SEALED

SEALED

FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)

RECEIVED
U.S. DISTRICT COURT
EASTERN DISTRICT OF LA.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF LOUISIANA

UNITED STATES OF AMERICA and MEDICAL ASSISTANCE PROGRAMS *ex rel.* Jessica Albores, Marie Ford, and Margaret Whiteman, and JESSICA ALBORES, MARIE FORD, and MARGARET WHITEMAN, individually,

Plaintiffs,

v.

E.M. DIMITRI, D.O. PMC, d/b/a DIMITRI DERMATOLOGY; AMERICAN MEDICAL SUPPORT SERVICES, LLC; DERMATOLOGIC CENTERS OF AMERICA, LLC; MISSISSIPPI DERMATOLOGY, LLC; MISSISSIPPI SUPPORT SOLUTIONS, LLC; PRECISION MEDICAL BILLING SERVICES LLC; REGIONAL SUPPORT SERVICES, LLC; SHAPIRO DIMITRI MEDICAL, LLC; THE DIMITRI CLINICS, LLC; ELIZABETH DIMITRI, D.O.; KAREN DRAKE; THOMAS ORGERON, M.D.; JOEL PERDOMO, M.D.; and, STEVEN SHAPIRO, M.D.,

Defendants.

DOCKET NO. 18-6936

SECT. H MAG. 3

FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)

JURY TRIAL DEMANDED

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiffs and *qui tam* Relators Jessica Albores, Marie Ford, and Margaret Whiteman (collectively "Relators"), by and through their undersigned counsel JTB Law Group, the Law Offices of Joe A. Flores, and Jackson+Jackson, allege of personal knowledge as to their observations and actions, and on information and belief as to all else, as follows:

I.
PRELIMINARY STATEMENT

1. Elizabeth Dimitri, D.O., operates multiple dermatology clinics in the states of Louisiana and Mississippi. Dimitri committed and directed the commission of the following acts of fraud:

a) performing simple services across multiple sessions to increase billing;

b) billing for injections of Botox that were diluted beyond recommended levels;

c) misdiagnosing patients for the purpose of performing and billing for unnecessary services;

d) billing for services provided by individuals not enrolled in Medicare or Medicaid under the names of enrolled providers;

e) billing for services provided by nurse practitioners under the names of physicians to obtain higher levels of payment;

f) billing for services not provided or for higher levels of service than actually provided; and

g) applying inappropriate billing code modifiers to obtain higher levels of payment.

2. In carrying out this fraud, Defendants knowingly (a) presented or caused to be presented false claims to obtain payments; (b) made or caused to be made or used false records or statements material to these false claims; and (c) conspired to cause these records or statements to be made or used, and/or these claims to be presented. A substantial number of Defendants' false claims were presented to and paid for by Medicare and Louisiana Medicaid.

3. Relators thus bring this *qui tam* action on behalf of the United States of America under the False Claims Act, 31 U.S.C. §§ 3729 *et seq.* (the "FCA"), to recover treble the damages sustained by, and civil penalties and restitution owed to, the United States as a result of Defendants' fraud.

4. Relators also bring this *qui tam* action on behalf of the State of Louisiana under the Louisiana Medical Assistance Programs Integrity Law, La. R.S. § 46:437.1 *et seq.* (the "Louisiana MAPIL"), to recover treble the damages sustained by, and civil penalties and restitution owed to, the State of Louisiana as a result of Defendants' fraud.

5. This Complaint has been filed *in camera* and under seal pursuant to 31 U.S.C. § 3730(b)(2). It will not be served on Defendants unless and until the Court so orders. A copy of the Complaint, along with written disclosure of substantially all material evidence and information that Relators possesses, has been served upon the Attorney General of the United States and on the United States Attorney for the Eastern District of Louisiana pursuant to 31 U.S.C. § 3730(b)(2) and Fed. R. Civ. P. 4(d), and upon the Louisiana Attorney General pursuant to La. R.S. § 46:439.2(A)(2).

II.
JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331, because this action is brought for violations of the False Claims Act, 31 U.S.C. §§ 3729 *et seq.*, a federal statute. In addition, this Court has jurisdiction over the State claims pursuant to 31 U.S.C. § 3732(b).

7. The Court has personal jurisdiction over Defendants because Defendants (a) are residents of, and/or are licensed to transact and do transact business in, this District; and (b) have carried out their fraudulent scheme in this District.

8. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391 (b)(2), because Defendants can be found in, and transact or have transacted business in this District, and the events and omissions that give rise to these claims have occurred in this District.

9. The Complaint has been filed within the period prescribed by 31 U.S.C. §§ 3730(h)(3) and 3731(b), and La. R.S. § 46.439.1(B).

III.
NO PUBLIC DISCLOSURE; DIRECT AND INDEPENDENT KNOWLEDGE OF VIOLATIONS OF THE FALSE CLAIMS ACT

10. There has been no public disclosure, relevant under 31 U.S.C. § 3730(e) and La. R.S. § 46.439.1(D)(1), of the "allegations or transactions" in this Complaint.

11. Relators make the allegations in this Complaint based on their own knowledge, experience and observations.

12. Relators are the original source of the information on which the allegations herein are based, have direct and independent knowledge of such information, and have voluntarily disclosed such information to the United States and the State of Louisiana before filing this action.

IV.
THE PARTIES

A. Government Plaintiffs

13. Plaintiff the United States brings this action by and through Relators. At all times relevant to this Complaint, the United States, acting through the Centers for Medicare & Medicaid Services ("CMS"), has reimbursed Defendants for the provision of various medical services and treatments for eligible individuals through the Medicare program.

14. Plaintiff the State of Louisiana brings this action by and through Relators. At all times relevant to this Complaint, the State of Louisiana, acting through the Louisiana Medical Assistance Program ("Louisiana Medicaid"), has reimbursed Defendants for the provision of various medical services and treatments for eligible individuals through the Medicaid program.

B. Relators

15. Relator Jessica Albores ("Albores") is a citizen of the United States, and a resident of Ascension Parish, Louisiana. At all relevant times, Albores has been a nurse practitioner licensed to practice in the State of Louisiana. Albores worked for Defendants at their offices in Covington, Gonzales, Gretna, Kenner, Metairie, New Orleans, and Slidell, Louisiana from approximately September 2017 until June 1, 2018.

16. Relator Marie Ford ("Ford") is a citizen of the United States, and a resident of Lauderdale County, Mississippi. At all relevant times, Ford has been a nurse practitioner licensed to practice in the State of Mississippi. Ford has worked for Defendants at their offices in Meridian and Brandon, Mississippi from approximately October 2016 until the present day.

17. Relator Margaret Whiteman ("Whiteman") is a citizen of the United States, and a resident of Ascension Parish, Louisiana. At all relevant times, Whiteman has been a nurse practitioner licensed to practice in the State of Louisiana. Whiteman worked for Defendants at their offices in Covington, Gonzales, Gretna, Kenner, Metairie, and Slidell, Louisiana from approximately October 2017 until June 1, 2018.

C. Defendants

18. E.M. Dimitri, D.O. PMC, d/b/a Dimitri Dermatology ("Dimitri Dermatology"), is a Louisiana professional medical corporation with its principal business address at 120 Meadowcrest Street, Suite 235, Gretna, LA 70056. Dimitri Dermatology provides dermatological services at this and seven other locations, including an office located at 2104 Gause Boulevard West, Suite A, Slidell, LA 70460.

19. American Medical Support Services, LLC, is a limited liability company with a mailing address of 2104 Gause Boulevard West, Suite A, Slidell, LA 70460. On information and

belief, American Medical Support Services, LLC, provides payroll, billing, and other related services for the other named Defendants.

20. Dermatologic Centers of America, LLC, is a limited liability company with a mailing address of 2104 Gause Boulevard West, Suite A, Slidell, LA 70460. On information, this company is an alias for Dimitri Dermatology.

21. Mississippi Dermatology, LLC, is a limited liability company with a mailing address of 2104 Gause Boulevard West, Suite A, Slidell, LA 70460. On information, this company is an alias for Dimitri Dermatology. Its listed members are Defendants Elizabeth Dimitri, D.O. and Steven Shapiro, M.D.

22. Mississippi Support Solutions, LLC, is a Mississippi limited liability company. Its listed registered agent is Defendant Karen Drake, located at 1312 22nd Avenue, Suite A, Meridian, MS 39301. Its listed member is Defendant Dimitri, located at 2104 Gause Boulevard West, Suite A, Slidell, LA 70460. On information, this company is an alias for Dimitri Dermatology. On information and belief, Relator Ford has received payments from Mississippi Support Solutions, LLC, in the course of her employment by Defendants.

23. Precision Medical Billing Services LLC is a limited liability company with a mailing address of 2104 Gause Boulevard West, Suite A, Slidell, LA 70460. On information and belief, Precision Medical Billing Services LLC provides payroll, billing, and other related services for the other named Defendants.

24. Regional Support Services, LLC, is a limited liability company located at 2104 Gause Boulevard West, Suite A, Slidell, LA 70460. On information and belief, Regional Support Services, LLC, provides payroll, billing, and other related services for the other named

Defendants. Relators Albores and Whiteman have received payments from Regional Support Services, LLC in the course of their employment by Defendants.

25. Shapiro Dimitri Medical LLC is a limited liability company with a mailing address of 2104 Gause Boulevard West, Suite A, Slidell, LA 70460. On information and belief, this company is an alias for Dimitri Dermatology. On information and belief, Relator Ford has received payments from Shapiro Dimitri Medical LLC in the course of her employment by Defendants.

26. The Dimitri Clinics, LLC, is a Louisiana limited liability company with a mailing address of 2104 Gause Boulevard West, Suite A, Slidell, LA 70460. On information, this company is an alias for Dimitri Dermatology.

27. Elizabeth Dimitri, D.O. ("Dimitri"), is the chief architect of the fraud alleged herein. On information and belief, Dimitri is an owner, member, and/or manager of all of the foregoing Defendant entities.

28. Karen Drake ("Drake") lists herself on LinkedIn as the Corporate General Manager of Dermatologic Centers of America, Dimitri Dermatology, Shapiro Dimitri Medical LLC, Precision Medical Billing Service, and American Medical Support Services. **Exhibit A**, Karen Drake's LinkedIn Profile.[1] According to LinkedIn, she has held these positions since June 2011. On information and belief, Drake has directly participated in the fraud alleged herein.

29. Thomas Orgeron, M.D. ("Orgeron") is a medical provider employed by Dimitri Dermatology and/or its alias companies. On information and belief, Orgeron has directly participated in the fraud alleged herein.

[1] *Available at* https://www.linkedin.com/in/karen-drake-17553069 (last accessed July 6, 2018).

