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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

RACHEL CONDRY, JANCE HOY, CHRISTINE ENDICOTT, LAURA BISHOP, FELICITY BARBER, and RACHEL CARROLL on behalf of themselves and all others similarly situated,

Plaintiffs,

v.

UnitedHealth Group Inc.; UnitedHealthcare, Inc.; UnitedHealthcare Insurance Company; UnitedHealthcare Services, Inc.; and UMR, Inc.,

Defendants.

Case No.: 3:17-cv-00183-VC

PLAINTIFFS' REPLY IN SUPPORT OF PLAINTIFFS' CROSS MOTION FOR PARTIAL SUMMARY JUDGMENT

Date: February 8, 2018
Time: 10:00 am
Place: Courtroom 4

Honorable Vince G. Chhabria

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Plaintiffs, Rachel Condry, Jance Hoy, Christine Endicott, Laura Hipple (nee Bishop), Felicity Barber, and Rachel Carroll (collectively, "Plaintiffs"), file this Reply in Support of Plaintiffs' Cross-Motion for Partial Summary Judgment (Dkt. 117, "Pl. SJ Br." or "Plaintiffs' SJ Motion"),which Defendants[1] oppose (Defendants' Response to Plaintiffs' Cross-Motion for Summary Judgment, Dkt. 119, "Defs. Resp.") Plaintiffs filed the Declaration of Kimberly Donaldson Smith, Dkt. 116-04 ("Smith SJ Decl."), and file contemporaneously herewith the Reply Declaration of Kimberly Donaldson Smith in Support of Plaintiffs' SJ Motion ("Smith Reply Decl.").

I. INTRODUCTION

Plaintiffs presented evidence, including UHC's own internal records, to demonstrate that UHC took the position, without support and amid internal dispute as to the credibility and workability of such position, that it did not need to do anything in response to the ACA-preventive coverage mandate for CLS. (*See* Pl. SJ Br. at 9:2-11:24.) Plaintiffs have offered evidence that UHC did nothing other than state that the CLS coverage mandate was accomplished through having OB/GYNs and pediatricians in UHC's network. [redacted] Moreover, Plaintiffs' evidence demonstrated that [redacted] Naturally, given that factual history, Plaintiffs were able to show that UHC did not coherently administer, review and adjudicate any CLS claims submitted by Plaintiffs, which action is not in compliance with the ACA and Defendants' ERISA and contractual duties.

Throughout this litigation, UHC's mantra has been that "meaningful access" has no place in the interpretation or enforcement of the ACA. [2] UHC's perhaps most direct and offensive assault on

[1] Defendants are comprised of UnitedHealth Group Inc., UnitedHealthcare, Inc., UnitedHealthcare Insurance Company, UnitedHealthcare Services, Inc. and UMR, Inc. (collectively, "UHC" or "Defendants").

[2] This Court held that: "The service must be available in a meaningful way for the plan to comply with the [ACA]." (8/15/17 Order, Dkt. 68 at 3); (*see also* the Court's comment at the 7/27/17 hearing: "But it seems like at a minimum, what [the ACA] requires is … meaningful access to lactation services." Dkt. 81-2, 7/27/17 Tr. at 5:1-3). That "access" is the point of the ACA is stated in the ACA Interim Final Rules. *See e.g.* 7/19/10

the ACA preventive service coverage requirement for CLS is demonstrated by its most recent stance that ACA "coverage [can] be accomplished if a patient cannot find the network provider." (Defs. Resp. at 7:14-15.) That position mirrors [redacted] Access, meaningful access or even "availability," as UHC now terms it, is fundamental to the ACA's objective to deliver preventive services. UHC's insistence that ACA's only focus is on "financial barriers" and that the ACA does not impose any requirements governing patients' access to preventive medical benefits, is unsupported and wrong. (Defs Resp. at 2:9-11). That CLS claims could be "financially" covered without meaningful access simply makes no sense. (S*ee* Pl. SJ Br. at 16.) It is ironic that in support of its position UHC relies on former Sen. Barbara Mikulski's remarks. (Defs Resp. at 2:11-12.) The actual focus of the remarks made by Senator Mikulski, whose retirement last year ended the longest tenure of a female member of Congress, was specifically on making certain that the health reform bill provided **"universal access"** to **"comprehensive services"** for preventive health services coverage for women.[3]

The documents produced by UHC provide important context for the Court to fully appreciate the litigation tactic being employed by UHC in attacking Plaintiffs' positions about Defendants' failures in providing CLS coverage, including the access point. UHC responds that its internal documents were cited "out of context," "have nothing to do with the named Plaintiffs' circumstances," and "only demonstrate Defendants' good faith efforts." (Defs. Resp. at 6:4-5.) On the contrary, UHC's documents reveal its ACA deficient stance on providers and scope of CLS, including that, [redacted] Tellingly, UHC offers no substantive response to the evidence other than to claim that

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Regulations (Smith SJ Decl., Ex. 5), noting that the ACA expanded coverage for preventive services (i) so that "access and utilization of these services [would] increase" (*id*. at 41730, Table 1) and (ii) to address "underutilization of preventive services." (*Id*. at 41731.)

[3] Senator Mikulski's remarked that the health reform bill should provide "universal ***access*** to health care …ending those punitive practices of the insurance companies…and ***improving quality in public health by using innovation and preventive services and quality***… I conclude by saying that we ***will end the confusion about what is needed in the area of preventive health services for women when our coverage is often skimpy and spartan. We want to make sure what we do enables us to have access to those comprehensive services***." (155 Cong. Rec. S11985-02, at S11988, Nov. 30, 2009) (emphasis added). (Defs Resp. at 2:11-12.)

Plaintiffs have "cherry-picked, irrelevant evidentiary materials." (Defs. Resp. at 1:16-17.)[4] But, UHC never offers a single piece of evidence to support that statement. The evidence confirms Plaintiffs' experiences and supports their claims. (*See* Section II, *infra*; Pl. SJ Br. at Sections II and III).

Plaintiffs' SJ Motion consists of accurate and thorough accounts of each named Plaintiff's experience with respect to CLS, and demonstrates the grounds on which each Plaintiff is entitled to summary judgment. (*See e.g.*, Pl. SJ Br. at fns. 10-16, 18-19, 29-30, 32; and pages 14:22-16:11, 17:7-20, 19:54-20:15, 22:7-15, 23:5-26:2, 28:13-29:12; *see* Pl. SJ Br., generally.) UHC's response presents no genuine dispute that in-network trained providers of CLS were not available to the Plaintiffs, and UHC denied and/or applied cost-sharing to claims that constituted CLS claims. Plaintiffs are therefore entitled to summary judgment on Counts I through III and V-VI because UHC's coverage for CLS did not comply with the ACA, in violation of ERISA and plan documents.

II. ARGUMENT

UHC's documents specific to the provision of CLS, UHC's treatment of Plaintiffs, and the opinions of Plaintiffs' experts, all demonstrate that UHC failed in executing its ERISA and contractual duties to provide Plaintiffs with CLS coverage. The failure was not based on a mistake or a processing error. Instead, when faced with having to implement the ACA-mandated preventive care coverage requirements for CLS, [redacted]

[4] UHC's view -- that morphing meaningful access into the creation of "a separate list" of in-network providers who can deliver CLS (Defs. Resp. at 7:4-17) -- ignores that UHC provided inaccurate and inconsistent information to Plaintiffs, and it ignores that [redacted] *See* Smith Reply Decl., Ex. 66, UHC_011837 [redacted]

[redacted]

A. UHC Failed to Provide Plaintiffs ACA-Compliant Coverage for CLS

1. Plaintiffs Did Not Have Access to In-Network Providers of CLS

UHC's alleged coverage for CLS – which was grounded on a position that the Plaintiffs had access to "tens of thousands of pediatricians, OB/GYNs and other providers" – was not ACA-compliant; it directly failed to comply with the ACA's regulatory framework and requirements that mandated coverage for comprehensive lactation services by a trained lactation provider at every phase of the breastfeeding continuum. (*See* Pl. SJ Br. at Sections II and III.A.1.)

