietitian used here is consistent with the one currently found under the transplant center process requirements at § 482.94(e), which defines a qualified dietitian as "an individual who meets practice requirements in the State in which he or she practices and is a registered dietitian with the Commission on Dietetic Registration." However, many of the registered dietitians who commented simply thanked CMS for the proposed changes, stated their support for them, and acknowledged the possible benefits that might be derived from the regulatory changes to § 482.28.

Conversely, one commenter, who included the names of 2,480 individuals who had signed on in support of the comment, stated that they cannot support "Medicare rules that create a monopoly for RDs at the expense of often better-qualified nutrition professionals." Similarly, various comments from "nutritionists," "nutrition professionals," "certified clinical nutritionists," and "certified nutrition specialists" argued that the rule would not serve patients since it excludes non-registered dietitians and other nutrition professionals and that the changes would create a practice monopoly for registered dietitians in hospitals. These commenters expressed the opinion that advanced degree nutrition professionals possess more extensive education and training backgrounds in nutrition than do registered dietitians. One commenter stated that they believe the professional organization representing registered

4/20/2015 Federal Register | Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Part II dietitians is attempting to "exclude other nutritional specialists," while many other commenters simply urged CMS to be "forward-looking by incorporating the most flexible, inclusive language to increase the qualified nutrition workforce rather than narrowing it to one private credential, essentially creating a monopoly."

Response: Our use of the term "registered dietitian," in the proposed regulatory language, along with our use of this term and the terms "qualified dietitian" and "RD" in the preamble, was not meant to be exclusive of other nutrition professionals qualified to practice in the hospital setting. We agree with commenters that the regulatory language for § 482.28 should be inclusive of all qualified nutrition professionals. We do not agree with commenters who requested that we use the term "registered dietitian" or define "qualified dietitian" as an individual specifically registered with the Commission on Dietetic Registration. We agree that a more flexible approach would be the best way to ensure that patients benefit from the improved quality of care that these professionals can bring to hospital food and dietetic services. Additionally, we believe that it is best left to individual States to determine the regulatory processes by which these professions are governed and that hospitals, through their medical staff privileging processes, should be allowed the flexibility to determine the credentials and qualifications for dietitians and nutrition professionals, in accordance with their respective State laws if and when they choose to grant ordering privileges to these professionals. Therefore, we are revising our proposed regulatory language in this final rule to now require that all patient diets, "including therapeutic diets, must be ordered by a practitioner responsible for the care of the patient, or by a qualified dietitian or qualified nutrition professional as authorized by the medical staff and in accordance with State law governing dietitians and nutrition professionals." [Emphasis added.]

Comment: A few commenters suggested that the term, "therapeutic diets," be clarified in the requirements as including both enteral and parenteral nutrition support because the commenters are concerned that the term might be interpreted as not including these nutrition modalities.

Response: While we understand the commenter's concerns, we believe that we have made it very clear in the preamble to this rule as well as in the preamble to the proposed rule that we consider all patient diets to be therapeutic in nature, regardless of the modality used to support the nutritional needs of the patient, and that the term would most certainly include enteral and parenteral nutrition support. Further, we believe that our extensive discussion of the research evidence supporting ordering privileges for RDs in both the proposed rule's preamble and its regulatory impact section leaves very little room for misinterpretation of this term since much of our discussion centered on the RD's role and expertise in ordering parenteral nutrition for patients.

Comment: Several commenters supported the proposed change and requested that CMS apply this revision to the Medicare requirements for long-term care facilities and other healthcare facilities in which RDs and nutrition professionals play a role.

Response: We appreciate the commenters' support and suggestions, but the recommendations are outside the scope of this rule. However, we will keep the suggestion to extend the proposed revisions to the requirements for other providers and suppliers in consideration if we pursue future rulemaking in these

4/20/2015 Federal Register | Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Part II areas.

Comment: One commenter noted that while these proposed changes address the nutritional aspects of diet management, they do not address "diet texture modification, which may be recommended by speech-language pathologists for patients with significant swallowing problems." The commenter further states that since speech-language pathologists "are the professionals who typically assess individuals with swallowing disorders . . . they, like dieticians, should have the authority to order diets that reflect changes based on their expert recommendations."