30. Joel Perdomo, M.D. ("Perdomo"), is a medical provider employed by Dimitri Dermatology and/or its alias companies. On information and belief, Perdomo has directly participated in the fraud alleged herein.

31. Steven Shapiro, M.D. ("Shapiro"), is a business partner of Elizabeth Dimitri. On information and belief, Shapiro is an owner, member, and/or manager of all of the foregoing Defendant entities. Shapiro also does business in the State of Mississippi under the following names:

a) Mississippi Dermatology Brandon, located at 908 Municipal Drive, Brandon, MS 39042. This business is also referred to as "The Dimitri Clinic" in online listings[2];

b) Mississippi Dermatology Meridian, located at 1312 22nd Avenue, Suite A, Meridian, MS 39301. This business is also referred to as "The Dimitri Clinic" in online listings[3]; and

c) Mississippi Dermatology Pascagoula, located at 4105 Hospital Street, Pascagoula, MS 39581.

V.
THE LEGAL FRAMEWORK

A. The False Claims Act

32. The False Claims Act, 31 U.S.C. §§ 3729 *et seq.*, (the "FCA"), reflects Congress's objective to "enhance the Government's ability to recover losses as a result of fraud against the Government." S. Rep. No. 99-345, at 1 (1986). As relevant here, the FCA establishes treble damages liability for an individual or entity that:

---

[2] "Mississippi Dermatology/The Dimitri Clinic," Yellow Pages, *available at* https://www.yellowpages.com/brandon-ms/mip/mississippi-dermatology-the-dimitri-clinic-538334594 (last accessed July 6, 2018).

[3] "Mississippi Dermatology/The Dimitri Clinic," Yellow Pages, *available at* https://www.yellowpages.com/meridian-ms/mip/mississippi-dermatology-the-dimitri-clinic-475497852?lid=1001788344353 (last accessed July 6, 2018).

> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; [or]
>
> (C) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid...

31 U.S.C. § 3729(a)(1).

33. "Knowing," within the meaning of the FCA, is defined to include reckless disregard and deliberate indifference. *Id* § 3729(b)(1).

34. For each false claim or other FCA violation, the FCA provides for the assessment of treble damages, plus a civil penalty.[4]

35. The FCA provides for payment of a percentage of the United States' recovery to a private individual who brings suit on behalf of the United States (the "Relator") under the FCA. *See* 31 U.S.C. § 3730(d).

B. The Medicare Program

Program Overview; Provider Enrollment

36. In 1965 Congress enacted Title XVIII of the Social Security Act, known as the Medicare program, to pay for certain healthcare services provided to certain segments of the population. Entitlement to Medicare is based on age, disability, or affliction with end-stage renal disease. *See* 42 U.S.C. §§ 1395 *et seq.*

37. The federal Department of Health and Human Services, through CMS,

[4] 31 U.S.C. § 3729(a)(1)(G) provides a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-410). The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, 28 U.S.C. 2461 note, substituted a different statutory formula for calculating inflation adjustments on an annual basis. On January 29, 2018, the Department of Justice promulgated a Final Rule increasing the penalty for FCA violations occurring after November 2, 2015. For such penalties assessed after January 29, 2018, the minimum penalty is $11,181 and the maximum is $22,363. *See* 28 C.F.R. § 85.5; 82 F.R. 3944 (Jan. 29, 2018).

administers the Medicare program.

38. Part B of the Medicare program authorizes payment of federal funds for outpatient health services, including services such as those provided by Defendants. Part D of the Medicare program authorizes payment for prescription medications, including injections, for Medicare beneficiaries.

39. CMS enters into agreements with healthcare providers such as Defendants to establish their eligibility to participate in the Medicare program. Individuals or entities who are participating providers in Medicare, such as Defendants, may seek reimbursement from CMS for services rendered to patients who are program beneficiaries.

40. To enroll as an authorized participant in Medicare Part B, a clinic or group practice is required to make the following certification:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to this supplier. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare.

Medicare Enrollment Application: Clinics/Group Practices, CMS-855B, at 31.[5]

41. Individual providers enroll in Medicare using the form CMS-855I, or through the online Provider Enrollment, Chain and Ownership System ("PECOS"). CMS-855I contains a certification substantially similar to that in CMS-855B. *See* Medicare Enrollment Application: Physicians and Non-Physician Practitioners, CMS-855I, at 25.[6]

---

[5] *Available* at https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms855b.pdf (last accessed July 11, 2018).

[6] *Available* at https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/cms855i.pdf (last accessed July 11, 2018).

42. Compliance with applicable Medicare program rules and regulations is material to the government's decision to pay and its subsequent payment of claims. In order to be reimbursable by Medicare, services must be medically necessary, must actually be provided, and must be documented in a manner that allows CMS to determine if the services are properly payable.

The Medicare Claims Process

43. In order to receive reimbursement from Medicare, providers such as Defendants must submit a claim form. *See* Form CMS-1500.[7] That claim form requires the provider to make the following certification:

> In submitting this claim for payment from federal funds, I certify that: 1) the information on this form is true, accurate and complete ... 3) I have provided or will provide sufficient information required to allow the government to make an informed eligibility and payment decision; 4) this claim, whether submitted by me or on my behalf by my designated billing company, complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment [and] ... 5) the services on this form were **medically necessary** ....

Id., at 2 (emphasis added).

44. A provider may also submit the electronic equivalent of this claim form, which contains a substantially similar certification.

45. CMS guidance as to electronic claims submission is found in Chapter 24 of the Medicare Claims Processing Manual, CMS Publication No. 100-04 (the "Claims Manual").[8] Among other things, the guidance specifies the minimum content of the enrollment form that a

[7] *Available at* https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms1500.pdf (last accessed July 10, 2018).

[8] *Available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c24.pdf (last accessed July 10, 2018).

local Medicare Administrative Contractor or "MAC"[9] may use to sign up providers such as Defendants to submit claims electronically. Per the Claims Manual, such an enrollment form must contain, and the enrolling provider must acknowledge, at least the following statements:

> The provider agrees to the following provisions for submitting Medicare claims electronically to CMS or to CMS' A/B MACs or CEDI:
>
> * * *
>
> 7. That it will submit claims that are accurate, complete, and truthful;
>
> * * *
>
> 12. That it will acknowledge that all claims will be paid from Federal funds, that the submission of such claims is a claim for payment under the Medicare program, and that anyone who misrepresents or falsified or causes to be misrepresented or falsified any record or other information relating to that claim that is required pursuant to this agreement may, upon conviction, be subject to a fine and/or imprisonment under applicable Federal law; [and]
>
> * * *
>
> 14. That it will research and correct claim discrepancies[.]

Claims Manual, Chapter 24 § 30.2.

46. The submission of such a certification, if false, is a violation of the FCA. 31 U.S.C. § 3729(a).

47. Each such false certification is a separate violation of the FCA.

C. Louisiana Medical Assistance Programs Integrity Law

48. The Louisiana Medical Assistance Programs Integrity Law (the "Louisiana MAPIL"), La. R.S. § 46:437.1 *et seq.*, provides:

> A. No person shall knowingly present or cause to be presented a false or fraudulent claim.

[9] A MAC is a private insurer awarded a geographic jurisdiction to process medical claims for Medicare beneficiaries. MAC jurisdictions can be found at https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/Downloads/AB-MAC-Jurisdiction-Map-Oct-2017.pdf (last accessed July 6, 2018). The current MAC for this jurisdiction, in which Defendants practiced, is Novitas Solutions, Inc.

> B. No person shall knowingly engage in misrepresentation or make, use, or cause to be made or used, a false record or statement material to a false or fraudulent claim.
>
> * * *
>
> D. No person shall conspire to defraud, or attempt to defraud, the medical assistance programs through misrepresentation or by obtaining, or attempting to obtain, payment for a false or fraudulent claim.

La. R.S. §§ 46.438.3.

49. For each violation of any of the above provisions, the Louisiana MAPIL provides for the assessment of actual damages, a civil fine equal to treble damages, a separate civil monetary penalty, interest, and attorneys' fees and costs.[10] *Id.* § 46.438.6(A).

50. Like the FCA, the Louisiana MAPIL permits a private person (the "Relator") to institute a civil action on behalf of Louisiana. *Id.* § 46.439.1(A). The Relator shall receive a percentage of Louisiana's recovery. *See Id.* § 46.439(A)(1), (C)(2).

D. The Louisiana Medicaid Program

51. In conjunction with Medicare, Congress enacted Medicaid under Title XIX of the Social Security Act, 42 U.S.C. §§ 1396 *et seq.*

52. Medicaid is a jointly funded cooperative venture between the federal and state governments to provide health care to certain groups, primarily the poor and the disabled. *See* 42 C.F.R. §§ 430.0 *et seq.* Under the Medicaid program, the federal government pays a specified percentage of each state's Medicaid program expenditures. *See* 42 U.S.C. § 1396d(b).

53. Medicaid programs such as the Louisiana Medical Assistance Program ("Louisiana Medicaid") currently provide coverage for outpatient services and prescription drugs

[10] The civil monetary penalty is subject to inflation according to the Federal Civil Penalties Inflation Adjustment Act of 1990, 28 U.S.C. 2461.

to eligible individuals. Individuals who are enrolled in both Medicare and Medicaid may also receive prescription drug coverage under Medicare Part D.

54. To enroll in Louisiana as an authorized provider, an entity or business must make the following certification:

> 11. The provider agrees to conduct activities/actions in accordance with the Medical Assistance Program Integrity Law (MAPIL Louisiana R.S. Title 46, Chapter 3, Part VI-A) as required to protect the fiscal and programmatic integrity of the medical assistance programs;
>
> * * *
>
> 13. The provider understands that services and/or supplies provided must be medically necessary and medically appropriate for each individual recipient based on needs presented on the date the service is provided and/or delivered; 14. The provider agrees to charge no more for services to eligible recipients than is charged on the average for similar services to others;
>
> * * *
>
> 17. The provider agrees to report and refund any discovered overpayments within sixty (60) days of discovery[.]

Enrollment Packet for the Louisiana Medical Assistance Program: Entities/Businesses, at Addendum Page 2.[11]

55. Individual providers must make an identical certification to enroll. *See* Enrollment Packet for the Louisiana Medical Assistance Program: Entities/Businesses, at Addendum p. 2.[12]

[11] *Available at* http://www.lamedicaid.com/provweb1/provider_enrollment/Enrollment_Entities.pdf (last accessed July 11, 2018).

[12] *Available at* http://www.lamedicaid.com/provweb1/provider_enrollment/Enrollment_Individuals.pdf (last accessed July 11, 2018).