In opposing Plaintiffs' SJ Motion, UHC argues about the construct of its in-network providers of CLS at the time Plaintiffs sought services, and the availability of CLS from in-network trained providers and premises those arguments on significant mischaracterizations and unsubstantiated conclusory assertions. Those arguments fail to credibly refute that UHC did not have trained providers of CLS available or accessible to Plaintiffs.

UHC's claim that each Plaintiff could have identified and accessed "a *multitude* of network providers" capable of rendering CLS is simply wrong. (Defs. Resp. at 2:18; emphasis added.) In support of this contention, UHC posits that it has an expansive network of CLS providers comprised primarily of the "hundreds or even thousands of network OB/GYNs and pediatricians within thirty miles of [each Plaintiff's] zip code[]…*many* of [which] publically [sic] held themselves out as providers of the ACA-mandated preventives [sic] services" (*id*. at 2:21-3:2; Defs. SJ Br. at 7:18-22) (emphasis added), and who "are able to bill for such services as covered services under their

[6] *See also* Smith Reply Decl., Ex. 67, UHC_012277 [redacted] *id.*, Ex. 69, UHC_092051 [redacted] *id.*, Ex. 70, UHC_008950-53 [redacted]

contracts" (Defs. Resp. at fn. 3).[7] UHC's position is based on the (wrong) presumption that all network OB/GYNs and pediatricians are trained providers of CLS. This presumption, which UHC has repeatedly asserted as "fact" despite a glaring lack of supporting evidence, is contradicted by UHC's internal documents and refuted by Plaintiffs' experts.

As demonstrated in Plaintiffs' SJ Motion (*see e.g.*, Pl. SJ Br. at 12:7-20), contrary to UHC's consistently vague generalizations, Plaintiffs did not receive CLS from in-network providers:[8]

(1) Carroll testified that she was observed breastfeeding at pediatric visits and not in relation to receipt of CLS, but rather solely due to the infant's nursing schedule which occurred during the visit. *See* Smith SJ Decl., Ex. 45, Carroll Tr. at 66:11-67:10 (the pediatrician would only "glance over every so often" and did not discuss "anything regarding breastfeeding.") Her testimony contradicts UHC's characterization, Defs. Resp. at 3:16-17. Likewise, Carroll did not admit, as UHC repeatedly suggests, that she saw in-network lactation consultants at [redacted] (*See* Defs. Resp. at 2:19-21; 3:16-17; 5:20-21; 7:26-27.)[9]

(2) Similarly, Endicott did not receive the "full complement"[10] of CLS when she sought assistance from the nurse at the in-network pediatrician's office who gave her a photocopy of a textbook concerning oversupply because, admittedly, the nurse was unfamiliar with oversupply issues and how to resolve them (*see* Smith SJ Decl., Ex. 50; Endicott Tr. at 64:5-65:10; *see also* Pl. SJ Br. at fn. 10). UHC did not identify the pediatric practice or the nurse as network providers of CLS. (*See* Nielsen SJ Decl., Dkt. 105-6, Ex. I at ¶¶4-21.)

(3) Barber's [redacted] told Barber to "***definitely see***" the lactation consultant that they "***always recommend***." (Smith SJ Decl., Ex. 46; Barber Dep. at

[7] UHC's position that OB/GYNs and pediatricians are "able to bill" for "[p]reventive lactation/breastfeeding services," a term that is undefined by UHC, under existing contracts is immaterial and unsupported. (Defs. Resp. at fn. 3; *see also* Nielsen Reply Decl., Dkt. 119-10, Ex. O at ¶4.) That position: (a) conflates a provider's *ability to bill* for a service with a provider's capability to *render* ACA-mandated CLS; (b) does not demonstrate that UHC even provided ACA-compliant coverage for such bills – *e.g., adjudicated with no cost-sharing*; (c) does not equate to UHC having informed insureds that these providers were network trained lactation providers so that members could access the preventive service and coverage as intended, *at no cost*; and (d) is inconsistent with UHC's definition of Network ("A provider may enter into an agreement to provide ***only certain Covered Health Services, but not all Covered Health Services***…). (*See* Pl. SJ Br. at fn. 11.) UHC has not raised a disputed material fact with the statement that providers are "able to bill."

[8] In response, UHC only claims that Carroll and Endicott received CLS through in-network providers, therefore conceding that the four other Plaintiffs did not. (Defs. Resp. at 3:14-17)

[9] Carroll did not know the name of the individual she saw at [redacted] or her credentials, or that provider's status in UHC's network (Smith SJ Decl., Ex. 45, Carroll Tr. at 63:9-64:5), and UHC has not offered any evidence that Carroll received CLS from [redacted] or that "in-network lactation consultants" are accessible through [redacted] Furthermore, neither the pediatrician nor [redacted] were identified in Carroll's searches for providers of CLS on UHC's online directory. (*See id.*, Ex. 45, Carroll Tr. at 102:6-23; Souza SJ Decl. "Souza SJ Decl."; Ex.G-16, Dkt. 111-33; Carroll Rog. Resp. 2(c) or included on UHC's proffered list of in-network CLS providers (*see* Nielsen SJ Decl. ("Nielsen SJ Decl."), Ex. I, Dkt. 105-6, ¶¶4-21).)

[10] [redacted]

72:5-24; 76:3-77:3; 80:15-81:13 (emphasis added); *see also* Pl. SJ Br. at fn. 10.)

(4) Hoy's pediatrician informed her that the practice did not have the expertise or knowledge to provide CLS, and urgently requested that she see a lactation consultant. (*See* Smith S.J. Decl., Ex. 47, Hoy Tr. at 85:5-25, 99:8-101:4; *see also* Pl. SJ Br. at fn. 10.)

(5) Bishop's ob-gyn faxed UHC a referral requesting that UHC process lactation services to be received from an IBCLC as in-network, and her pediatrician addressed her breastfeeding issues by recommending [redacted] (Smith Reply Decl., Ex. 71; Bishop Tr. at 83:6-84:8; 154:6-16; *see also* Pl. SJ Br. at fn. 10.)

(6) Neither Condry's nurse practitioner nor midwife provided CLS to Condry, resulting in a referral to an IBCLC, who the nurse practitioner encouraged Condry to "continue working with." (*See* Smith SJ Decl., Ex. 49; Condry Tr. at 29:14-30:10; 116:17-23; 173:21-174:22; *see also* Pl. SJ Br. at fn. 10.)

UHC's assertion that each Plaintiff had "***hundreds or even thousands*** of network OB/GYNs and pediatricians" (Defs. Resp. at 2:21-3:2, emphasis added) who could have provided CLS, is completely undermined by UHC's meager list of such providers. (*See* Nielsen SJ Decl., ¶¶4-20.) Plaintiffs' SJ Motion amply addresses this point (*see e.g.*, Pl. SJ Br. at 14:8-15:28). Unlike Plaintiffs, UHC has access to its internal network databases, provider contracts, and claims data, among other resources, yet even with all of those resources, had to resort to internet searches to identify only 14 purported in-network OB/GYN and pediatric practices[11] who UHC contends are CLS providers within Plaintiffs' five geographic regions, which include major metropolitan cities such as San Francisco, Philadelphia and Austin, Texas[12] (*See* Nielsen SJ Decl., ¶¶4-20.) Tellingly, this information only surfaced during the course of this litigation and the OB/GYN and pediatric practices that UHC suggest were in-network providers of CLS when Plaintiffs sought services **were not** identified through UHC's online provider portal and/or UHC's customer service:

(1) Carroll's search results for providers of CLS on UMR's online provider portal did not include

[11] The Nielsen SJ Decl. enumerates 17 OB/GYN and pediatric practices that purportedly offer CLS, but there are only 14 practices since three of the practices are listed twice under different office locations or specific physicians' names, neither of which are accredited with providing CLS. *See* Nielsen SJ Decl., ¶¶4-5, 7-8, and 14-15; *see also* Defs. SJ Butler Aff. ("Butler Aff.), Dkt. 107-6, Exs. K-4, K-12, K-13-15.)