Response: While we agree with the commenter that speech-language pathologists may be the professionals best qualified to make recommendations for patients with swallowing disorders, we do not believe that § 482.28 is the appropriate place for such a change. Additionally, we believe that the recent changes to the medical staff CoP (§ 482.22) with regard to non-physician practitioners allow hospitals to determine if specific categories of practitioners, along with individual practitioners within those categories, should be granted certain privileges within the hospital, including ordering privileges. The changes finalized here for § 482.28 in no way prohibit hospitals from granting specific ordering privileges to speech-language pathologists, or to other non-physician practitioners, as long as those privileges are in accordance with State laws and regulations, including scope-of-practice laws.

Comment: Several commenters disagreed with CMS' assertion in the proposed rule that dietitians are the professionals best qualified to assess a patient's nutritional status and to design and implement a nutritional treatment plan. These commenters also disagreed with our statement in the proposed rule that "physicians often lack the training and educational background to manage the sometimes complex nutritional needs of patients with the same degree of efficiency and skill as registered dieticians." These commenters further stated that they believe that "in some cases, such as post-abdominal surgery care, the physician is best suited to determine patient diet." They urged CMS to clarify in the final rule that "in some cases, per medical staff directive, the dietician must defer to or consult with the physician responsible for the care of the patient." The same commenters did agree with "CMS' deference to the authorization of the medical staff at § 482.28" and stated that they believe that "the medical staff should be the arbiter of policies regarding when a dietician is qualified to order patient diets in the hospital."

Response: We agree with the commenters that there are some cases where the dietitian or nutrition professional must defer to, or consult with, the practitioner responsible for the care of the patient, often the practitioner who admitted the patient. We further agree that the medical staff should determine which specific practitioners, including dietitians and nutrition professionals, are qualified for which specific privileges. However, we must point out that this requirement does not require hospitals and medical staff to grant or authorize specific privileges to specific practitioners, but only allows them the flexibility to do so if they choose, and only if State law allows for it.

Comment: Another commenter asked for clarification on whether the proposed requirement only provides a hospital with the option of credentialing and privileging a dietitian.

4/20/2015 Federal Register | Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Part II

Response: The requirement, including the revisions we are finalizing here, does not require hospitals to credential and privilege dietitians as a condition of participation, but, as previously stated, allows for it as an option if consistent with State law.

Comment: A few commenters stated that they were concerned about ordering diets for critically ill patients or making specific patients "NPO." They further state that they would feel comfortable ordering diets only if there was a "diet order per dietitian' order from the doctor."

Response: As we have stated, the requirement does not require dietitians and nutrition professionals to order diets, but only allows for it as an option if consistent with State law and if a hospital chooses to grant such privileges after considering the recommendations of its medical staff. An individual dietitian or nutrition professional would then need to apply for these ordering privileges.

Comment: A few commenters asked for clarification on laboratory ordering privileges for dietitians as part of the proposed requirement. The commenters cited conflicts with the Medicare payment requirements as well as EHR incentives if dietitians were authorized to order lab and other diagnostic services.

Response: As proposed, and as finalized here, the regulatory language did not include privileges for ordering lab or other diagnostic services by dietitians or nutrition professionals. However, the preamble to this section of the proposed rule did include a discussion of such privileges in the context of some of the research cited. Such privileges for dietitians and nutrition professionals are not required or specifically allowed by this requirement, but are instead an option left to hospitals and their medical staffs to determine in consideration of relevant State law as well as any other requirements and/or incentives that CMS or other insurers might have.

In accordance with the comments discussed above, we are finalizing the proposed changes to § 482.28 with the revisions to the regulatory language as noted above.

4. Nuclear Medicine Services (§ 482.53)

The current requirement at § 482.53(b)(1) requires that the in-house preparation of radiopharmaceuticals be performed by, or under the direct supervision of, an appropriately trained registered pharmacist or a doctor of medicine or osteopathy. Direct supervision means that one of these professionals must be physically present in the hospital and immediately available during the preparation of all radiopharmaceuticals. Hospitals have reported to us that this requirement is extremely burdensome when the presence of a pharmacist or physician is required for the provision of off-hour nuclear medicine tests that require only minimal in-house preparation of radiopharmaceuticals. Information from stakeholders regarding this issue has revealed that minimal in-house preparation is required for most radiopharmaceuticals. Many are batch-prepared by the manufacturer for hospital use as a way of reducing radiation exposure of hospital personnel, ensuring that on-site hospital preparation of radiopharmaceuticals generally requires only a few final steps, if any.