VI.
DEFENDANTS' FRAUD

A. Defendants Spread Out Simple Services for the Purpose of Duplicative and Wasteful Billing

56. Patients commonly visit Defendants' offices for the treatment of actinic keratosis ("AK"), which is a pre-cancerous skin growth caused by excessive exposure to ultraviolent radiation.

57. Removal of AK skin growths may be accomplished using methods including cryosurgery (application of intense cold) or chemosurgery (application of chemicals).

58. Defendants bill for the removal of AK using the following Common Procedural Terminology ("CPT") codes[13]:

a) 17000: destruction of one skin growth. The Medicare allowable amount in Louisiana for code 17000 is $63.41[14];

b) 17003: destruction of each subsequent skin growth number 2 through 14.[15] The Medicare allowable amount in Louisiana for code 17000 is $5.06;

c) 17004: destruction of 15 or more skin growths. Unlike the above codes, 17004 is a "bundled" code that is billed alone, and only once, for a procedure involving 15 or more growths. It is thus reimbursed at a significantly higher rate than 17000 or 17003. The Medicare allowable amount in Louisiana for code 17004 is $138.95.

---

[13] To obtain payment from Medicare and Medicaid, providers use Healthcare Common Procedure Coding System ("HCPCS") codes to represent the medical procedures claimed for payment. Level I HCPCS codes are identical to CPT codes. All medical procedure codes referenced in this Complaint are Level I HCPCS codes, and are thus interchangeable with CPT codes. *See* Medicare CPT/HCPCS Codes, *available at* https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Risk-Adjustors-Items/CPT-HCPCS.html (last accessed July 9, 2018).

[14] *See* CMS Physician Fee Schedule, *available at* https://www.cms.gov/apps/physician-fee-schedule/search/search-results.aspx?Y=0&T=0&HT=0&CT=2&H1=17000&C=73&M=5 (last accessed July 10, 2018). The Medicare allowable amount differs varies depending on factors including the year of service, geographic area, and type of facility in which the service was performed. For the purpose of this Complaint, the relevant Medicare allowable amount is the amount charged in all parts of Louisiana outside of New Orleans.

[15] For instance, a patient who had 5 skin growths removed would be billed under 17000 once, and under 17003 four times.

59. Payments for AK removals are thereby "frontloaded" in the sense that the first removal is worth substantially more than each subsequent removal performed during the same session:

Number of Growths	Total Allowable Amount	Effective Allowable Amount Per Growth
1	$63.41	$63.41
2	$68.47	$34.24
3	$73.53	$24.51
* * *	* * *	* * *
14	$129.19	$9.23
15	$138.95	$9.26
16	$138.95	$8.68

60. In addition, Defendants bill for an evaluation and management ("E/M") office visit on each separate occasion the patient was treated. Defendants billed for visits using the following CPT codes:

a) 99212: established patient office visit, typically 10 minutes. The Medicare allowable amount in Louisiana for code 99212 is $42.00;

b) 99213: established patient office visit, typically 15 minutes. The Medicare allowable amount in Louisiana for code 99213 is $70.51;

c) 99214: established patient office visit, typically 25 minutes. The Medicare allowable amount in Louisiana for code 99214 is $104.30; and

d) 99215: established patient office visit, typically 40 minutes. The Medicare allowable amount in Louisiana for code 99215 is $141.19.

61. At Dimitri's direction, Defendants' physicians and nurse practitioners deliberately and without medical necessity split up chemosurgery skin growth removal into multiple procedures. For instance, instead of removing all skin growths on the face during a single session, providers would instead remove growths on only one cheek. Defendants would then schedule follow-up visits to treat other portions of the patient's face.

62. Defendants also fraudulently bill using code 17004 to obtain the maximum reimbursement despite performing fewer than 15 skin growth removals.

63. Medicare establishes a 10-day post-operative global period for minor surgeries such as the removal of AK skin growths.[16] In effect, "Medicare does not allow separate payment for post-operative visits or services within 10 days of the surgery that are related to recovery from the procedure."[17]

64. To circumvent the global period restrictions, Defendants schedule AK removal procedures such that more than 10 days elapse before a patient receives another procedure.

65. Using this scheme, Defendants substantially increased the amount billed for their services. At the instruction of Dimitri, providers including Relators told patients that spreading out the procedure was necessary for insurance payment purposes.

66. Defendant Thomas Orgeron, M.D., has been especially aggressive in billing for AK removals. In 2016, Orgeron billed Medicare for 520 incidences of code 17004, spread out among 176 unique beneficiaries.[18] In other words, Orgeron's average patient was billed for approximately three procedures justifying code 17004 that year, and thus purportedly had a total of 45 or more skin growths removed. In contrast, the average provider who billed Medicare under 17004 only did so 1.34 times per unique beneficiary in 2016.[19]

67. Relator Ford has knowledge of some of the patients for whom Orgeron billed numerous incidents of 17004. Two patients who stand out in terms of excessive billing are:

---

[16] *See* CMS Global Surgery Booklet, at 5. *Available at* https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/GlobalSurgery-ICN907166.pdf (last accessed July 13, 2018).
[17] *Id.*, at 8.
[18] *See* Medicare Provider Utilization and Payment Data: Physician and Other Supplier PUF CY2016, *available at* https://data.cms.gov/Medicare-Physician-Supplier/Medicare-Provider-Utilization-and-Payment-Data-Phy/utc4-f9xp/data (last accessed July 18, 2018).
[19] *Id.*

a) Patient Doe I: a 100-year-old patient who was billed for the removal of 145 or more skin growths between January 9, 2018 and July 16, 2018. Ford's full-body examination of Doe I revealed AK growths only on Doe I's face.

b) Patient Doe II: a 70-year-old patient who was billed for the removal of 120 or more skin growths across 8 visits between approximately April and July of 2018. For each of Doe II's examination notes, Orgeron used substantially identical and generic language to describe the patient visit. In particular, Orgeron noted that for each visit, "Time was spent educating this patient about surveillance for new potentially precancerous lesions." Orgeron then used this "education time" to justify billing for longer E/M visits.

B. Defendants Provided Unacceptably Low Levels of Botox to Medicaid Beneficiaries

68. Louisiana Medicaid covers prescriptions of OnabotulinumtoxinA (*i.e.* Botox) for beneficiaries diagnosed with conditions including axillary hyperhidrosis (excessive sweating) and chronic migraine.[20]

69. Botox is distributed in vials containing either 100 or 200 units of dried neurotoxin complex. Before applying Botox to patients, providers must first reconstitute the Botox using saline to create an injectable solution.

70. At Dimitri's direction, Defendants' providers administer Botox to Louisiana Medicaid beneficiaries at dilution levels of 100 Units/6 mL or 200 Units/10.5 mL. Defendants use these dilution levels regardless of whether the treatment is for axillary hyperhidrosis or migraines.

71. Specifically, Dimitri sent the following e-mail to Defendants' providers:

> The botox [*sic*] dilution is 6 cc for 100 units and 10.5 cc for 200 units.... Please understand that this dilution is standardized across all clinics to make it more difficlut [*sic*] for our nursing staff to make errors....

[20] *See* Louisiana Department of Health Memorandum dated Feb. 10, 2017, at 8. *Available at* http://www.lamedicaid.com/provweb1/pharmacy/Humira_and_Dysport_Policy_2-13-17.pdf (last accessed July 10, 2018).

> Remember, you aren't the only one using the bottle and everyone is working under ther [*sic*] assumption that there are 10 units per 1/2 cc.

Exhibit B, Dimitri's Botox Instruction.

72. Allergen, the manufacturer of Botox, published the following recommended dilution level for treating axillary hyperhidrosis: "The recommended dilution is 100 Units/4 mL with preservative-free 0.9% Sodium Chloride Injection...." *See* **Exhibit C**, Excerpt from Botox package insert, at 9. Applying this recommendation, each 100-unit vial of Botox should yield approximately 4 mL of injectable solution with a concentration of 2.5 units of Botox per 0.1 mL.

73. As a result of their excessive dilution, Defendants create approximately 6 mL of solution with a concentration of 1.67 units per 0.1 mL. Despite Defendants' solution being only two-thirds of the recommendation concentration, Defendants inject axillary hyperhidrosis patients with the same volume of Botox as if it had been diluted as recommended. As a result, these patients receive substantially less than the full amount of Botox for which Louisiana Medicaid pays.

74. Allergen also provides the following recommended dilution level for treating chronic migraines: "The recommended dilution is 200 Units/4 mL or 100 Units/2 mL, with a final concentration of 5 units per 0.1 mL...." **Exhibit C**, at 6.

75. As a result of their excessive dilution, Defendants create approximately 6 mL of solution with a concentration of 1.67 units per 0.1 mL, or 10 mL with a concentration of 2 units per 0.1 mL. Despite Defendants' solution containing as little as one-third of the recommendation concentration, Defendants inject chronic migraine patients with the same volume of Botox as if it had been diluted as recommended. As a result, these patients receive substantially less than the full amount of Botox for which Louisiana Medicaid paid.

76. Defendants then use the leftover Botox solution to provide cosmetic injections to patients who pay out-of-pocket. Because these injections have already been paid for by Louisiana Medicaid, Defendants earn substantial margins on these services.

77. Each vial of Botox is accompanied by a lot number. Generally, this lot number is recorded by both the pharmacy that dispensed the Botox and the provider that applies it.

78. Just like other prescriptions, each vial of Botox is intended only for the use of the patient to whom it is prescribed.

79. Defendants' log books contain entries showing that the same vial of Botox, as indicated by lot number, has been used to treat multiple patients.

C. Defendants Deliberately Misdiagnosed Patients to Justify Unnecessary Procedures

80. Defendants' providers, including Dimitri, deliberately misdiagnosed Medicare and Louisiana Medicaid beneficiaries to justify and bill for unnecessary procedures.

81. As alleged above, AK skin growths may be removed using the application of chemicals. Defendants perform such a procedure using trichloroacetic acid ("TCA").

82. TCA is also used as an over-the-counter "chemical peel," to be applied to the face for cosmetic purposes.

83. Defendants' providers, including Dimitri, urge Medicare and Louisiana Medicaid beneficiaries to undergo TCA treatment for cosmetic purposes even when such patients did not suffer from AK.

84. If the patient assents to TCA treatment, as they often do after pressure from Defendants, Defendants' providers falsely document that the patient has been diagnosed with AK.

85. Defendants then bill for these purely cosmetic procedures using code 17004, indicating that 15 or more skin growths have been removed.