[12] According to the webpages submitted by UHC (*see* Butler Aff., Exs. K-1-24), neither the OB/GYNs nor the pediatricians associated with the practices are, in fact, the providers rendering CLS, with the exception of two practices (Nielson Decl., ¶¶16-17). And in some instances, the practices do not advertise that they offer CLS, but rather provide links to external lactation consultancy services and resources, including: Austin Breastfeeding, Austin's Breastfeeding Coalition, FeedingExpert.com operated by the formula company Similac, and La Leche League, among others. (*See* Butler Aff. Exs. K-10, K-12; s*ee also* Smith Reply Decl., Ex. 72, https://web.archive.org/web/20150722003302/http://www.kangospediatrics.com/breast-feeding.html (archived July 22, 2015).)

[redacted] which UHC claims has "network lactation consultants" (*see* Defs. Resp. at 2:19-21; 3:16-17; 5:20-21; 7:26-27; *see also* Defs. SJ Br. at 7:3-5; 12:19-24), the Youth Clinic, or *any* providers within 100-miles of her zip code. (*See* Smith SJ Decl., Ex. 45; Carroll Tr. at 102:6-23; *see also* Souza SJ Decl., Ex.G-16, Dkt. 111-31, Carroll Rog. Resp. 2(c).)[13]

(2) Bishop conducted a "comprehensive" search on UHC's provider portal for trained providers of lactation services, but she was not able to locate any providers, even after expanding the default mile distance (Smith SJ Decl., Ex. 48, Bishop Tr. at 146:8-147:22), and UHC's customer service representative was unable to identify any in-network providers "who could help support [Bishop] with [her] lactation needs" (*Id.*, Bishop Tr. at 54:15-24; 193:2-194:7; *id.*, Souza SJ Decl., Ex.G-17, Dkt. 111-33, Bishop Rog. Resp.2(c); Pl. SJ Br. at fn. 14.)

(3) Hoy performed "comprehensive searches of relevant [CLS] search terms" on UHC's provider portal, but there were no in-network providers within 30 miles of her zip code, and when Hoy contacted UHC's customer service she was informed that only lactation services during the hospital stay following a child's birth were covered. (Smith SJ Decl., Ex. 47, Hoy Tr. at 32:1-34:25; *see also* Pl. SJ Br. at fn. 15.)

(4) Barber used the "lactation specialist" search option on UHC's online provider portal in an attempt to identify in-network trained providers of CLS, but the search returned no results. (Smith Reply Decl., Ex. 73, Barber Tr. At 169:3-171:10; *Id.*, Ex. 74, PL_FB000016-17.)

Ignoring Plaintiffs' evidence (Pl. SJ Br. at 14:22-16:11), UHC contends that its provider directories listed in-network lactation specialists located within a 30-mile radius of Plaintiffs Barber, Condry and Endicott's zip codes. While UHC alleges that there was one lactation specialist within 30 miles of Endicott (*see* Nielsen Reply Decl., Dkt. 119-10, Ex. O at ¶5), this assertion is nullified by the fact that Endicott was told by UHC's customer service that, "There is no coverage for services billed by a ***lactation specialist***…***Lactation specialists*** are generally an exclusion." (*see* Smith SJ Decl., Ex. 54) (emphasis added). Also, UHC's statement that Plaintiffs "confuse[] driving distance with radius" [redacted] (Defs. Resp. at 3:20-21.)[14]

Moreover, UHC relies on new "evidence" in its Response Brief, that is cobbled together, two-

[13] As Pl. SJ Br. at fn. 13 explained, Carroll only located the Youth Clinic, the one Colorado practice listed in the Nielsen SJ Decl. (*see* ¶20), through her own research and outreach, but lactation services were available only to established patients, (*see* Butler Aff., K-20), which would have required her to switch pediatric providers. (Pl. SJ Br. at fn.13, *cf.* Defs. Resp. at 3:23-24 ("Carroll does not explain why the Youth Clinic's reservation of services for 'established patients' precluded her from seeking care at that facility'").)

[14] *See* Smith Reply Decl., Ex. 75, UHC_039465 [redacted]

months after the discovery deadline (*see* Dkt. No. 77), in an attempt to augment its alleged network of lactation consultants who were within 30 miles of Condry and Barber. (*See* Souza Reply Decl., Dkt. 119-3, Ex. N (¶6), Exs. N-5-N-6 (*undated* UHC provider finder printouts); *and* Nielsen Reply Decl. at ¶¶7-10, Exs. O-1-O-4 (excerpts from UHC's 2015 and 2016 Spring/Summer and Fall/Winter provider directories for the San Francisco/Central Coast region).) What UHC has highlighted with this attempt, however, is its *own* inability to identify, completely and in a timely fashion, in-network lactation consultants. It also highlights that UHC's information -- the 2015 and 2016 directories (Nielsen Reply Decl., Exs. O-1-O-4), the provider finder printouts (*see* Souza Reply Decl., Exs. 5-6), and the provider information (both names and locations) reflected in the Nielsen Reply Decl. (¶¶7-10) – are inconsistent as to who supposedly were network lactation specialists available and within geographic proximity to Condry and Barber when they sought coverage. For example:

- According to the UHC's Winter 2016 directory (*see* Nielsen Reply Decl., Ex. O-3 at 23, 25), the only network lactation specialists in February 2016, when Barber sought CLS, included Maree E. Makins ("Makins"), Cheryl M. Dronkers ("Dronkers")[15] and Jennifer P. Scales ("Scales"), from the Nielsen Reply Decl. (¶¶7-10), not Shelia Dukas-Janakos ("Janakos). According to the Winter 2016 directory, all three providers were associated with four addresses, **none of which were within 30 miles of Barber's zip code**. (*See* Smith Reply Decl., Ex. 76.)

- When Condry sought CLS in March and April 2015, only Scales and Janakos were listed as lactation specialists in UHC's Spring/Summer 2015 directory, not Makins or Dronkers (*see* Nielsen Reply Decl., Ex. O-1 at 15-16) (reflecting a last updated date of January 12, 2015), and **neither provider's place of service was located within 30 miles of Condry's zip code**. (*See* Smith Reply Decl., Ex. 76.) Furthermore, the lactation specialists listed in the Spring/Summer 2015 Directory do not coincide with those listed in Defendants' finder printouts for Condry. (*See* Souza Reply Decl., Ex. 5) (Janakos is omitted, but other lactation consultants appear which were not listed in the Spring/Summer 2015 directory).