4/20/2015 Federal Register | Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Part II

There are about 4,900 hospitals that are certified by Medicare and/or Medicaid. We use these figures to estimate the potential impacts of this final rule. We use the following average hourly costs for registered dietitians, advanced practice registered nurses, physician assistants, pharmacists, and physicians respectively: \$57, \$92, \$93, \$116, and \$192 (BLS Wage Data by Area and Occupation at http://www.bls.gov/bls/blswage.htm, adjusted upward by 5 percent to inflate—on a projected basis—to 2014 dollars and by a further 100 percent to include fringe benefits and overhead costs).

Ordering Privileges for Registered Dietitians (RDs) (Food and Dietetic Services § 482.28)

We are revising the hospital requirements at 42 CFR 482.28 (b), "Food and dietetic services," which currently requires that therapeutic diets must be prescribed by the practitioner or practitioners responsible for the care of the patients. Specifically, we are revising § 482.28(b)(1) and (2) that would change the CMS requirements to allow for flexibility in this area by requiring that all patient diets, including therapeutic diets, must be ordered by a practitioner responsible for the care of the patient, or by a qualified dietitian or qualified nutrition professional as authorized by the medical staff and in accordance with State law. With these changes to the current requirements, a hospital will have the regulatory flexibility either to appoint RDs to the medical staff and grant them specific dietary ordering privileges (including the capacity to order specific laboratory tests to monitor nutritional interventions and then modify those interventions as needed) or to authorize the ordering privileges without appointment to the medical staff, all done through the hospital's medical staff and its rules, regulations, and bylaws. In either instance, medical staff oversight of RDs and their ordering privileges will be ensured.

As we discussed previously in this rule, a 2010 retrospective cohort study 11 of 1,965 patients at an academic medical center looked at the influence of RDs with ordering privileges on appropriate parenteral nutrition (PN) usage and showed a reduction in medically inappropriate PN usage, which translated to an approximately \$135,233 annual savings to the hospital after RDs were granted ordering privileges; included in this savings estimate were solution, materials and pharmacy labor costs specifically related to PN. In order to estimate the reduced costs that our changes to § 482.28 might bring to hospitals, we based our calculations on this study and its finding of \$135,233 savings for a single hospital that granted ordering privileges to RDs. The study presented its figures in 2003 dollars, and to adjust to a comparable figure in 2014 dollars we used the increase in the Gross Domestic Product deflator over this period. Since that index will be up about 25 percent, our savings estimate, rounded, is \$169,000. We note that Peterson et al.'s cost reduction estimate includes only PN solution and pharmacy labor costs, not the savings estimates due to the time needed to administer PN by nurses, time saved by supervising physicians, or many other categories of potential savings. There may, of course, be some minor cost increasing changes, but we know of none that would be consequential (for example, the marginal cost of a day or two eating a regular hospital diet rather than parenteral feeding would at most be a few dollars per patient, and likely close to zero). Importantly, the Peterson et al study found that inappropriate use of PN decreased only to 27 percent of patients when using

4/20/2015 Federal Register | Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Part II nutrition support teams. Other studies have found greater reduction. [2] We use the Peterson et al estimates of dietary changes and add some, but not all, of the other likely savings to our overall estimate of savings.

We estimate that possibly 5 percent (that is, 245) of all hospitals are out of compliance with the CoPs and already granting RDs ordering privileges through appointment to the medical staff or other mechanisms and have already realized these savings. Additionally, an October 2008 study [3] surveyed 1,500 clinical nutrition managers in acute healthcare facilities nationwide in an attempt to describe the level of RD independent prescriptive authority and to explore the barriers to obtaining that authority. The authors of the study reference current CMS policy, stating that: "... independent prescriptive authority via clinical privileges would not be a CMS-accepted pathway for RDs to write orders." This mention of the CMS requirements leads us to believe that our requirements (included in the survey response "regulatory agencies") might present a significant barrier to RDs obtaining dietary ordering privileges. Indeed, the results of the survey indicate that roughly 15 percent of the respondents cited "regulatory agencies" as a barrier to obtaining independent prescriptive authority (or dietary ordering privileges as we refer to it in this rule). However, several limitations inherent in this study lead us to question how heavily we should rely on it for the purposes of estimating how many hospitals will take advantage of this allowance under the CoPs. The survey only looked at the perceptions of clinical nutrition managers regarding barriers to RD ordering privileges and did not survey hospital administrators or governing body members on the reasons why hospitals were unable to grant these privileges to RDs at this time. We believe that such a study, had it been performed, would have been much more meaningful and reliable for our purposes in estimating how many hospitals would possibly implement the granting of ordering privileges to RDs. The authors of the study also state that "... the limitations of this study must be considered and a major limitation was the small response rate (23.4) percent). . ." (or only 351 respondents from the 1,500 clinical nutrition managers surveyed).