86. Furthermore, Defendants' providers, including Dimitri and Orgeron, falsely diagnose Medicare and Louisiana Medicaid beneficiaries as suffering from pruritus. Pruritus is chronic itchiness of the skin, and may be a symptom of acne. When a patient arrives to seek treatment for acne, Defendants reflexively diagnose that patient with pruritus regardless of whether or not the patient experiences any itching.

87. Defendants use this false diagnosis of pruritus to justify the provision of phototherapy using ultraviolet B light. Defendants bill for this phototherapy using CPT code 96910. The Medicare allowable amount in Louisiana for code 96910 is $102.73.

88. Defendants then schedule patients for multiple follow-up visits to continue phototherapy, even though the procedure was never necessary to begin with.

89. In addition, Defendants' providers, including Dimitri, falsely diagnose chronic migraines or axillary hyperhidrosis to accommodate patients seeking Botox solely for cosmetic purposes. By using these false diagnoses, Defendants are able to bill Louisiana Medicaid and other insurance plans for non-covered cosmetic Botox.

90. The improper purpose of such Botox treatments is evident from their injection locations. To treat chronic migraines, Botox is injected in sites including muscles of the forehead, neck, and upper shoulders. *See* **Exhibit C**, at 7. For cosmetic treatments, Defendants inject Botox in sites including areas around the eyes and mouth. On multiple occasions, Defendants' providers, including Dimitri, have injected Botox in the eye and mouth areas of patients who were diagnosed with, and supposedly seeking treatment for, chronic migraines.

91. To treat axillary hyperhidrosis, Botox is typically injected in the underarm. *Id.*, at 9-10. On at least one occasion, Defendants' medical records indicated that a patient's underarms were shaved in preparation for a Botox injection to treat axillary hyperhidrosis, but also indicated that the injection was only applied to the orbicularis oris (mouth muscle).

D. Defendants Bill for Services Performed by Ineligible Providers

92. Defendants employ or contract with providers who are not enrolled as Medicare providers, and are thus ineligible to submit claims for payment to Medicare.

93. Nevertheless, non-enrolled providers regularly render services to Medicare beneficiaries. Defendants submit the claims for such services to Medicare under the names of enrolled providers who work for Defendants, but who did not actually render or even supervise the underlying services.

94. Alternatively, Defendants bill for services of non-enrolled providers as "incident to" the services of an enrolled provider. To be covered by Medicare, services billed as "incident to" must be "[f]urnished by the physician or by auxiliary personnel under the physician's direct supervision."[21]

95. Similarly, Defendants' providers who are not enrolled in Louisiana Medicaid bill for services rendered to Louisiana Medicaid beneficiaries under the names of, or incident to services provided by, providers who are enrolled but did not actually provide or supervise the services.

[21] *See* Medicare Ch. 15, § 60.1B, *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf (last accessed July 13, 2018).

E. Defendants Bill for Non-Physician Services under the Physician Fee Schedule

96. Under Medicare guidelines, a nurse practitioner ("NP") is reimbursed for services at 80 percent of the actual charge or 85 percent of the Medicare Physician Fee Schedule charge, whichever is less.[22]

97. Under the direction of Dimitri, Defendants bill for services rendered by NPs, including Relators, under the names of physicians who did not provide or even supervise such services. Alternatively, Defendants bill for services of NPs as "incident to" the services of physicians who did not supervise such services.

98. Defendants thereby obtained reimbursement at the full physician rate, instead of at the appropriate discounted level.

F. Defendants Bill for Services Not Provided or Higher Levels than Actually Provided

99. Defendants' providers routinely bill for services that were not actually provided.

100. As alleged above, Defendants' providers bill using CPT code 17004, indicating that 15 or more skin growths were removed, despite performing fewer than 15 removals.

101. Defendant Orgeron routinely bill using CPT code 10061 for the complicated incision and drainage of abscesses, even though no such procedure was performed. Orgeron billed in this manner for substantially all of his Medicare patients seeking acne treatment.

102. Furthermore, at Dimitri's direction, Defendants' providers routinely billed for longer office visits than actually transpired.

103. On multiple occasions, Dimitri expressed displeasure toward Relator Ford for truthfully billing E/M office visits under CPT code 99212, indicating a visit of typically 10 minutes. Dimitri told Ford to bill using 99213, indicating a visit of typically 15 minutes.

---

[22] *See* Medicare Claims Processing Manual, Ch. 12 § 120A, *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c12.pdf (last accessed July 10, 2018).

104. When an insurer, including Medicare and Medicaid, refused to cover certain procedures such as UV phototherapy, Dimitri instructed providers including Relators Albores and Ford to "upcode" E/M visits to make up for the loss. To justify upcoding, Dimitri instructed providers to falsely alter medical documentation after the fact.

G. Defendants Bill Using Inappropriate Coding Modifiers

105. Medicare will reimburse for an E/M service occurring on the same day as a surgical procedure only if it is "a significant, separately identifiable E/M service that is above and beyond the usual pre- and post-operative work of the procedure."[23]

106. To indicate that an E/M service meets the above criterion and is therefore eligible for reimbursement, a provider must append CPT code modifier 25 to the regular E/M code.

107. Defendants routinely, and without justification, append CPT modifier 25 to their E/M office visit billing. For instance, Defendants apply modifier 25 to substantially all E/M billing related to AK removal procedures.

108. However, Defendants' providers do not perform significant, separately identifiable E/M services above and beyond the usual pre- and post-operative work. Instead, any E/M service provided is solely incident to or part of the underlying procedure. The lack of reimbursable E/M service is most apparent during AK removal follow-up visits, which are scheduled solely for the purpose of completing a procedure intentionally delayed for billing purposes, as alleged above.

109. To lend credence to their use of modifier 25, Defendants' providers document irrelevant diagnoses on patient examination notes, or otherwise embellish the nature and extent of the visit. For example, Relator Ford once attended to a patient seeking phototherapy treatment

[23] *Id.* § 30.6.6B.

for psoriasis. Upon finding that said patient had a history of hypertension, Dimitri instructed Relator Ford to document hypertension as the patient's primary diagnosis. This diagnosis of hypertension was used to justify a separate E/M service on top of the phototherapy treatment.

110. As alleged above, Orgeron repetitively documented that "Time was spent educating this patient about surveillance for potentially precancerous lesions," even though said patient had received such education seven prior times.

111. On multiple occasions, Dimitri has reprimanded Relator Albores for failing to bill for a separate E/M code in addition to the underlying procedure. Dimitri told Albores that if Albores looked hard enough, she should be able to find issues to justify additional coding.

COUNT I
FEDERAL FALSE CLAIMS ACT: PRESENTATION OF FALSE CLAIMS

112. Relators repeat and re-allege all preceding paragraphs of the Complaint inclusive, as if fully set forth herein.

113. As alleged above, Defendants presented claims to CMS for:

a) performing AK removal services across multiple sessions to increase billing;

b) misdiagnosing patients for the purpose of performing and billing for unnecessary services;

c) billing for services provided by individuals not enrolled in Medicare under the names of enrolled providers;

d) billing for services provided by nurse practitioners under the names of physicians to obtain higher levels of payment;

e) billing for services not provided or for higher levels of service than actually provided; and

f) applying inappropriate billing code modifiers to obtain higher levels of payment.

114. For each of their claims for reimbursement, Defendants certified that the information they were providing was true, accurate and complete; and that the claim complied with all applicable Medicare laws, regulations, and instructions for payment.

115. Each such representation was false, for the reasons described above.

116. Accordingly, Defendants knowingly, or in reckless disregard for the truth, presented false or fraudulent claims for payment in violation of 31 U.S.C. § 3729(a)(l)(A).

117. The submission by Defendants of these false claims caused CMS to pay out monies that CMS would not have paid if it had known of the falsity of Defendants' claims and certifications.

118. Each false or fraudulent claim submitted to CMS is a separate violation of the FCA.

119. By reason of the false or fraudulent claims that Defendants knowingly presented, the United States has been damaged in a substantial amount to be proven at trial.

COUNT II
FEDERAL FALSE CLAIMS ACT: MAKING OR USING FALSE RECORD OR STATEMENT TO CAUSE FALSE CLAIM TO BE PAID

120. Relators repeat and re-allege all preceding paragraphs of the Complaint inclusive, as if fully set forth herein.

121. As described above, Defendants knowingly, or in reckless disregard for the truth, used false records and statements when they submitted claims for payment, including false documentation of patients' diagnoses.

122. Accordingly, Defendants knowingly used false records or statements material to false or fraudulent claims for payment, in violation of 31 U.S.C. § 3729(a)(l)(B).

123. The submission of these false records or statements caused CMS to pay out monies that CMS would not have paid if it had known of the falsity of Defendants' records or statements.

124. Each submission of a false record or statement is a separate violation of the FCA.

125. By reason of the false or fraudulent records or statements that Defendants knowingly submitted, the United States has been damaged in a substantial amount to be proven at trial.

COUNT III
FEDERAL FALSE CLAIMS ACT:
CONSPIRACY TO GET A FALSE CLAIM PAID

126. Relators repeat and re-allege all preceding paragraphs of the Complaint inclusive, as if fully set forth herein.

127. As described above, the named Defendants conspired among themselves to submit false claims in violation of 31 U.S.C. § 3729(a)(l)(C).

128. As a result of this conspiracy, the United States has been damaged in a substantial amount to be proven at trial.

COUNT IV
LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW
PRESENTATION OF FALSE CLAIMS

129. Relators repeat and re-allege all preceding paragraphs of the Complaint inclusive, as if fully set forth herein.

130. As alleged above, Defendants presented claims to Louisiana Medicaid for:

a) performing AK removal services across multiple sessions to increase billing;

b) billing for injections of Botox that were diluted beyond recommended levels;

c) misdiagnosing patients for the purpose of performing and billing for unnecessary services;

d) billing for services provided by individuals not enrolled in Louisiana Medicaid under the names of enrolled providers;

e) billing for services provided by nurse practitioners under the names of physicians to obtain higher levels of payment;

f) billing for services not provided or for higher levels of service than actually provided; and

g) applying inappropriate billing code modifiers to obtain higher levels of payment.

131. For each of their claims for reimbursement, Defendants certified that the information they were providing was true, accurate and complete; and that the claim complied with the Louisiana MAPIL and other laws, regulations, and instructions for payment.

132. Each such representation was false, for the reasons described above.

133. Accordingly, Defendants knowingly, or in reckless disregard for the truth, presented false or fraudulent claims for payment in violation of La. R.S. § 46.438.3(A).

134. The submission by Defendants of these false claims caused Louisiana Medicaid to pay out monies that Louisiana Medicaid would not have paid if it had known of the falsity of Defendants' claims and certifications.