Further, UHC's proposition that the availability of a gap exception alleviates any deficiency of UHC's policy for CLS coverage, also does not raise a disputed issue of fact. UHC states that, "nothing prevented [Plaintiffs] from seeking a gap exception" (Defs. Resp. at 3:20-21). In fact, however, such attempts were futile. (*See* Pl. SJ Br. at fn. 19) (Bishop's request to coordinate in-

[15] UHC's protest (Defs. Resp. at 3:24-26) of Plaintiffs' attempts to contact Makins and Dronkers at the phone numbers reflected on recent UHC provider searches is telling. (*See* Pl. SJ Br. at fn. 16.) Just as UHC and its counsel conducted and submitted results of web searches to support UHC's contentions, Plaintiffs used the phone numbers currently on UHC's website portal to, albeit unsuccessfully, contact these two providers UHC now offers up as in-network lactation specialists available to Plaintiffs Condry and Barber.

network benefits for CLS was received by UHC, but as conceded by UHC, the request was disregarded and the resulting claim was denied). (*See also* Smith SJ Decl., Ex. 56) (nothing in UHC customer service's call log notes with Hoy, before she sought CLS, indicate that the representative's statement that Hoy "would not be able to get a gap [exception]" was premised, as now alleged by UHC, "*only on the assumption* that she could seek the services from her in-network providers." (Defs. Resp. at 3:27-28 (emphasis added).) Furthermore, the gap exception process, as outlined in Defs. Resp., Huckaby Reply Decl., Dkt. 119-1, Ex. M at ¶6, is wholly inadequate as it is devoid of any specific timeframes in which UHC is required to conduct its network investigation and issue a response, if any (*see* Pl. SJ Br. at 17:7-20). Also, as pointed out in Plaintiffs' SJ Motion, to which UHC never responds, UHC admits that the gap exception is futile for CLS: [redacted] (Smith SJ Decl., Ex. 22, UHC_056772-74.)

Plaintiffs irrefutably demonstrated that UHC fundamentally failed to establish the infrastructure and policies to administer and cover CLS, with the consequence that each Plaintiff sought CLS from out-of-network trained lactation providers, for which claims UHC improperly denied or wrongfully shifted cost in adjudicating the claims.

2. Plaintiffs' Services Constituted CLS

UHC has not offered a material disputed fact in response to Plaintiffs detailed showing that they received preventive lactation-related services (Pl. SJ Br. at 19-21.) As an initial matter, UHC's response persists in its failure to acknowledge that CLS includes the word "comprehensive," the plain meaning of which is: "(1) covering everything or all important points, (2) not lacking any part or member that properly belongs to it, (3) trying all possibilities" (Smith SJ Decl., Ex. 4 at 14.)

UHC's position that CLS does not include the clinical management of lactation and common complications of lactation is at odds with the relevant authority,[16] including, (i) the HRSA Guidelines

[16] UHC concedes that the guidance regarding the "ACA-mandated preventive benefit" has not changed since 2012 (Defs. Resp. fn. 14), but cites only to USPSTF and continues to ignore the role of HRSA and the clinical guidance supporting the HRSA requirements by IOM, WPSI and ACOG, discussed in Pl. SJ Br. in Sections II and III. (*See also* Smith Reply Decl., Ex. 80; WPSI Final at 41 ("The IOM recommendation includes an explicit description of a more comprehensive set of services than the U.S. Preventive Services

based on recommendations of the independent Institute of Medicine ("IOM") and its report, "*Clinical Preventive Services for Women: Closing the Gaps.*" (Pl. SJ Br. at 3:18-5:18; Pl. Ex. 8, "IOM Report"), and (ii) authority relied on by UHC and its own experts, namely, the ACOG Committee Opinion Number 658, "*Optimizing Support for Breastfeeding as Part of Obstetric Practice.*" (Smith Reply Decl., Ex. 77, ACOG 658 at 4-5).[17] As ACOG 658 states:

- Clinical Management of Breastfeeding includes: (1) issues such as pain, low milk supply, breast infections and maternal medication safety, (2) careful examination by a certified lactation professional to ensure frequent breast stimulation and milk removal is the most effective strategy to increase milk production and (3) conditions to avoid disrupted lactation, which ACOG identified as common, due to multiple conditions such as breast pain, low milk supply, and the infant latching on the breast. (Smith Reply Decl., Ex. 77, ACOG at 5.)

- Physician office staff should be prepared to triage common breastfeeding concerns and refer to an IBCLC as needed, and that "embedding lactation consultants with the offices of an OB/GYN may be feasible now that *coverage of lactation services is included as a preventive service under the ACA*." (*Id.*, emphasis added.)

ACOG 658 recognizes that the full scope or complement of CLS requires access to a trained provider who is "a certified lactation professional" (for example, in order to provide a "careful examination" "to ensure frequent breast stimulation and milk removal")(Smith Reply Decl., Ex. 77, ACOG 658 at 5).

UHC's position is also at odds with the fact that the ACA *expanded* the required preventive lactation coverage beyond the prenatal and in-hospital, education-focused counseling that had been provided by OB/GYNs and pediatricians before the ACA, and that it specifically requires "comprehensive support" by "trained providers." (*See* Smith SJ Decl., Ex. 8, IOM Report at 113); (Smith Reply Decl., Ex. 80, Women's Preventive Services Initiative "WPSI" 2016 Final Report, "WPSI Final," at 39); (*id.*, Ex. 81, Meek Tr. 69:10-19) (Souza SJ Decl., Ex. G-13, Meek Report ¶¶37, 43-53, 55-59); (*id.*, Ex. G-12, Morton Report at 13-14); (Pl. SJ Br. 3:18–26; 4:1-12).) In this regard, UHC's treatment of the Plaintiffs and CLS coverage ignores that the ACA preventive mandate is grounded on the principle that "no single provider can be identified as the sole primary care provider

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Task Force (USPSTF).")

[17] Each of UHC's experts relied on ACOG 658. (*See* Souza SJ Decl., Ex. G-13, Meek Report ¶¶19, 22, 26-30); (*id.*, Ex. G-12, Morton Report at 3-4, 7-8, 9-10, 11-12); (Smith Reply Decl., Ex. 78, Morton Tr. 29:24-25 to 30:1-13, 31:5-19)).

for women" and that a woman may require "more than one visit, potentially to more than one provider, to achieve the full scope of recommended preventive service. (Smith Reply Decl., Ex. 79, IOM Report at 124); (*id.*, Ex. 82, WPSI Draft Recommendation at 11); (Smith SJ Decl., Ex. 4, Martin Report at 8-9); (Souza SJ Decl., Ex. G-12, Morton Report at 14).

UHC also attempts to circumscribe the requirement to provide CLS by ignoring IOM (citing to it only in a footnote and misstating its guidance (Defs. Resp. at n. 14). IOM, recognizing that the U.S. health system is focused on responding to urgent needs rather than prevention,[18] defined Preventive Health Services as "measures—including medications, procedures, devices, tests, education and counseling—shown to ***improve well-being***, and/or ***decrease the likelihood or delay the onset of a targeted disease or condition.***" (Pl. SJ Br. at 3:23-25.) As stated by IOM, "[t]o 'prevent' is to forestall the onset of a condition; detect a condition at early stage, when it is more treatable; or to slow the progress of a condition that may worsen or result in additional harm", and "Preventive treatment involves a procedure intended to prevent the occurrence of a disease or condition or to prevent the progression of a disease from one stage to another." (Smith Reply Decl., Ex. 79, IOM Report at 20, 25). In the context of CLS, services provided by a trained lactation provider to address and treat the presenting circumstances that put sustained breastfeeding at risk (for example, addressing breast or nipple pain or abrasion, low milk supply, and infant latching and suck issues), promote, permit and ensure initiated and sustained breastfeeding, to improve their well-being and to secure the preventive health benefits linked with breastfeeding.[19] (*See* Pl. SJ Br. at 21:1-13; Smith SJ Decl., Ex. 8, IOM Report at 111; Smith Reply Decl., Ex. 77, ACOG 658 at 5; *id.*, Ex. 78, Morton Tr. 44:4-21, 45:25, 46:1-17; Souza SJ Decl., Ex. G-13, Meek Report ¶¶23-24, 26-30, 34, and Ex. G-12,

[18] *See* Smith Reply Decl., Ex. 79, IOM Report at 16-17; Souza SJ Decl., Ex. G-13, Meek Report ¶25 and Ex. G-12, Morton Report at 5, 12.