As a result of our concerns as to the validity of this study, we specifically discussed this issue with the American Hospital Association (AHA) and the Federation of American Hospitals (FAH), who both assured us that most hospitals will be eager to implement this change and will begin the process of granting the privileges to dietitians upon publication of the rule. Input from all stakeholders has been overwhelmingly, if not universally, supportive. Not one public comment identified any regulatory impediment, other than the hospital CoPs, to change and the comments were overwhelmingly supportive of the policy. Consequently, we believe this survey's results to be flawed or erroneous, and largely irrelevant at this point in time. However, we have decided to use its conclusions as the lower bound of possible hospital policy and practice changes based on this final rule. Therefore, based on this study, it is possible that as few as 15 percent of hospitals (or only 735 hospitals) would take advantage of these changes to revise hospital policy and realize the estimated savings.

Additionally, because there is still some degree of uncertainty involved in estimating how many hospitals will immediately take advantage of this allowance under the CoPs versus how many will elect to gradually phase in such changes to RD ordering privileges, we have chosen to present a primary estimate (based on our experience with hospitals and our discussions with stakeholders) in which 3,675 4/20/2015 Federal Register | Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Part II hospitals (or 75 percent) elect to make these changes, though we believe that an upper bound estimate of nearly 95 percent of hospitals might ultimately implement these changes at some point in the future. Because 75 percent is our primary estimate, we are presenting only those savings estimates and numbers here and not those for the 15-percent lower bound estimate and the 95-percent upper bound estimate. (Our Accounting Table, however, does allow for a wide range of possible lower and upper bound savings, some of which could include both upward and downward changes partially offsetting each other.) Our extensive experience with hospitals, hospital organizations, and RD professional organizations leads us to believe that by finalizing this change here, a significant number of hospitals will move to grant RDs ordering privileges. We also based our savings estimates on the following assumptions:

- The Peterson, et al., study was conducted at a 613-bed tertiary academic medical center; hospitals smaller than the one studied will have lower PN usage due to lower patient censuses and will thus have lower net savings;
- We adjusted the net savings relative to average bed size for hospitals of 164 beds (from AHA Hospital Statistics), meaning that average annual savings will be \$36,513 per hospital using the 2003 figure, but \$45,641 after adjusting for inflation; and
- The savings are based on the impact that RD ordering privileges had on reducing inappropriate PN usage alone and do not include other positive impacts that RD ordering privileges might have on reducing costs to hospitals, such as potential reductions in nursing time needed for dietary administration when patients switch from inappropriate PN to enteral nutrition or a regular hospital diet.

Based on the studies and these assumptions, we estimate a savings of \$167,730,675 (3,675 hospitals \times \$45,641 in savings from reduced inappropriate PN usage = \$167,730,675) annually.

As noted above, the changes we are finalizing might also help hospitals to realize other significant savings. One 2008 study [4] indicates that patients whose PN regimens were ordered by RDs have significantly fewer days of hyperglycemia (57 percent versus 23 percent) and electrolyte abnormalities (72 percent versus 39 percent) compared with patients whose PN regimens were ordered by physicians. Also, a recent literature review concludes that for at least general surgery and trauma patients, starting enteral feeding as soon as possible reduces infectious complications. [5] This will most likely translate into decreased length of stays for these patients as well as quicker recovery times and reduced incidents of readmissions after discharge from the hospital. However, we do not have any reasonable means for estimating these potential cost savings at this time.

More obviously, RDs with ordering privileges will also be able to provide medical nutrition therapy (MNT) and other nutrition services at lower costs than physicians (as well as APRNs and PAs, two categories of non-physician practitioners that have traditionally also devised and written patient dietary plans and orders). This cost savings stems in some part from significant differences in the average salaries between the professions and the time savings achieved by allowing RDs to autonomously plan, order, monitor, and modify services as needed and in a more complete and timely manner than they are

4/20/2015 Federal Register | Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Part II currently allowed. We have estimated the savings that would be realized by hospitals through our changes in terms of the physician/APRN/PA time and salaries saved.