135. Each false or fraudulent claim submitted to Louisiana Medicaid is a separate violation of the Louisiana MAPIL.

136. By reason of the false or fraudulent claims that Defendants knowingly presented, the State of Louisiana has been damaged in a substantial amount to be proven at trial.

COUNT V
LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW
FALSE RECORD OR STATEMENT

137. Relators repeat and re-allege all preceding paragraphs of the Complaint inclusive, as if fully set forth herein.

138. As described above, Defendants knowingly, or in reckless disregard for the truth, used false records and statements when they submitted claims for payment, including false documentation of patients' diagnoses.

139. Accordingly, Defendants knowingly used false records or statements material to false or fraudulent claims for payment, in violation of La. R.S. § 46.438.3(B).

140. The submission of these false records or statements caused Louisiana Medicaid to pay out monies that Louisiana Medicaid would not have paid if it had known of the falsity of Defendants' records or statements.

141. Each submission of a false record or statement is a separate violation of the Louisiana MAPIL.

142. By reason of the false or fraudulent records or statements that Defendants knowingly submitted, the State of Louisiana has been damaged in a substantial amount to be proven at trial.

COUNT VI
LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW
CONSPIRACY TO GET A FALSE CLAIM PAID

143. Relators repeat and re-allege all preceding paragraphs of the Complaint inclusive, as if fully set forth herein.

144. As described above, the named Defendants conspired among themselves to submit false claims in violation of La. R.S. § 46.438.3(D)

145. As a result of this conspiracy, the State of Louisiana has been damaged in a substantial amount to be proven at trial.

PRAYER FOR RELIEF

WHEREFORE, Relators respectfully requests that this Court enter judgment in their favor and that of the United States and the State of Louisiana, and against Defendants, granting the following on all Counts:

(A) an award to the United States for treble its damages, a statutory penalty for each violation of the FCA, and for its costs pursuant to 31 U.S.C. § 3729(a)(3);

(B) an award to the State of Louisiana for its actual damages, a civil fine equal to treble damages, a civil monetary penalty for each violation, interest, and for its costs pursuant to La. R.S. § 46.438.6(A);

(C) an award to Relators in the maximum amount permitted under 31 U.S.C. § 3730(d), and for the reasonable attorneys' fees, costs, and expenses they incurred in prosecuting this action;

(D) an award to Relators in the maximum amount permitted under La R.S. §§ 46.439(A)(1) or 46.439(C)(2), and for the reasonable attorneys' fees, costs, and expenses they incurred in prosecuting this action;

(E) awards to the United States, the State of Louisiana, and Relators for pre- and post-judgment interest at the rates permitted by law; and

(F) an award of such other and further relief as this Court may deem to be just and proper.

[this space intentionally left blank]

FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)

DEMAND FOR TRIAL BY JURY

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Relators demands trial by jury on all questions of fact raised by the Complaint.

Dated: July 24, 2018

Respectfully submitted,

By: */s/ Mary Bubbett Jackson*
Jody Forester Jackson, (# 28938)
Mary Bubbett Jackson, (# 29110)
JACKSON+JACKSON
201 St. Charles Avenue, Suite 2500
New Orleans, Louisiana 70170
Telephone: (504) 599-5953
Fax: (888) 988-6499
jjackson@jackson-law.net
mjackson@jackson-law.net

JTB LAW GROUP - BROWN LLC
Jason T. Brown
(*pro hac vice* application forthcoming)
Benjamin Lin
(*pro hac vice* application forthcoming)
Patrick S. Almonrode
(*pro hac vice* application forthcoming)
155 2nd Street, Suite 4
Jersey City, NJ 07302
(877) 561-0000 (office)
(855) 582-5297 (fax)
jtb@jtblawgroup.com
ben.lin@jtblawgroup.com
patalmonrode@jtblawgroup.com

LAW OFFICES OF JOE A. FLORES
Joe A. Flores
(*pro hac vice* application forthcoming)
500 N. Water Street, Suite 515
Corpus Christi, TX 78478
(361) 887-8670 (office)
(361) 887-8651 (fax)
jaflores0756@sbcglobal.net

Attorneys for Relators

FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)

CERTIFICATE OF SERVICE

I hereby certify that on July 24, 2018, I caused a true copy of the Complaint in the matter captioned *United States of America and Medical Assistance Programs ex rel. Jessica Albores, et. al. v. E.M. Dimitri, D.O. PMC, et al.* to be served upon the following, along with written disclosure of substantially all material evidence and information possessed by Relators:

by hand delivery to

Duane A. Evans
United States Attorney's Office
Eastern District of Louisiana
650 Poydras Street, Suite 1600
New Orleans, Louisiana 70130

by USPS Registered Mail, Return Receipt Requested, to

Jeff Landry
Louisiana Department of Justice
1885 North Third Street
Baton Rouge, LA 70802

Office of the Attorney General of the United States
United States Department of Justice
950 Florida Avenue, NW
Washington, DC 20530-0001

/s/Mary Bubbett Jackson
Mary Bubbett Jackson

EXHIBIT A

Karen Drake

Corporate General Manager

Slidell Louisiana | Medical Practice

79 connections

Current: Dimitri Dermatology

Recommendations: 1 person has recommended Karen Drake

Karen Drake's Activity

Karen Drake liked this

Love this

Experience

Corporate General Manager

Dimitri Dermatology

June 2011 – Present (7 years 2 months) | Slidell, La. 70460

Corporate General Manager of
Dermatologic Centers of America, Dimitri Dermatology, Shapiro Dimitri Medical LLC, Precision Medical Billing Service, American Medical Support Services

Skills & Endorsements

Recommendations

A preview of what LinkedIn members have to say about Karen:

> *Karen was my direct supervisor. Her knowledge and dedication to her position with Dimitri Dermatology made my transition into the company an easy one....*
>
> See more

EXHIBIT B

Date: 01/12/2017 10:49:45 AM

From: Dimitri, Elizabeth M

To:
zzAverett,Courtney;Birkhoff,Janice;zzCallender,Mark;Cordle,Mary;Cruz,Jorge;Dimitri,Elizabeth;Ford,Marie;Hubble,Clay;Janeski,Belinda;Malley,Jennifer;Mosadegh,Mehdi;Orgeron,Thomas;Perdomo,Joel;zzReed,Patricia;Shapiro,Steven;Tran,Thuy;West,Michelda

Subject: Botox Dilution

The botox dilution is 6 cc for 100 units and 10.5 cc for 200 units. The reason is the air in the diluent syringe. When we dilute with 6 cc, for some reason we never get more than a hair over 5 cc out of the bottle. The 200cc vial can only accomodate 10.5cc MAX. Please understand that this dilution is standardized across all clinics to make it more difficlut for our nursing staff to make errors. Please respond that you have recieved this message and understand. Remember, you aren't the only one using the bottle and everyone is working under ther assumption that there are 10 units per 1/2 cc. Thanks Elizabeth

Here are the Directions sent to use per Dr. Dimitri about Botox dilution.

There is no air in the syringes We use a certain type of syringe that allows you to inject ALL medication - I can show you the difference in these syringes if needed.

EXHIBIT C

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use BOTOX® safely and effectively. See full prescribing information for BOTOX.

BOTOX (onabotulinumtoxinA) for injection, for intramuscular, intradetrusor, or intradermal use
Initial U.S. Approval: 1989

WARNING: DISTANT SPREAD OF TOXIN EFFECT

See full prescribing information for complete boxed warning.

The effects of BOTOX and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life threatening and there have been reports of death. The risk of symptoms is probably greatest in children treated for spasticity but symptoms can also occur in adults, particularly in those patients who have an underlying condition that would predispose them to these symptoms. (5.2)

RECENT MAJOR CHANGES

Dosage and Administration, Instructions for Safe Use (2.1) 5/2018

INDICATIONS AND USAGE

BOTOX is an acetylcholine release inhibitor and a neuromuscular blocking agent indicated for:

- Treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication (1.1)
- Treatment of urinary incontinence due to detrusor overactivity associated with a neurologic condition [e.g., spinal cord injury (SCI), multiple sclerosis (MS)] in adults who have an inadequate response to or are intolerant of an anticholinergic medication (1.1)
- Prophylaxis of headaches in adult patients with chronic migraine (≥15 days per month with headache lasting 4 hours a day or longer) (1.2)
- Treatment of spasticity in adult patients (1.3)
- Treatment of cervical dystonia in adult patients, to reduce the severity of abnormal head position and neck pain (1.4)
- Treatment of severe axillary hyperhidrosis that is inadequately managed by topical agents in adult patients (1.5)
- Treatment of blepharospasm associated with dystonia in patients ≥12 years of age (1.6)
- Treatment of strabismus in patients ≥12 years of age (1.6)

Important Limitations: Safety and effectiveness of BOTOX have not been established for:

- Prophylaxis of episodic migraine (14 headache days or fewer per month) (1.2)
- Treatment of upper or lower limb spasticity in pediatric patients (1.3)
- Treatment of hyperhidrosis in body areas other than axillary (1.5)

DOSAGE AND ADMINISTRATION

- Follow indication-specific dosage and administration recommendations; Do not exceed a total dose of 400 Units administered in a 3 month interval (2.1)
- See Preparation and Dilution Technique for instructions on BOTOX reconstitution, storage, and preparation before injection (2.2)
- Overactive Bladder: Recommended total dose 100 Units, as 0.5 mL (5 Units) injections across 20 sites into the detrusor (2.3)
- Detrusor Overactivity associated with a Neurologic Condition: Recommended total dose 200 Units, as 1 mL (~6.7 Units) injections across 30 sites into the detrusor (2.3)
- Chronic Migraine: Recommended total dose 155 Units, as 0.1 mL (5 Units) injections per each site divided across 7 head/neck muscles (2.4)
- Upper Limb Spasticity: Select dose based on muscles affected, severity of muscle activity, prior response to treatment, and adverse event history; Electromyographic guidance recommended (2.5)
- Lower Limb Spasticity: Recommended total dose 300 Units to 400 Units divided across ankle and toe muscles (2.5)
- Cervical Dystonia: Base dosing on the patient's head and neck position, localization of pain, muscle hypertrophy, patient response, and adverse event history; use lower initial dose in botulinum toxin naïve patients (2.6)
- Axillary Hyperhidrosis: 50 Units per axilla (2.7)
- Blepharospasm: 1.25 Units-2.5 Units into each of 3 sites per affected eye (2.8)
- Strabismus: The dose is based on prism diopter correction or previous response to treatment with BOTOX (2.9)

DOSAGE FORMS AND STRENGTHS

For Injection: 100 Units or 200 Units vacuum-dried powder in a single-dose vial (3)