[19] UHC's position of arbitrarily applying a narrowed construct of CLS also disregards the stated issues the ACA's mandate of preventive coverage for CLS address: (1) "mothers may have no means of identifying or obtaining the skilled support needed to address their concerns about lactation and breastfeeding" following discharge from the hospital and (2) "gaps existed between providers' intentions surrounding breastfeeding counseling and their training, experience and practice in supporting patients with breastfeeding." (Pl. SJ Br. at 21:1-13; Smith SJ Decl., Ex. 8, IOM Report at 111; *see also* Smith Reply Decl., Ex. 80, WPSI Final at 50.) WPSI found that multiple barriers continue to discourage breastfeeding, "including lack of knowledge, inadequate support, lactation problems, constraints of employment, and limited access to appropriate health services and lactation supplies."

Morton Report at 3-8, 11, 14.) The foregoing authority demonstrates why UHC is wrong in its contention that that the ACA does not set "a certain standard of care for lactation counseling above and beyond what OB/GYNs and pediatricians provide." (Defs. Resp. 4:19-21.)[20]

Accordingly, UHC's contention that Plaintiffs received "diagnostic" services rather than CLS is unsupportable and misleading. (Defs. Resp. at 9:1-2.) Plaintiffs sought services that prevent the onset of disrupted lactation and forestall the onset of other conditions that breastfeeding serves to prevent. (*See supra;* SJ Souza Decl., Ex. G-12; Morton Report at 21, 23, discussing that Plaintiffs' lactation services included treatment for slow weight gain, cracked and bleeding nipples, engorgement/oversupply and pain.) Further, UHC's argument is logically flawed, as the standard of care for lactation specialists does not include a diagnosis – trained lactation providers provide comprehensive support to sustain lactation (Smith SJ Decl., Ex. 51, Chetwynd Report at 23-24.)

Importantly, the precise lactation services that Plaintiffs received, for which UHC denied coverage, are identified by ACOG and IOM as preventive CLS services under the ACA. In adjudicating Plaintiffs' claims, UHC was presented with codes related to the clinical management of lactation, for services that prevent the premature termination of breastfeeding and that were recognized as a preventive service for women per IOM and ACOG. (Defs. Resp. at 12:1-3, *cf;* Pl. SJ Br. at 3:23-25, citing to IOM; Smith Reply Decl., Ex. 77, ACOG 658 at 5; Souza SJ Decl., Ex. G-12; Morton Report at 111.)[21] The following summarizes the purported "diagnostic" services that UHC contends do not constitute preventive CLS services and Plaintiffs' response:

- [redacted]: None of the Plaintiffs' providers billed this code (*See* Smith Reply Decl., Ex. 83, Claims Chart.)
- [redacted]: These codes were submitted to UHC by Bishop's provider

[20] The IOM recommendation was based on "systemic evidence reviews, federal and international goals and clinical professional guidelines such as those set forth by AAFFP, AAP and ACOG". (Smith SJ Decl., Ex. 8, IOM Report at 116; SJ Souza Decl., Ex. G-12, Morton Report at 10.) The role of ACOG is of significant note; ACOG developed recommendations with respect to breastfeeding support during the pre-ACA deliberations, through the implementation period and was engaged by HRSA in March 2016 to provide an update to the IOM report regarding preventive services for women, the basis of the 2016 HRSA recommendation. (Smith SJ Decl, Ex. 4, Martin Report at 8.)

[21] Also contradicting its position is UHC's [redacted] (Smith Reply Decl., Ex. 84, UHC_011839-855), [redacted] UHC_0011848- [redacted] (*id.* at UHC_0011852) [redacted]

only after UHC had adjudicated the claim. (*Id.*, fn 3.) Thus, UHC's reliance on the use of purported diagnostic codes is wrong, as they were irrelevant to UHC's claim adjudication.

- [redacted]**:** These codes were submitted for services received by Carroll along with ***V24.1*** (*id.*), which is a lactation related diagnosis code and the code UHC's Coverage Determination Guideline ("CDG") recognized as such. (*See* Pl. SJ Br. at 19:12-20.)

- [redacted]**:** These codes for unspecified disorder of lactation, overfeeding of infant and neonatal difficulty feeding at breast, respectively, were submitted on behalf of Endicott. (*Id.*) No diagnosis code was even required per UHC's CDG, given that the preventive medicine service code of 99404 was also used. (*Id.* 19:17-23.) Further, these codes identify directly with preventive lactation services per ACOG. (Smith Reply Decl., Ex. 77; ACOG 658 at 5 and IOM; Pl. SJ Br. at 3:23-25, citing to IOM, and *supra*.)

The fact that UHC improperly adjudicated Plaintiffs' claims is also demonstrated by [redacted] (Smith Reply Decl., Ex. 85; UHC_014141.) (Emphasis added.) [redacted]

Defendants have offered no credible, supported response to Plaintiffs' showing that their claims were also **preventive** CLS (Pl. SJ Br. at 19:12-20):[23]

- Of the 13 claims at issue, 8 included lactation specific ICD code [redacted], (Barber, Carroll,[24] Endicott and Hoy, which is in conformance with both UHC's CDG and the CDC Billing Codes[25] (Defs. Resp. at 11:22-26.)[26]. (*See* Smith Reply Decl., Ex. 83, Claims Chart)

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[22] The fact that Plaintiff Carroll's child was listed as the patient does not change her entitlement to judgment on her claims for these additional reasons: First, UHC contends that its network of trained lactation specialists includes Pediatricians; logically, of course, it is the child and not mother who is the patient of the Pediatrician. Second, in adjudicating Plaintiff Carroll's claim, as Plaintiffs stated in its SJ Br. at 20:7-9, which UHC ignores, UHC did not state such reason as why UHC was denying coverage. *C.f.*, Defs. Resp. at fn. 12.

[23] *See* Pl. SJ Br. at 19:4-20:22 (CDG Comparison); *see also id.* at fn. 25 (discussing UHC's CDG and that it did not specify any limitations on CLS based on diagnosis, as it did for other preventive services).

[24] Plaintiffs do not concede that the coding for Carroll's claims was not in compliance with the CDG (Defs. Resp. at fn 12). [redacted] (Smith Reply Decl., Ex. 83, Claims Chart.)

[25] Further, UHC's contention that the CDC billing codes further limit the guidance provided in UHC's CDG is unsupportable; UHC's CDG includes only three references to the CDC or the ACIP (the Advisory Committee on Immunization Practices of the CDC), and each is limited to CDC guidance ***regarding immunizations***. (Huckaby Decl., Exs. H-1 at UHC_149629-31, H-5 at UHC_149493-95.)

[26] Plaintiffs do not concede the relevance of the CDC Billing Codes, but offer this comparison to illustrate the soundness of Plaintiffs' claims as to the scope of preventive CLS.

- Of the claims that did not include codes [redacted], three included service code [redacted] or [redacted] (Bishop, Condry, Endicott) (Smith Reply Decl., Ex. 83, Claims Chart), which do not require a diagnosis code per UHC's CDG (Pl. SJ Br. at 19:12-20).