Physicians, APRNs, and PAs often lack the training and educational background to manage the nutritional needs of patients with the same efficiency and skill as RDs. The addition of ordering privileges enhances the ability that RDs already have to provide timely, cost-effective, and evidencebased nutrition services as the recognized nutrition experts on a hospital interdisciplinary team. A 2011 review article [6] discusses a number of additional studies that provide further evidence for the significant differences in nutrition education that exist between physicians and RDs, along with several other studies supporting the cost-effectiveness and positive patient outcomes that hospitals might achieve by granting RDs ordering privileges.

To calculate these cost savings for hospitals, we based our savings estimates on the following assumptions (some of which we have revised from those used in the proposed rule):

- Using the estimate established above, 3,675 hospitals will realize these savings;
- There is an average hourly cost difference of \$69 between RDs on one side (\$57 per hour) and the hourly cost average for physicians, APRNs, and PAs (\$126 per hour) on the other;
- There are on average 7,000 inpatient hospital stays per hospital per year (from AHA Hospital Statistics) with each of these stays requiring at least one dietary plan and orders;
- The average hospital stay is about 5 days (from AHA Hospital Statistics);
- On average, each non-complex dietary order, including ordering and monitoring of laboratory tests, subsequent modifications to orders, and dietary orders for discharge/transfer/outpatient follow-up as needed, will take 8 minutes (0.13 hours) of a physician's/APRN's/PA's/RD's time per patient during an average 5-day stay;
- On average, MNT or more complex dietary orders (for example, PN, tube feedings, patients with multiple co-morbidities, transition of patient from parenteral to enteral feeding, etc.), including ordering and monitoring of laboratory tests, subsequent modifications to orders, and dietary plans and orders for discharge/transfer/outpatient follow-up as needed, will take 18 minutes (0.30 hours) of a physician's/APRN's/PA's/RD's time per patient during an average 5-day stay; and
- The average number of hospital inpatient stays where the patient is determined to be either "at risk for malnutrition" or "malnourished" and/or requires MNT or a more complex dietary plan and orders for other clinical reasons is 1,400 (or 20 percent of inpatient hospital stays) [7] per hospital per year, with a remaining average of 5,600 (or 80 percent) of hospital inpatient stays per hospital per year where the patient is determined to be "not at risk for malnutrition" and/or requires a less complex dietary plan and orders.

The resulting savings estimate is \$291,104,100 ((3,675 hospitals \times 5,600 inpatient hospital stays \times 0.13 hours of a physician's/APRN's/PA's/RD's time × \$69 per hourly cost difference) + (3,675 hospitals × 1,400 inpatient hospital stays \times 0.30 hours of a physician's/APRN's/PA's/RD's time \times \$69 per hourly cost difference)) annually. These hourly estimates are about 57 percent higher than in the proposed rule, due to the improved estimate for fringe benefits and overhead costs, plus inflation update.

4/20/2015 Federal Register | Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Part II

However, we have reduced our estimate of hours saved to reflect the likelihood that physician supervision will remain substantial in some cases. When combined with the savings estimate of \$167,730,675 from reduced inappropriate PN usage, this brings the total savings estimate from the CoP changes to \$458,834,775 (or approximately \$459 million) annually. We note again that these estimates exclude some categories of cost increases (for example, internal hospital meetings to plan changes), and some substantial categories of potential savings in medical treatment costs that we have no current basis for estimating. The net effect of these omitted calculations would be substantially cost saving, and therefore would have no effect on the overall conclusion that the net benefits of this final rule are positive.

We acknowledge several additional kinds of uncertainty in our estimates of the provision's savings. For instance, we have assumed that the time physicians, APRNs or PAs save due to being relieved of dietordering duties will equal the time spent by RDs on those duties. RDs, being the experts in this area and more proficient in evaluating and treating the nutritional needs of patients, might actually need less time than physicians, PAs, or APRNs. As we have stated previously, we have based many of our assumptions and estimates on what we believe is the best available evidence we have from our review of the literature in this area. We have also based our overall assumptions and best estimates on our practical, ongoing experiences with hospitals in these matters. Finally, we have restricted our estimates to inpatient hospital stays and we did not include a discussion of hospital outpatient visits for nutritional services and the impact that these changes might have on hospital costs in this area. We invited public comments on the assumptions and estimates we put forth in the analysis in the proposed rule. The comments we received on the impact of this regulatory change are as follows:

Comment: Several commenters agreed with our assumptions that this regulatory change will reduce burden on physicians and create savings for hospitals.