CONTRAINDICATIONS

- Hypersensitivity to any botulinum toxin preparation or to any of the components in the formulation (4.1, 5.4, 6)
- Infection at the proposed injection site (4.2)
- Intradetrusor Injections: Urinary Tract Infection or Urinary Retention (4.3)

WARNINGS AND PRECAUTIONS

- Potency Units of BOTOX are not interchangeable with other preparations of botulinum toxin products (5.1, 11)
- Spread of toxin effects; swallowing and breathing difficulties can lead to death. Seek immediate medical attention if respiratory, speech or swallowing difficulties occur (5.2, 5.6)
- Potential serious adverse reactions after BOTOX injections for unapproved uses (5.3)
- Concomitant neuromuscular disorder may exacerbate clinical effects of treatment (5.5)
- Use with caution in patients with compromised respiratory function (5.6, 5.7, 5.10)
- Corneal exposure and ulceration due to reduced blinking may occur with BOTOX treatment of blepharospasm (5.8)
- Retrobulbar hemorrhages and compromised retinal circulation may occur with BOTOX treatment of strabismus (5.9)
- Bronchitis and upper respiratory tract infections in patients treated for spasticity (5.10)
- Urinary tract infections in patients treated for OAB (5.12)
- Urinary retention: Post-void residual urine volume should be monitored in patients treated for OAB or detrusor overactivity associated with a neurologic condition who do not catheterize routinely, particularly patients with multiple sclerosis or diabetes mellitus. (5.13)

ADVERSE REACTIONS

The most common adverse reactions (≥5% and >placebo) are (6.1):

- OAB: urinary tract infection, dysuria, urinary retention
- Detrusor Overactivity associated with a neurologic condition: urinary tract infection, urinary retention
- Chronic Migraine: neck pain, headache
- Spasticity: pain in extremity
- Cervical Dystonia: dysphagia, upper respiratory infection, neck pain, headache, increased cough, flu syndrome, back pain, rhinitis
- Axillary Hyperhidrosis: injection site pain and hemorrhage, non-axillary sweating, pharyngitis, flu syndrome

To report SUSPECTED ADVERSE REACTIONS, contact Allergan at 1-800-678-1605 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

Patients receiving concomitant treatment of BOTOX and aminoglycosides or other agents interfering with neuromuscular transmission (e.g., curare-like agents), or muscle relaxants, should be observed closely because the effect of BOTOX may be potentiated (7)

USE IN SPECIFIC POPULATIONS

- Pregnancy: Based on animal data, may cause fetal harm. (8.1)
- Pediatric Use: Safety and efficacy are not established in patients under 18 years of age for the prophylaxis of headaches in chronic migraine, treatment of OAB, detrusor overactivity associated with a neurologic condition, spasticity, and axillary hyperhidrosis; in patients under 16 years of age for treatment of cervical dystonia; and in patients under 12 years of age for treatment of blepharospasm and strabismus (8.4)

See 17 for PATIENT COUNSELING INFORMATION and Medication Guide.

Revised: 05/2018

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

WARNING: DISTANT SPREAD OF TOXIN EFFECT

Postmarketing reports indicate that the effects of BOTOX and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These may include asthenia, generalized muscle weakness, diplopia, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence and breathing difficulties. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life threatening and there have been reports of death. The risk of symptoms is probably greatest in children treated for spasticity but symptoms can also occur in adults treated for spasticity and other conditions, particularly in those patients who have an underlying condition that would predispose them to these symptoms. In unapproved uses, including spasticity in children, and in approved indications, cases of spread of effect have been reported at doses comparable to those used to treat cervical dystonia and spasticity and at lower doses. ***[See Warnings and Precautions (5.2)]***

1 INDICATIONS AND USAGE

1.1 Bladder Dysfunction

Overactive Bladder

BOTOX (onabotulinumtoxinA) for injection is indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency, in adults who have an inadequate response to or are intolerant of an anticholinergic medication.

Detrusor Overactivity associated with a Neurologic Condition

BOTOX is indicated for the treatment of urinary incontinence due to detrusor overactivity associated with a neurologic condition (e.g., SCI, MS) in adults who have an inadequate response to or are intolerant of an anticholinergic medication.

1.2 Chronic Migraine

BOTOX is indicated for the prophylaxis of headaches in adult patients with chronic migraine (≥15 days per month with headache lasting 4 hours a day or longer).

Important Limitations

Safety and effectiveness have not been established for the prophylaxis of episodic migraine (14 headache days or fewer per month) in seven placebo-controlled studies.

1.3 Spasticity

Upper Limb Spasticity

BOTOX is indicated for the treatment of upper limb spasticity in adult patients, to decrease the severity of increased muscle tone in elbow flexors (biceps), wrist flexors (flexor carpi radialis and flexor carpi ulnaris), finger flexors (flexor digitorum profundus and flexor digitorum sublimis), and thumb flexors (adductor pollicis and flexor pollicis longus).

Lower Limb Spasticity

BOTOX is indicated for the treatment of lower limb spasticity in adult patients to decrease the severity of increased muscle tone in ankle and toe flexors (gastrocnemius, soleus, tibialis posterior, flexor hallucis longus, and flexor digitorum longus).

Important Limitations

Safety and effectiveness of BOTOX have not been established for the treatment of other upper or lower limb muscle groups. Safety and effectiveness of BOTOX have not been established for the treatment of spasticity in pediatric patients under age 18 years. BOTOX has not been shown to improve upper extremity functional abilities, or range of motion at a joint affected by a fixed contracture. Treatment with BOTOX is not intended to substitute for usual standard of care rehabilitation regimens.

1.4 Cervical Dystonia

BOTOX is indicated for the treatment of adults with cervical dystonia, to reduce the severity of abnormal head position and neck pain associated with cervical dystonia.

1.5 Primary Axillary Hyperhidrosis

BOTOX is indicated for the treatment of severe primary axillary hyperhidrosis that is inadequately managed with topical agents.

Important Limitations

The safety and effectiveness of BOTOX for hyperhidrosis in other body areas have not been established. Weakness of hand muscles and blepharoptosis may occur in patients who receive BOTOX for palmar hyperhidrosis and facial hyperhidrosis, respectively.

Patients should be evaluated for potential causes of secondary hyperhidrosis (e.g., hyperthyroidism) to avoid symptomatic treatment of hyperhidrosis without the diagnosis and/or treatment of the underlying disease.

Safety and effectiveness of BOTOX have not been established for the treatment of axillary hyperhidrosis in pediatric patients under age 18.

1.6 Blepharospasm and Strabismus

BOTOX is indicated for the treatment of strabismus and blepharospasm associated with dystonia, including benign essential blepharospasm or VII nerve disorders in patients 12 years of age and above.

2 DOSAGE AND ADMINISTRATION

2.1 Instructions for Safe Use

The potency Units of BOTOX (onabotulinumtoxinA) for injection are specific to the preparation and assay method utilized. They are not interchangeable with other preparations of botulinum toxin products and, therefore, units of biological activity of BOTOX cannot be compared to nor converted into units of any other botulinum toxin products assessed with any other specific assay method *[see Warnings and Precautions (5.1) and Description (11)]*.

Indication specific dosage and administration recommendations should be followed. When initiating treatment, the lowest recommended dose should be used. In treating adult patients for one or more indications, the maximum cumulative dose should not exceed 400 Units, in a 3 month interval.

The safe and effective use of BOTOX depends upon proper storage of the product, selection of the correct dose, and proper reconstitution and administration techniques. An understanding of standard electromyographic techniques is also required for treatment of strabismus, upper or lower limb spasticity, and may be useful for the treatment of cervical dystonia. Physicians administering BOTOX must understand the relevant neuromuscular and structural anatomy of the area involved and any alterations to the anatomy due to prior surgical procedures and disease, especially when injecting near the lungs.

Do not use BOTOX and contact Allergan (1-800-890-4345) if:

- the carton labeling does not contain an intact seal with a translucent silver Allergan logo (on both ends of the carton) or the seal has a black circle with a diagonal line through it (i.e., prohibition sign),
- the vial label does not contain a holographic film containing the name "Allergan" within rainbow colored horizontal lines, or
- the U.S. License number 1145 is not present on the vial label and carton labeling *[see How Supplied/Storage and Handling (16)]*.

2.2 Preparation and Dilution Technique

Prior to injection, reconstitute each vacuum-dried vial of BOTOX with only sterile, preservative-free 0.9% Sodium Chloride Injection, USP. Draw up the proper amount of diluent in the appropriate size syringe (see Table 1, or for specific instructions for detrusor overactivity associated with a neurologic condition see Section 2.3), and slowly inject the diluent into the vial. Discard the vial if a vacuum does not pull the diluent into the vial. Gently mix BOTOX with the diluent by rotating the vial. Record the date and time of reconstitution on the space on the label. BOTOX should be administered within 24 hours after reconstitution. During this time period, unused reconstituted BOTOX should be stored in a refrigerator (2° to 8°C) for up to 24 hours until time of use. BOTOX vials are for single-dose only. Discard any unused portion.

Table 1: Dilution Instructions for BOTOX Vials (100 Units and 200 Units)**

Diluent* Added to 100 Unit Vial	Resulting Dose Units per 0.1 mL	Diluent* Added to 200 Unit Vial	Resulting Dose Units per 0.1 mL
1 mL	10 Units	1 mL	20 Units
2 mL	5 Units	2 mL	10 Units
4 mL	2.5 Units	4 mL	5 Units
8 mL	1.25 Units	8 mL	2.5 Units
10 mL	1 Unit	10 mL	2 Units

*Preservative-free 0.9% Sodium Chloride Injection, USP Only

**For Detrusor Overactivity associated with a Neurologic Condition Dilution see Section 2.3

Note: These dilutions are calculated for an injection volume of 0.1 mL. A decrease or increase in the BOTOX dose is also possible by administering a smaller or larger injection volume - from 0.05 mL (50% decrease in dose) to 0.15 mL (50% increase in dose).

An injection of BOTOX is prepared by drawing into an appropriately sized sterile syringe an amount of the properly reconstituted toxin slightly greater than the intended dose. Air bubbles in the syringe barrel are expelled and the syringe is attached to an

appropriate injection needle. Patency of the needle should be confirmed. A new, sterile needle and syringe should be used to enter the vial on each occasion for removal of BOTOX.

Reconstituted BOTOX should be clear, colorless, and free of particulate matter. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration and whenever the solution and the container permit.

2.3 Bladder Dysfunction

General

Patients must not have a urinary tract infection (UTI) at the time of treatment. Prophylactic antibiotics, except aminoglycosides, *[see Drug Interactions (7.1)]* should be administered 1-3 days pre-treatment, on the treatment day, and 1-3 days post-treatment to reduce the likelihood of procedure-related UTI.