In response to Plaintiffs' showing that their claims conformed to UHC's CDGs,[27] (Pl. SJ Br. at 19:12-24, 20:1-22), UHC backpedaled and claimed that its own CDG is not applicable, proffering, for the first time, a "Nonphysician Health Care Professionals Billing Evaluation and Management Codes Policy" ("NP Policy") (Defs. Resp. at fn 13). UHC's response contradicts UHC's previous contention that the CDGs "instruct the public about what codes need to be billed to obtain reimbursement for preventive services, including ACA-mandated "Breastfeeding Support, Supplies, and Counseling." (Huckaby Decl., Dkt. 105, Ex. H at ¶5.) Also, UHC's reliance on the NP Policy does not raise a genuine disputed issue of material fact because:

(1) the 11/9/2016 NP Policy proffered was not in effect at the time the Plaintiffs sought care (Huckaby Reply Dec., Ex. M at ¶5, Ex. M-1), as the latest date of service for the Plaintiffs is 2/24/2016 (*see* Smith Reply Decl., Ex. 83, Claims Chart);

(2) the NP Policy does not include the list of professionals to which the policy purportedly applies (*see* UHC 002636, "[f]or purposes of this policy, the specialties that are considered nonphysician health care professionals are listed in the attachment section…" and UHC 002637, noting that no list was included in Huckaby Reply Dec., Ex. M-1; and

(3) the NP Policy is silent with respect to preventive care.[28]

Plaintiffs' evidence and the foregoing also undermines UHC's litigation tactic of introducing a "diagnosis" distinction for CLS, as that was not what UHC conveyed to Plaintiffs:[29]

- Not one of the notices of adverse benefit determinations refers to a diagnosis (Smith Reply Decl., Ex. 83, Claims Chart; Pl. SJ Br. at 23:10-14, 24:3-7, 24:15-18.)
- Five claims (Bishop, Condry and Hoy) were adjudicated with Preventive Medicine as the type of service. (Smith Reply Decl., Ex. 83, Claims Chart.)
- With respect to two of Carroll's claims with identical ICD coding, two different benefit

[27] UHC mischaracterized Plaintiffs' position with respect to therapeutic service performed at the same time as a preventive service (Defs; Resp at fn 11, and 20 *quoting* Huckaby Decl., Ex. H-1 at UHC_149632). Encounters where the purpose is to initiate or sustain breastfeeding are preventive, CLS may require more than one preventive encounter, any therapeutic service done as an integral part of any preventive CLS encounter(s) is preventive per the CDG. (*See* Pl. SJ Br. at 20.)

[28] An absurd result emerges from applying UHC's NP Policy restrictions to the CDG: no codes remain for use by nonphysicians for a one-on-one preventive breastfeeding counseling encounter (*See*, Smith Reply Decl., Ex. 81, Code Chart) and the only lactation specific code [redacted] for Barber's two claims. (Smith Reply Decl., Ex. 83, Claims Chart).

Although UHC contends it can question the validity of a preventive coding (Defs. Resp. at fn 13), UHC has offered no evidence that it investigated the scope of services provided to Plaintiffs on such ground, and, other than through this litigation, UHC never informed Plaintiffs that their benefit determination was purportedly based on diagnosis. The evidence outlined here, however, demonstrates otherwise.

determinations were made: [redacted] (*Id.*)

- Barber's two claims coded as [redacted] (*Id.*)
- Endicott's claims were adjudicated [redacted] (*Id.* at fn. 12.)

The foregoing is plainly reflective of UHC's utter and knowing failure to put the necessary administrative infrastructure in place to comply with the ACA's CLS coverage mandate, and to properly adjudicate Plaintiffs' claims.[30] Accordingly, Plaintiffs are entitled to Summary Judgment.

B. Plaintiffs Are Entitled To Summary Judgment On Count I For UHC's Failure To Conduct A Full And Fair Review

1. The Uncontroverted Evidence Establishes That UHC Did Not Provide Plaintiffs A Full And Fair Review Of Their Benefits Claims

The uncontroverted evidence establishes that UHC breached its duty to conduct a "full and fair review" with respect to Plaintiffs Condry, Hoy, Bishop, Endicott, and Barber's claims for coverage/reimbursement under their respective Plans. *See supra*, Section A, and Pl. SJ Br. at 5:23-11:24; 12:3-22:6, 22:8-26:2. Lacking an effective response, UHC simply regurgitates the same baseless arguments set forth in its opening brief.

Condry's March 4, 2015 Claim. UHC devotes a paragraph re-asserting that it had no

[30] "Discretion" does not justify, excuse or explain UHC's lack of compliance and treatment of the Plaintiffs. (Defs. Resp. 9:15-18, 10:1; 4:23; 12:3-4). Discretion is not unchecked; it is has to be grounded and, here, exercised within the ACA and HRSA-stated CLS comprehensive scope (Pl. SJ Br. at 21:14-21; 22:1-6, Section II A.), and must be based on "relevant clinical evidence" and on "established …techniques" (*Id.* at 22:1-3, Section II A.). UHC's highly restricted CLS scope that it requests this Court to adopt is unsupported. It contradicts UHC's CDG (Pl. SJ Br. at 19:12-24; 20:1-22). Also, it contradicts UHC's actual response to the IOM Report (*supra*): [redacted] (Smith Reply Decl, Ex. 84, UHC_011839-855). UHC's argument about the scope of CLS was contrived in the context of responding to this litigation.

obligation to review Condry's March 19 and April 14, 2015 claims because they were never submitted.[31] Defs. Br. at 12:14-21. But UHC never addresses Condry's basis for Count I, *i.e.*, her initial, March 4, 2015 claim that was submitted and rejected. Pl. SJ Br. at 23:5-9. That failure is a tacit admission that UHC failed to conduct a full and fair review of the March 4, 2015 claim.

UHC's "Explanations" For Denying Plaintiffs' Claims. UHC's terse "explanations" that "[t]here may be a more appropriate CPT or HCPCS code that describes this service" and that "[t]he service code is not separately reimbursable in this setting" does not provide a "specific reason or reasons for the adverse determination" in "a manner calculated to be understood" by Condry, Hoy, and Bishop. Pl. SJ Br. at 23:10-24:2. It was also unreasonable to expect Condry, Hoy, and Bishop to understand, what, if any, additional material or information these "explanations" were requesting. *Id.* at 24:3-14. In response, UHC first asserts that Condry, Hoy, and Bishop understood these "explanations" -- even though they specifically testified that they did not (Pl. SJ Br. at 23 n. 30) -- because they understood that their lactation consultants had provided codes to UHC. Defs. Resp. at 13:1-3. But the inference UHC tries to force is absurd. That Condry, Hoy, and Bishop believed their providers understood what the "codes" were does not mean that Plaintiffs Condry, Hoy and Bishop understood what the "codes" were; ERISA does not recognize a "transitive property of knowledge" from provider to claimant. *See Wong v. Aetna Life Ins. Co.*, 51 F. Supp. 3d 951, 964 (S.D. Cal. 2014) ("cyptic jargon" not calculated for participant's understanding). Condry, Hoy and Bishop are not medical professionals and do not understand, or have any reason to understand, the significance of "coding" – they simply understood that their claims had been summarily denied without an explanation that was meaningful to them or any other layperson.

UHC also contends that it was "reasonably clear" that the words "more appropriate" were sufficient to inform "Plaintiffs of the type of additional information that might be needed to perfect their claims." Defs. Resp. at 13:1-11. This is ludicrous. Expecting a claimant to recognize the cryptic statement that "[t]here may be a more appropriate CPT or HCPCS code that describes this service" as a specific request is plainly unreasonable. As the Ninth Circuit stated emphatically, "if the plan

[31] As discussed in Plaintiffs' SJ Motion, Condry did not submit claims for the March 19 and April 14, 2015 services because UHC had already demonstrated the futility of such submissions by their denial of her claim for the March 4, 2015 services.

administrators believed that more information is needed to make a reasoned decision, ***they must ask for it***." *Booton v. Lockhead Med. Benefit Plan*, 110 F.3d 1461, 1463 (9th Cir. 1997)(emphasis added). Despite their protestations to the contrary, Defendants made no such request, or, at least, did not make one that was recognizable as such.