Response: These comments support our expectation that hospitals are likely to exercise the flexibility that this final rule provides.

Comment: One commenter stated that our low estimate for nutrition savings is "arbitrary and implausible." The commenter pointed out that it is based on a public opinion poll taken of dietitians who are not regulatory experts and could not have been expected to know that it is an existing CMS rule, not hospital staff, which has prevented them from assuming duties commensurate with their expertise. The commenter further stated that "the 'low' estimate should be only a few percent below the primary estimate, and reflect the implausibility that any large fraction of hospitals would not take such obvious savings, even though faced with immense cost pressures from the Affordable Care Act provisions that will over time drastically reduce payments to hospitals."

Response: We agree that the previous "low" estimate was below the likely response of hospitals to the new cost-saving option we provide. Furthermore, in this final rule we are adding other categories of professionals who may establish diets, further adding to hospital flexibility. The commenter's point that professionals expert in the performance of their duties do not necessarily understand the ultimate legal source of regulatory requirements they experience in their daily work is valid and important.

4/20/2015 Federal Register | Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Part II

Nonetheless, we cannot reasonably assume that all hospitals will exercise the flexibility we provide, or do so as soon as permitted. Accordingly, we have modified our estimate.

Comment: One commenter stated their belief that we may have underestimated the possible monetary benefits of this provision. For example, the commenter stated, a dollar estimate of what may be substantial patient health benefits has been omitted.

Response: We agree that there are potentially important and substantial health benefits from allowing the most qualified professional staff to make binding judgments on patient diets. It is quite likely that there will be both morbidity and mortality reduction benefits, as predicted in the professional literature. Nonetheless, we have no empirical data on which to estimate this category of benefit.

Nuclear Medicine Services (§ 482.53)

We proposed, and are finalizing, a change to the current requirement at § 482.53(b)(1), which requires that the in-house preparation of radiopharmaceuticals be performed by, or under the direct supervision of, an appropriately trained registered pharmacist or a doctor of medicine or osteopathy. We are removing the term "direct" from the current requirement. This revision allows for other appropriately trained hospital staff to prepare in-house radiopharmaceuticals under the supervision or oversight of a registered pharmacist or doctor of medicine or osteopathy, but it will not require that such supervision or oversight be exercised by the physical presence in the hospital of one of these professionals, particularly during off-hours when such a professional is not routinely present. The change directly reduces the burden of the current direct supervision requirement where it is most needed— in-house preparation of radiopharmaceuticals for after-hours/emergency performance of nuclear medicine diagnostic procedures.

Based on statistics from the Society of Nuclear Medicine and Molecular Imaging, an estimated 16 million nuclear medicine imaging and therapeutic procedures are performed each year in the United States. We based our estimated savings for this change on the conservative assumptions that:

- Most hospitals will take advantage of this allowance on supervision since it is consistent with the Society of Nuclear Medicine and Molecular Imaging recommendations on this issue;
- The percentage of nuclear medicine procedures performed off-hours (7 p.m.-7 a.m.) is only 10 percent of all procedures performed (or 1.6 million);
- It requires 15 minutes of an MD/DO/PharmD's time for direct supervision; and
- The average hourly cost for these categories of practitioners in 2014 is \$192 including fringe benefits and overhead costs.

Therefore, we estimate hospitals savings will be \$76.8 million for the change (1.6 million off-hour procedures × \$192 hourly salary for MD/DO/PharmD × 15 minutes for direct supervision). We did not receive any public comments on our estimates for savings related to nuclear medicine services.

We are finalizing other revisions to the Hospital CoPs, but we do not believe those provisions will

§ 482.28 Condition of participation: Food and dietetic services.

- * * * * *
- (b) * * *
- (1) Individual patient nutritional needs must be met in accordance with recognized dietary practices.
- (2) All patient diets, including therapeutic diets, must be ordered by a practitioner responsible for the care of the patient, or by a qualified dietitian or qualified nutrition professional as authorized by the medical staff and in accordance with State law governing dietitians and nutrition professionals.

* * * * *

17. Section 482.53 is amended by revising paragraph (b)(1) to read as follows:

§ 482.53 Condition of participation: Nuclear medicine services.

* * * * *

- (b) * * *
- (1) In-house preparation of radiopharmaceuticals is by, or under the supervision of, an appropriately trained registered pharmacist or a doctor of medicine or osteopathy.