Patients should discontinue anti-platelet therapy at least 3 days before the injection procedure. Patients on anti-coagulant therapy need to be managed appropriately to decrease the risk of bleeding.

Appropriate caution should be exercised when performing a cystoscopy.

Overactive Bladder

An intravesical instillation of diluted local anesthetic with or without sedation may be used prior to injection, per local site practice. If a local anesthetic instillation is performed, the bladder should be drained and irrigated with sterile saline before injection.

The recommended dose is 100 Units of BOTOX, and is the maximum recommended dose. The recommended dilution is 100 Units/10 mL with preservative-free 0.9% Sodium Chloride Injection, USP (see Table 1). Dispose of any unused saline.

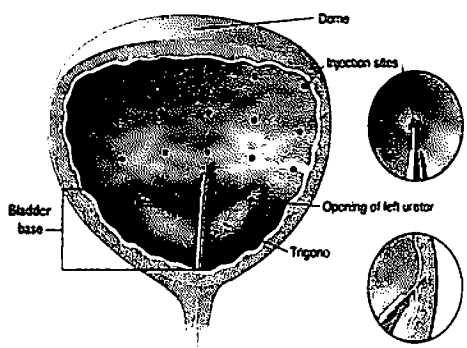
Reconstituted BOTOX (100 Units/10 mL) is injected into the detrusor muscle via a flexible or rigid cystoscope, avoiding the trigone. The bladder should be instilled with enough saline to achieve adequate visualization for the injections, but over-distension should be avoided.

The injection needle should be filled (primed) with approximately 1 mL of reconstituted BOTOX prior to the start of injections (depending on the needle length) to remove any air.

The needle should be inserted approximately 2 mm into the detrusor, and 20 injections of 0.5 mL each (total volume of 10 mL) should be spaced approximately 1 cm apart (see Figure 1). For the final injection, approximately 1 mL of sterile normal saline should be injected so that the remaining BOTOX in the needle is delivered to the bladder. After the injections are given, patients should demonstrate their ability to void prior to leaving the clinic. The patient should be observed for at least 30 minutes post-injection and until a spontaneous void has occurred.

Patients should be considered for reinjection when the clinical effect of the previous injection has diminished (median time until patients qualified for the second treatment of BOTOX in double-blind, placebo-controlled clinical studies was 169 days [~24 weeks]), but no sooner than 12 weeks from the prior bladder injection.

Figure 1: Injection Pattern for Intradetrusor Injections for Treatment of Overactive Bladder and Detrusor Overactivity associated with a Neurologic Condition



Detrusor Overactivity associated with a Neurologic Condition

An intravesical instillation of diluted local anesthetic with or without sedation, or general anesthesia may be used prior to injection, per local site practice. If a local anesthetic instillation is performed, the bladder should be drained and irrigated with sterile saline before injection.

The recommended dose is 200 Units of BOTOX per treatment, and should not be exceeded.

200 Unit Vial of BOTOX

- Reconstitute a 200 Unit vial of BOTOX with 6 mL of preservative-free 0.9% Sodium Chloride Injection, USP and mix the vial gently.
- Draw 2 mL from the vial into each of three 10 mL syringes.
- Complete the reconstitution by adding 8 mL of preservative-free 0.9% Sodium Chloride Injection, USP into each of the 10 mL syringes, and mix gently. This will result in three 10 mL syringes each containing 10 mL (~67 Units in each), for a total of 200 Units of reconstituted BOTOX.
- Use immediately after reconstitution in the syringe. Dispose of any unused saline.

100 Unit Vial of BOTOX

- Reconstitute two 100 Unit vials of BOTOX, each with 6 mL of preservative-free 0.9% Sodium Chloride Injection, USP and mix the vials gently.
- Draw 4 mL from each vial into each of two 10 mL syringes. Draw the remaining 2 mL from each vial into a third 10 mL syringe for a total of 4 mL in each syringe.
- Complete the reconstitution by adding 6 mL of preservative-free 0.9% Sodium Chloride Injection, USP into each of the 10 mL syringes, and mix gently. This will result in three 10 mL syringes each containing 10 mL (~67 Units in each), for a total of 200 Units of reconstituted BOTOX.
- Use immediately after reconstitution in the syringe. Dispose of any unused saline.

Reconstituted BOTOX (200 Units/30 mL) is injected into the detrusor muscle via a flexible or rigid cystoscope, avoiding the trigone. The bladder should be instilled with enough saline to achieve adequate visualization for the injections, but over-distension should be avoided.

The injection needle should be filled (primed) with approximately 1 mL of reconstituted BOTOX prior to the start of injections (depending on the needle length) to remove any air.

The needle should be inserted approximately 2 mm into the detrusor, and 30 injections of 1 mL (~6.7 Units) each (total volume of 30 mL) should be spaced approximately 1 cm apart (see Figure 1). For the final injection, approximately 1 mL of sterile normal saline should be injected so that the remaining BOTOX in the needle is delivered to the bladder. After the injections are given, the saline used for bladder wall visualization should be drained. The patient should be observed for at least 30 minutes post-injection.

Patients should be considered for re-injection when the clinical effect of the previous injection diminishes (median time to qualification for re-treatment in the double-blind, placebo-controlled clinical studies was 295-337 days [42-48 weeks] for BOTOX 200 Units), but no sooner than 12 weeks from the prior bladder injection.

2.4 Chronic Migraine

The recommended dilution is 200 Units/4 mL or 100 Units/2 mL, with a final concentration of 5 Units per 0.1 mL (see Table 1). The recommended dose for treating chronic migraine is 155 Units administered intramuscularly using a sterile 30-gauge, 0.5 inch needle as 0.1 mL (5 Units) injections per each site. Injections should be divided across 7 specific head/neck muscle areas as specified in the diagrams and Table 2 below. A one inch needle may be needed in the neck region for patients with thick neck muscles. With the exception of the procerus muscle, which should be injected at one site (midline), all muscles should be injected bilaterally with half the number of injection sites administered to the left, and half to the right side of the head and neck. The recommended re-treatment schedule is every 12 weeks.

Diagrams 1-4: Recommended Injection Sites (A through G) for Chronic Migraine

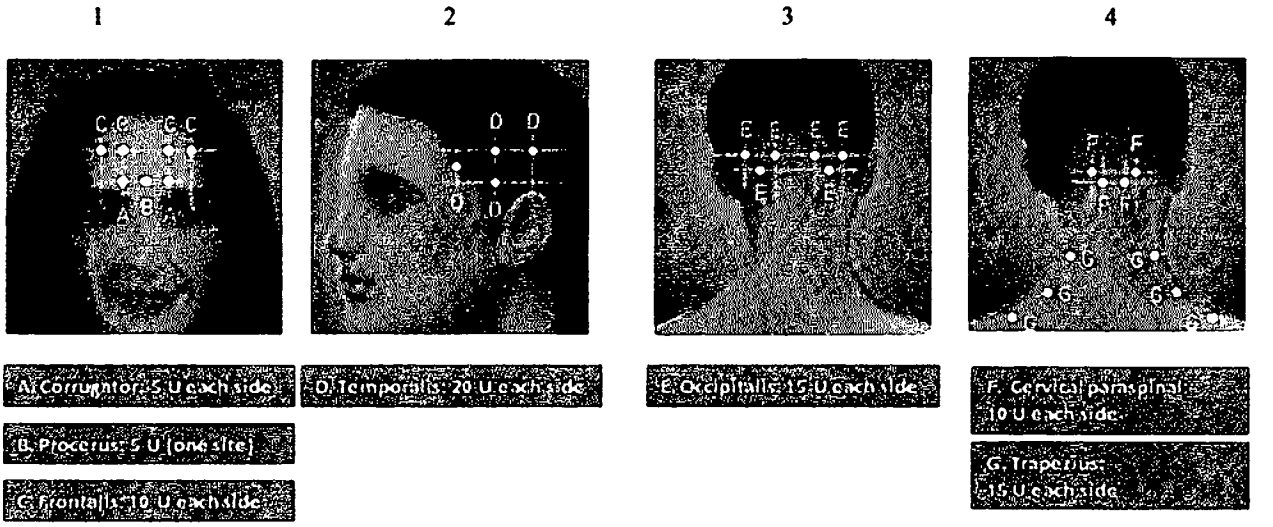


Table 2: BOTOX Dosing by Muscle for Chronic Migraine

Head/Neck Area	Recommended Dose (Number of Sites[a])
Frontalis[b]	20 Units divided in 4 sites
Corrugator[b]	10 Units divided in 2 sites
Procerus	5 Units in 1 site
Occipitalis[b]	30 Units divided in 6 sites
Temporalis[b]	40 Units divided in 8 sites
Trapezius[b]	30 Units divided in 6 sites
Cervical Paraspinal Muscle Group[b]	20 Units divided in 4 sites
Total Dose:	**155 Units divided in 31 sites**

[a] Each IM injection site = 0.1 mL = 5 Units BOTOX
[b] Dose distributed bilaterally

2.5 Spasticity

Dosing in initial and sequential treatment sessions should be tailored to the individual based on the size, number and location of muscles involved, severity of spasticity, the presence of local muscle weakness, the patient's response to previous treatment, or adverse event history with BOTOX.

The recommended dilution is 200 Units/4 mL or 100 Units/2 mL with preservative-free 0.9% Sodium Chloride Injection, USP (see Table 1). The lowest recommended starting dose should be used, and no more than 50 Units per site should generally be administered. An appropriately sized needle (e.g., 25-30 gauge) may be used for superficial muscles, and a longer 22 gauge needle may be used for deeper musculature. Localization of the involved muscles with techniques such as needle electromyographic guidance or nerve stimulation is recommended.

Repeat BOTOX treatment may be administered when the effect of a previous injection has diminished, but generally no sooner than 12 weeks after the previous injection. The degree and pattern of muscle spasticity at the time of re-injection may necessitate alterations in the dose of BOTOX and muscles to be injected.