As for Barber and Endicott, UHC baldly concludes, without any elaboration, that its explanations for the denials of their claims were sufficient. Defs. Resp. at 13:12-19. UHC does not address the fact that its denial of Barber's claim as a "non-medical service or personal item" is facially absurd, as Barber's CLS is indisputably a medical service, nor does it acknowledge or address the fact that it failed to explain how it reached that conclusion, or that it failed to suggest any means for Barber to "perfect her claim." Pl. SJ Br. at 24:15-18. Additionally, UHC never addresses how its initial denial of Endicott's claim on the basis that it "asked [her] for more information and didn't receive it in time" squares with its previous representation to Endicott that she did "not need to respond or take any action." *Id.* at 24:19-25:4.

UHC's Failure To Respond To Plaintiffs' Claims And Appeals In A Timely Manner. It is undisputed that UHC failed to directly respond to Hoy's October 28, 2015 appeal with a substantive notice informing her of the grounds for the denial, and that she could obtain more "appropriate" codes from her provider to cure her claims. Pl. SJ Br. at 25:9-26:2. UHC's response is to, again, assert that the "explanation" that "[t]here may be a more appropriate CPT or HCPCS code that describes this service" in the EOBs generated on December 22, 2015 and December 23, 2015—almost two months after Hoy first appealed and more than 30 days after UHC informed Hoy that she would receive a substantive response to her appeal "shortly"—was sufficient notice to Hoy of the steps she should take. Defs. Resp. at 13:20-14:2; (Seay/Hoy Decl., Exs. A-4, A-8, A-9).[32] Glaringly, the EOBs did not address or mention Hoy's appeal in any way. (Seay/Hoy Decl., Exs. A-8, A-9). In any event, as discussed, that "explanation" does not amount to the required specific request for more information.[33]

[32] Indeed, UHC sent the same form letter again for Hoy's second appeal in January 2016, even though UHC had, by that point, finally sent Hoy a letter "explaining" its denial. (Seay/Hoy Decl., Ex. A-12.)

[33] Though UHC cites *Brogan v. Holland*, 105 F.3d 158 (4th Cir. 1997), as discussed previously, *Brogan* does nothing to support UHC's position regarding "substantial compliance" because UHC never cured its notice deficiencies. Pl. SJ Br. at 25 n.34.

2. Plaintiffs Are Entitled To Summary Judgment For Count I Under Both ERISA Section 502(a)(1)(B) and 502(a)(3)

First, UHC argues that Plaintiffs have not demonstrated entitlement under ERISA Section 502(a)(3) because monetary relief is available under Section 502(a)(1)(B), *citing Moyle v. Liberty Mut. Ret. Ben. Plan*, 823 F.3d 948 (9th Cir. 2016). Defs. Resp. at 14:7-14:26. Ironically, *Moyle* states the exact opposite: "***[w]hile Amara did not explicitly state that litigants may seek equitable remedies under § 1132(a)(3) if § 1132(a)(1)(B) provides adequate relief, Amara's holding in effect does precisely that.***"[34] *Id.* at 960 (emphasis added.) And neither *Moyle* or *CIGNA Corp. v. Amara*, 563 U.S. 421 (2011), both of which were appeals to grants of summary judgment, limited a plaintiff's ability to seek simultaneous relief under both sections to "pleading alternative causes," contrary to UHC's assertion. ***Second***, UHC also contends that Plaintiffs have not asserted any issues with the plan's overall methodology for determining benefits, which, according to UHC, may justify separate relief under Section 502(a)(3). Defs. Resp. at 15:1-16. But Plaintiffs have actually done just that (*see supra*) by demonstrating that UHC's methodology for administering CLS claims is, as a whole, fatally flawed and incapable of "providing timely and substantive responses to requests for out-of-network benefits and/or appeals to denials of requests for out-of-network benefits." *See Wit v. United Behavioral Health*, No. 14-CV-02346-JCS, 2014 WL 6626894, at *10 (N.D. Cal. Nov. 20, 2014) (claims under both Sections 502(a)(1)(B) and 502(a)(3) permitted where "plaintiffs alleged both that they had been improperly denied benefits and that the plan administrator was using an improper methodology in adjudicating claims").

C. Plaintiffs Are Entitled To Summary Judgment On Count III For UHC's Co-Fiduciary And Liable Non-Fiduciary Claims

UHC argues that Plaintiffs are not entitled to summary judgment on their co-fiduciary and liable non-fiduciary claims in Count III based on the recycled legal arguments this Court previously

[34] Plaintiffs relied upon *Moyle* in their opening brief. Pl. SJ Br. at 26:14-15. UHC also cites *O'Rourke v. N. California Elec. Workers Pension Plan*, No. 3:16-CV-02007-WHO, 2017 WL 5000335 (N.D. Cal. Nov. 2, 2017), for the proposition that equitable relief is not simultaneously available under Section 502(a)(3) and Section 502(a)(1)(B). There, the court appears to have quoted *Moyle* out of context. *See Moyle*, 823 F.3d 959, 965 (explaining that "[c]ourts have subsequently interpreted *Varity* to mean that equitable relief under § 1132(a)(3) is not available if § 1132(a)(1)(B) provides an adequate remedy" but clarifying that under *Amara*, "[a]ppellants may pursue simultaneous claims under 29 U.S.C. § 1132(a)(1)(B) and § 1132(a)(3)"). UHC's other authorities, *Forsyth v. Humana, Inc.*, 114 F.3d 1467 (9th Cir. 2012) and *Ford v. MCI Commc'ns Corp. Health & Welfare Plan*, 399 F.3d 1076 (9th Cir. 2005), predate *Amara*.

rejected and willful ignorance or disregard of the evidence Plaintiffs have submitted.[35] Defs. Resp., at 15:17-17:7; Pl. SJ Br., at 27:1-8. The evidence establishes that UHC's CLS coverage was created and executed by a key group of persons for all of the UHC Defendants. Pl. SJ Br. at 27:11-17. As such, all UHC Defendants were knowingly complicit in each other's fiduciary breaches. Whether the UHC Defendants are classified as "functional fiduciaries,"[36] or participating non-fiduciaries to the Plans, each was administering, is beside the point; they are all jointly and severally liable for each other's fiduciary breaches. *See* Dkt. No. 68, at 4-5; *Harris Tr. & Sav. Bank v. Salomon Smith Barney, Inc.*, 530 U.S. 238, 246 (2000).

UHC's only retort to the evidence Plaintiffs submitted is that it is "speculative". This paltry response does not create a genuine issue of fact. *Dep't of Toxic Substances Control v. Technichem, Inc.*, No. 12-CV-05845-VC, 2016 WL 1029463, at *2 (N.D. Cal. Mar. 15, 2016)("'to survive summary judgment, [the defendants] must establish a genuine factual dispute, which involves more than some metaphysical doubt as to the material facts'")(quoting *Stanislaus Food Prods. Co. v. USS-POSCO Indus.*, 803 F.3d 1084, 1088 (9th Cir. 2015)) (Chhabria, J.).[37] As such, Plaintiffs are entitled to summary judgment as to Count III as well.