* * * * *

18. Section 482.54 is amended by adding paragraph (c) to read as follows:

§ 482.54 Condition of participation: Outpatient services.

* * * * *

- (c) Standard: Orders for outpatient services. Outpatient services must be ordered by a practitioner who meets the following conditions:
- (1) Is responsible for the care of the patient.
- (2) Is licensed in the State where he or she provides care to the patient.
- (3) Is acting within his or her scope of practice under State law.

violation of the Act or this subtitle by the student or graduate.

- A student or graduate shall not receive compensation of any kind directly or indirectly from a patient, except for a salary based on hours worked under supervision.
- A graduate eligible to practice under § 4504.1(b) may practice for no more than twelve (12) months or for the duration of the graduate's postgraduate training program.
- A student or graduate shall be subject to all of the applicable provisions of the Act and this chapter. In accordance with Chapter 41 of this title, the Board may deny an application for a license by, or may take disciplinary action against, a student or graduate who is found to have violated the Act or this chapter.
- 4504.12 As used in this section, the following definitions shall apply:
 - (a) "General supervision" means supervision in which the supervisor is available on the premises or within vocal communication either directly or by a communication device at the time the student or graduate is practicing;
 - (b) "Immediate supervision" means supervision in which the supervisor is with the student or graduate and is either discussing or observing the student's or graduate's practice; and
 - (c) "Supervisor" means a registered nutritionist or dietitian licensed under the Act who is responsible for the supervision of a student or graduate.

4505 CDR EXAM

- Except as provided in 4505.2 of this chapter, all applicants for licensure in the District of Columbia shall receive a passing score on the national registration examination for dietitians offered by the Commission on Dietetic Registration ("CDR Exam").
- 4505.2 The following shall not be required to complete the CDR exam:
 - (a) An applicant for licensure by endorsement;
 - (b) An applicant who is currently certified as a registered dietitian by the Commission on Dietetic Registration of the American Dietetic Association (CDRADA); or
 - (c) An applicant who is currently certified by the Certified Board for Nutrition Specialists as a Certified Nutrition Specialist (CNS).





Alliance for Natural Health USA

3525 Piedmont Road NE Building 6, Suite 310 Atlanta, GA 30305

email: office@anh-usa.org tel: 800.230.2762 202.803.5119 fax: 202.315.5837 www.anh-usa.org

ANH-USA is a regional office of ANH-Intl

INTERNATIONAL anhinternational.org

June 11, 2015

Board of Dietetics and Nutrition 899 North Capitol Street, NE, Room 216 Washington, DC 20002

Re: Regulation of Unlicensed Persons

Dear Board Members:

The Alliance for Natural Health USA ("ANH-USA") respectfully requests that the District of Columbia Board of Dietetics and Nutrition ("Board") cease unlawfully restricting the practice of nutrition and restricting speech concerning nutrition in the District of Columbia. The current structure and practices of the Board are in violation of the U.S. Supreme Court's ruling in *N.C. State Bd. of Dental Exam'rs v. FTC*, 135 S.Ct. 1101 (2015) and the First Amendment. Appropriate changes must be made in order to come into compliance or the Board and its members will be vulnerable to federal prosecution and civil damages.

Illegally Monopolizing Nutrition Services:

In *N.C. State Bd. of Dental Exam'rs v. FTC*, the U.S. Supreme Court held that "active market participants cannot be allowed to regulate their own market free from antitrust accountability." 135 S.Ct. at 1111. The Supreme Court found that state licensing boards may be held liable for anticompetitive actions under the Sherman Antitrust Act when they are comprised of active market participants who use the power of the state to force out competition and protect their own financial interest. 135 S.Ct. 1101. The District of Columbia Board of Dietetics and Nutrition is controlled by members of the very trade it purports to regulate and thus is vulnerable to federal felony prosecution and civil damages. Accordingly, the composition of the Board must be converted to a majority of non-conflicted members or all actions of the Board must be subject to active state supervision.

If the composition of the Board is not altered to include a majority of non-conflicted members, state supervision must "provide 'realistic assurance' that a nonsovereign actor's anticompetitive conduct 'promotes safe policy, rather than merely the party's individual interests." *Id.* at 1116 (*quoting Patrick v. Burget*, 486 U.S. 94, 100-101 (1988)). The Court in *North Carolina* explicitly explains that this supervision must be actual and not theoretical or

peripheral, stating "the supervisor must review the substance of the anticompetitive decision, not merely the procedures followed to produce it; the supervisor must have the power to veto or modify particular decisions to ensure they accord with state policy; and the mere potential for state supervision is not an adequate substitute for a decision by the State." 135 S.Ct. at 1116 (omitting internal citations and quotation).