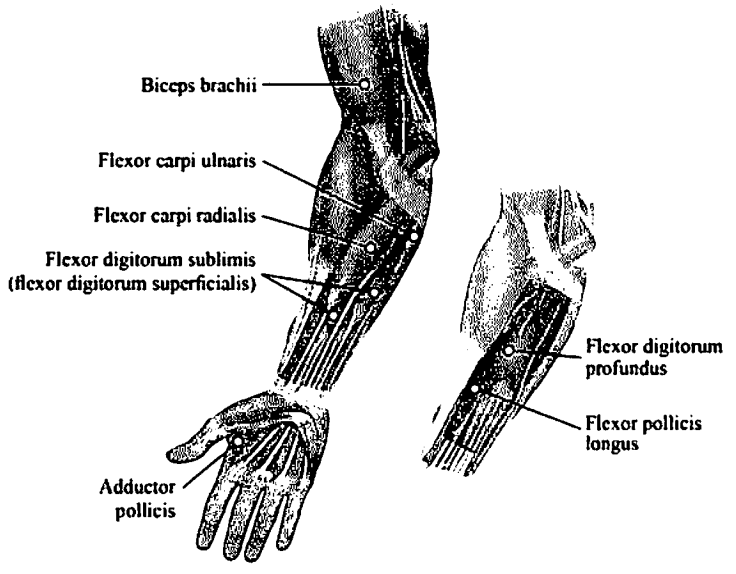
Upper Limb Spasticity

In clinical trials, doses ranging from 75 Units to 400 Units were divided among selected muscles (see Table 3 and Figure 2) at a given treatment session.

Table 3: BOTOX Dosing by Muscle for Upper Limb Spasticity

Muscle	Recommended Dose Total Dosage (Number of Sites)
Biceps Brachii	100 Units-200 Units divided in 4 sites
Flexor Carpi Radialis	12.5 Units-50 Units in 1 site
Flexor Carpi Ulnaris	12.5 Units-50 Units in 1 site
Flexor Digitorum Profundus	30 Units-50 Units in 1 site
Flexor Digitorum Sublimis	30 Units-50 Units in 1 site
Adductor Pollicis	20 Units in 1 site
Flexor Pollicis Longus	20 Units in 1 site

Figure 2: Injection Sites for Upper Limb Spasticity



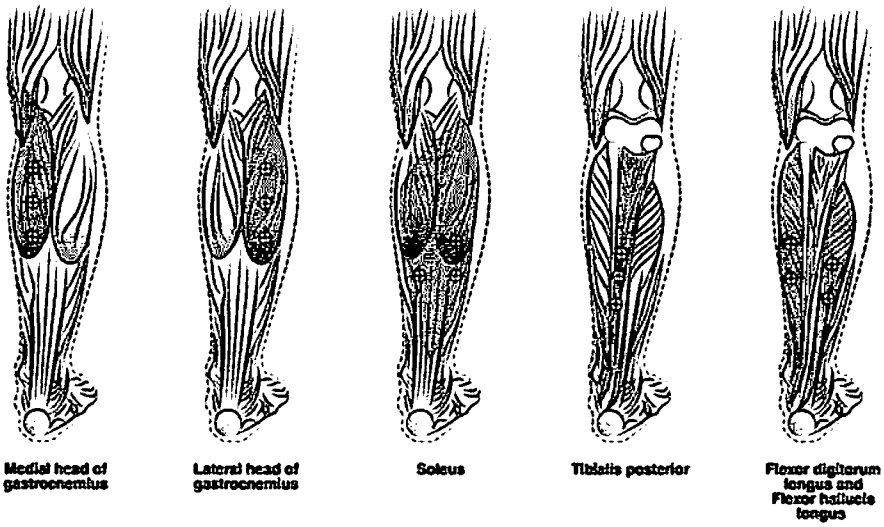
Lower Limb Spasticity

The recommended dose for treating lower limb spasticity is 300 Units to 400 Units divided among 5 muscles (gastrocnemius, soleus, tibialis posterior, flexor hallucis longus and flexor digitorum longus) (see Table 4 and Figure 3).

Table 4: BOTOX Dosing by Muscle for Lower Limb Spasticity

Muscle	Recommended Dose Total Dosage (Number of Sites)
Gastrocnemius medial head	75 Units divided in 3 sites
Gastrocnemius lateral head	75 Units divided in 3 sites
Soleus	75 Units divided in 3 sites
Tibialis Posterior	75 Units divided in 3 sites
Flexor hallucis longus	50 Units divided in 2 sites
Flexor digitorum longus	50 Units divided in 2 sites

Figure 3: Injection Sites for Lower Limb Spasticity



2.6 Cervical Dystonia

A double-blind, placebo-controlled study enrolled patients who had extended histories of receiving and tolerating BOTOX injections, with prior individualized adjustment of dose. The mean BOTOX dose administered to patients in this study was 236 Units (25th to 75th percentile range of 198 Units to 300 Units). The BOTOX dose was divided among the affected muscles *[see Clinical Studies (14.5)]*.

Dosing in initial and sequential treatment sessions should be tailored to the individual patient based on the patient's head and neck position, localization of pain, muscle hypertrophy, patient response, and adverse event history. The initial dose for a patient without prior use of BOTOX should be at a lower dose, with subsequent dosing adjusted based on individual response. Limiting the total dose injected into the sternocleidomastoid muscle to 100 Units or less may decrease the occurrence of dysphagia *[see Warnings and Precautions (5.2, 5.5, 5.6)]*.

The recommended dilution is 200 Units/2 mL, 200 Units/4 mL, 100 Units/1 mL, or 100 Units/2 mL with preservative-free 0.9% Sodium Chloride Injection, USP, depending on volume and number of injection sites desired to achieve treatment objectives (see Table 1). In general, no more than 50 Units per site should be administered using a sterile needle (e.g., 25-30 gauge) of an appropriate length. Localization of the involved muscles with electromyographic guidance may be useful.

Clinical improvement generally begins within the first two weeks after injection with maximum clinical benefit at approximately six weeks post-injection. In the double-blind, placebo-controlled study most subjects were observed to have returned to pre-treatment status by 3 months post-treatment.

2.7 Primary Axillary Hyperhidrosis

The recommended dose is 50 Units per axilla. The hyperhidrotic area to be injected should be defined using standard staining techniques, e.g., Minor's Iodine-Starch Test. The recommended dilution is 100 Units/4 mL with preservative-free 0.9% Sodium Chloride Injection, USP (see Table 1). Using a sterile 30 gauge needle, 50 Units of BOTOX (2 mL) is injected intradermally in 0.1 to 0.2 mL aliquots to each axilla evenly distributed in multiple sites (10-15) approximately 1-2 cm apart.

Repeat injections for hyperhidrosis should be administered when the clinical effect of a previous injection diminishes.

Instructions for the Minor's Iodine-Starch Test Procedure:
Patients should shave underarms and abstain from use of over-the-counter deodorants or antiperspirants for 24 hours prior to the test. Patient should be resting comfortably without exercise, hot drinks for approximately 30 minutes prior to the test. Dry the underarm area and then immediately paint it with iodine solution. Allow the area to dry, then lightly sprinkle the area with starch powder. Gently blow off any excess starch powder. The hyperhidrotic area will develop a deep blue-black color over approximately 10 minutes.

Each injection site has a ring of effect of up to approximately 2 cm in diameter. To minimize the area of no effect, the injection sites should be evenly spaced as shown in Figure 4.

Figure 4: Injection Pattern for Primary Axillary Hyperhidrosis

Each dose is injected to a depth of approximately 2 mm and at a 45° angle to the skin surface, with the bevel side up to minimize leakage and to ensure the injections remain intradermal. If injection sites are marked in ink, do not inject BOTOX directly through the ink mark to avoid a permanent tattoo effect.

2.8 Blepharospasm

For blepharospasm, reconstituted BOTOX is injected using a sterile, 27-30 gauge needle without electromyographic guidance. The initial recommended dose is 1.25 Units-2.5 Units (0.05 mL to 0.1 mL volume at each site) injected into the medial and lateral pre-tarsal orbicularis oculi of the upper lid and into the lateral pre-tarsal orbicularis oculi of the lower lid. Avoiding injection near the levator palpebrae superioris may reduce the complication of ptosis. Avoiding medial lower lid injections, and thereby reducing diffusion into the inferior oblique, may reduce the complication of diplopia. Ecchymosis occurs easily in the soft eyelid tissues. This can be prevented by applying pressure at the injection site immediately after the injection.

The recommended dilution to achieve 1.25 Units is 100 Units/8 mL; for 2.5 Units it is 100 Units/4 mL (see Table 1).

In general, the initial effect of the injections is seen within three days and reaches a peak at one to two weeks post-treatment. Each treatment lasts approximately three months, following which the procedure can be repeated. At repeat treatment sessions, the dose may be increased up to two-fold if the response from the initial treatment is considered insufficient, usually defined as an effect that does not last longer than two months. However, there appears to be little benefit obtainable from injecting more than 5 Units per site. Some tolerance may be found when BOTOX is used in treating blepharospasm if treatments are given any more frequently than every three months, and is rare to have the effect be permanent.

The cumulative dose of BOTOX treatment for blepharospasm in a 30-day period should not exceed 200 Units.

2.9 Strabismus

BOTOX is intended for injection into extraocular muscles utilizing the electrical activity recorded from the tip of the injection needle as a guide to placement within the target muscle. Injection without surgical exposure or electromyographic guidance should not be attempted. Physicians should be familiar with electromyographic technique.

To prepare the eye for BOTOX injection, it is recommended that several drops of a local anesthetic and an ocular decongestant be given several minutes prior to injection.

The volume of BOTOX injected for treatment of strabismus should be between 0.05-0.15 mL per muscle.

The initial listed doses of the reconstituted BOTOX *[see Dosage and Administration (2.2)]* typically create paralysis of the injected muscles beginning one to two days after injection and increasing in intensity during the first week. The paralysis lasts for 2-6 weeks and gradually resolves over a similar time period. Overcorrections lasting over six months have been rare. About one half of patients will require subsequent doses because of inadequate paralytic response of the muscle to the initial dose, or because of mechanical factors such as large deviations or restrictions, or because of the lack of binocular motor fusion to stabilize the alignment.

Initial Doses in Units

Use the lower listed doses for treatment of small deviations. Use the larger doses only for large deviations.

- For vertical muscles, and for horizontal strabismus of less than 20 prism diopters: 1.25 Units-2.5 Units in any one muscle.
- For horizontal strabismus of 20 prism diopters to 50 prism diopters: 2.5 Units-5 Units in any one muscle.
- For persistent VI nerve palsy of one month or longer duration: 1.25 Units-2.5 Units in the medial rectus muscle.

Subsequent Doses for Residual or Recurrent Strabismus

- It is recommended that patients be re-examined 7-14 days after each injection to assess the effect of that dose.
- Patients experiencing adequate paralysis of the target muscle that require subsequent injections should receive a dose comparable to the initial dose.
- Subsequent doses for patients experiencing incomplete paralysis of the target muscle may be increased up to two-fold compared to the previously administered dose.
- Subsequent injections should not be administered until the effects of the previous dose have dissipated as evidenced by substantial function in the injected and adjacent muscles.
- The maximum recommended dose as a single injection for any one muscle is 25 Units.