It is for the above reasons that the composition of the District of Columbia Board of Dietetics and Nutrition must be reformed to include a majority of non-conflicted members or a state supervision mechanism must be immediately created to insure that all action by the Board promotes sound public policy rather than the individual interests of Board members. Without these changes, the actions of the Board will not qualify for immunity under the state action doctrine, ¹ and the Board and its members are potentially vulnerable to federal prosecution and civil damages.

Violating the First Amendment:

The First Amendment provides protection to persons speaking about nutrition outside of a professional relationship, also referred to in this document as general nutrition advice. Courts will likely invalidate licensing schemes, as applied, if they are used to restrict the commercial or non-commercial speech of those who are neither in the regulated class (licensed dietitian or licensed nutritionist) nor hold themselves out to be, or if they are used to suppress commercial speech that is truthful and non-misleading. In other words, regulating nutrition and diet-related speech is limited to circumstances in which an unlicensed person holds himself out to be or otherwise specifically engages in licensed acts in exchange for compensation.

Where the personal nexus between professional and client does not exist, and a speaker does not purport to be exercising expert judgment on behalf of any particular individual with whose circumstances he is directly acquainted, government regulation ceases to function as legitimate regulation of professional practice with only incidental impact on speech; it becomes regulation of speaking or publishing, and as such, is subject to the First Amendment's command that "Congress shall make no law . . . abridging the freedom of speech, or of the press." *Lowe v. SEC*, 472 U.S. 181, 232 (1985) (White, J., concurring).

Individuals have standing to bring First Amendment claims against licensing boards when those licensing boards limit the dissemination of truthful and general advice regarding diet, nutrition, and lifestyle. For instance, the Fourth Circuit Court of Appeals recently held that bloggers who dispensed nutritional advice outside of a practitioner-patient relationship and without claiming a state license, or registration holder had standing to sue licensing boards that prohibited the dissemination of that content. *See Cooksey v. Futrell*, 721 F.3d 226, 239 (4th Cir. 2013). The North Carolina Board of Dietetics/Nutrition eventually settled with the plaintiff and agreed to promulgate new guidelines permitting unlicensed persons, such as bloggers, and general health, wellness and exercise coaches and instructors, to provide dietary, weight loss and nutritional advice.

2

¹ Parker v. Brown, 317 U.S. 341 (1943).

Reforms to Anticompetitive Activities:

In light of the U.S. Supreme Court's decision to extend antitrust liability to regulatory boards and the protection the First Amendment lends to persons providing general nutrition advice and services, ANH-USA respectfully requests that the Board voluntarily curtail regulation of non-state licensed individuals that provide such services. Specifically, ANH-USA requests that the Board limit its enforcement action to title defense only, defined as limiting the use of restricted and specific titles including "Licensed Dietitian," "Registered Dietitians," "Dietitian," and "Licensed Nutritionists." ANH-USA also requests that the Board issue a guidance document to ensure that regulated individuals understand the Board's new enforcement approach, limited to title defense as explained above. The guidance document should additionally explain the rights of regulated individuals under antitrust law and the First Amendment and to ensure the Board is not currently acting in conflict with the law.

In order to comply with current federal antitrust law, it is imperative that the composition of the District of Columbia Board of Dietetics and Nutrition be reformed to include a majority of non-conflicted members or that a mechanism for active state supervision be created to insure actions by the Board promote a specific and articulated public policy rather than the individual interests of Board members and their trade association. Until proper action is taken, the Board must cease operations contrary to law and public policy.

If the Board is not able to make the necessary reforms, ANH requests the Board cease operations entirely until such a time as state law can be changed to reflect the rulings in *North Carolina* and *Cooksey*. Such action will preserve market competition under applicable antitrust and First Amendment laws while providing clarity to state residents regarding the license status of practitioners.

I look forward to engaging with your office on a course of action that will bring the Board into compliance with federal law and to receiving a timely response to our above stated concerns, explaining an expected course of action.

Sincerely,

Allison Murphy, Esq.

Legislative Director

Alliance for Natural Health USA

cc: Attorney General Licensing Board