[35] UHC continues to assert that non-fiduciary liability is limited to only prohibited transaction claims under ERISA Section 406. Defs. Resp., at 16:14-17:7. But, as post-*Harris Trust* courts have recognized, the Supreme Court held that "there is 'no limit [...] on the universe of possible defendants' who knowingly participate in a fiduciary's violation." *Solis v. Couturier*, No. 2:08CV02732-RRB-GGH, 2009 WL 1748724, at *4 (E.D. Cal. June 19, 2009) (concluding that "'no limit' means 'no limit'"); *see Bush v. Liberty Life Assurance Co. of Boston*, 130 F. Supp. 3d 1320, 1331 (N.D. Cal. 2015) (citing cases). Indeed, this Court already addressed *Landwehr v. DuPree*, 72 F.3d 726 (9th Cir. 1995), which predates *Harris Trust*. Pl. Memo, at 27 n.37. UHC also cites *Davidson v. Hewlett-Packard Co.*, No. 5:16-CV-01928-EJD, 2017 WL 106398, at *2 (N.D. Cal. Jan. 11, 2017), where the court dismissed the *pro se* plaintiff's claim that the "individual defendants knowingly participated in wrongful transactions" because there were no allegations that those transactions were "barred under § 406(a)." The *Davidson* court went on, however, to clarify that the plaintiff did not assert a claim for "knowingly participat[ing] in fiduciary breaches as in *Couturier*. *See id.*

[36] "ERISA treats as a fiduciary those explicitly named as such in a plan, 29 U.S.C. § 1102(a)(1), as well as those who perform certain fiduciary functions regardless of official designation." *Monper v. Boeing Co.*, 104 F. Supp. 3d 1170, 1178 (W.D. Wash. 2015).

[37] Though the evidentiary and legal standards are different, where, as here, UHC has failed to proffer any rebuttal evidence and asserts the same purely legal arguments, the Court's prior legal analysis including on the motion to dismiss should apply here with the same force. *See Moonin v. Nevada ex rel. Dep't of Pub. Safety Highway Patrol*, No. 3:12-CV-000353-LRH, 2015 WL 4113289, at *6 (D. Nev. July 8, 2015), *aff'd sub nom. Moonin v. Tice*, 868 F.3d 853 (9th Cir. 2017)(noting that even though the law of the case from a motion to dismiss decision is not fully applicable on a motion for summary judgment, "the [c]ourt may reconsider its preliminary reasoning in light of the totality of the evidence gathered during discovery").

D. Carroll Demonstrated Her Entitlement to Pursue Her Claims

For the reasons set forth *supra* and in Plaintiffs' SJ Motion, Plaintiff Carroll is entitled to summary judgment on Counts V and VI.[38] UHC makes a conclusory retort, that ignores undisputed facts, to Carroll's demonstration (Pl. SJ Br. at 28) that pursuit of an appeal would have been futile. Incredulously, UHC states that an "appeal would have given Carroll the opportunity to demonstrate her position that ***no in-network providers exist*** and, therefore, her entitlement to a ***gap exception***." *Id.* at 18:7-9. That is fantasy: UHC explicitly took the position that care is available from any of the thousands of pediatricians and OB/GYNs. As a [redacted] (Smith SJ Decl., Ex. 22, UHC_056770, 056772, 056774 (emphasis added.)). Furthermore, even when Plaintiff Bishop tried to coordinate CLS coverage with UHC from an out of network provider, UHC denied the claim; therefore, UHC was not, even under a GAP exception complying with the ACA. *See* Pl. SJ Br. at 17:17-20. Carroll demonstrates the futility of imposing an exhaustion requirement on her.

III. CONCLUSION

For all the foregoing reasons, Plaintiffs' Motion for Partial Summary Judgment must be granted.

Dated: January 19, 2018

CHIMICLES & TIKELLIS LLP

By: */s/ Kimberly Donaldson Smith*

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[38] Regarding Count VI, as stated in Plaintiffs' SJ Motion at 28, n9, Carroll sufficiently pleads her claim in the alternative, and the facts adduced support a finding that UHC acted with fraud and bad faith.

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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

RACHEL CONDRY, JANCE HOY, CHRISTINE ENDICOTT, LAURA BISHOP, FELICITY BARBER, and RACHEL CARROLL on behalf of themselves and all others similarly situated,

Plaintiffs,

v.

UnitedHealth Group Inc.; UnitedHealthcare, Inc.; UnitedHealthcare Insurance Company; UnitedHealthcare Services, Inc.; and UMR, Inc.,

Defendants.

Case No.: 3:17-cv-00183-VC

DECLARATION OF KIMBERLY DONALDSON SMITH IN SUPPORT OF PLAINTIFFS' REPLY IN SUPPORT OF PLAINTIFFS' CROSS-MOTION FOR PARTIAL SUMMARY JUDGMENT

Honorable Vince G. Chhabria

I, Kimberly Donaldson Smith, hereby declare and state as follows:

1. I am a Partner of the firm of Chimicles & Tikellis LLP, counsel for Plaintiffs Rachel Condry, Jance Hoy, Christine Endicott, Laura Hipple (nee Bishop), Felicity Barber, and Rachel Carroll (collectively, "Plaintiffs") in this action. I make this declaration in support of Plaintiffs' Reply in Support of Plaintiffs' Cross-Motion for Partial Summary Judgment. I have personal knowledge of the following facts, and if called as a witness, I could and would competently testify to them.

2. True and correct copies of the following exhibits are submitted in support of Plaintiffs' Reply in Support of Plaintiffs' Cross-Motion for Partial Summary Judgment and attached hereto:

Exhibit No.	Description
66	Copy of UHC Conference Call Meeting Agenda Re: Preventive Benefit Women's Health (UHC_011837)
67	Copy of UHC Email Re: AMA Meeting and Prev Care (UHC_012277-12286)
68	Copy of UHC Email Re: Preventive Coding Summary (UHC_009191-9192)
69	Copy of UHC Women's Preventive Health Coding Summary for Providers (UHC_092051-92053)
70	Henry Mayo Newhall Hospital requests information about the development of an outpatient lactation clinic, and how to bill for the lactation consultants' services (UHC_008950-53)
71	Excerpts from the Deposition Transcript of Plaintiff Laura Bishop
72	Kangos Pediatrics - Breast Feeding Webpage as of July 22, 2015
73	Excerpts from the Deposition Transcript of Plaintiff Felicity Barber
74	Copy of Felicity Barber's UHC Provider Search Results (PL_FB000016-17)
75	UHC Network Gap Exceptions Standard Operating Procedure (SOP) (UHC_039465-39478)
76	Distance of Purported Lactation Specialists from Condry and Barber's Zip Codes
77	ACOG Committee Opinion Number 658, "Optimizing Support for Breastfeeding as Part of Obstetric Practice", Feb, 2016 (UHC_003629-3635)
78	Excerpts from the Deposition Transcript of Dr. Jane Morton

Exhibit No.	Description
79	IOM Clinical Prevention Services for Women - Closing the Gap (excerpts)
80	Women's Preventive Services Initiative "WPSI" 2016 Final Report (excerpts)
81	Code Chart
82	Women's Preventive Services Initiative Draft Recommendation
83	Claims Chart
84	UHC IOM - Women's Health Preventive Coding (UHC_011839-11855)
85	UHC New Preventive Code Email and List (UHC_014141-14142)
86	Copy of UHC EOB Statement to Laura Bishop (PL_LB000005-08)
87	Copy of Lactation Claims for Rachel Carroll and UHC EOB (PL_RAC000003-06; PL_RAC000131-132)

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on January 19, 2018

By: */s/ Kimberly Donaldson Smith*

Kimberly Donaldson Smith
CHIMICLES & TIKELLIS LLP
361 W. Lancaster Avenue
Haverford, PA 19041
Phone: (610) 642-8500
Fax: 610-649-3633
KMD@Chimicles.com

EXHIBIT 66

REDACTED VERSION OF DOCUMENT(S) SOUGHT TO BE SEALED

EXHIBIT 67

REDACTED VERSION OF DOCUMENT(S) SOUGHT TO BE SEALED

EXHIBIT 68

REDACTED VERSION OF DOCUMENT(S) SOUGHT TO BE SEALED

EXHIBIT 69

REDACTED VERSION OF DOCUMENT(S) SOUGHT TO BE SEALED

EXHIBIT 70

REDACTED VERSION OF DOCUMENT(S) SOUGHT TO BE SEALED

EXHIBIT 71

REDACTED VERSION OF DOCUMENT(S) SOUGHT TO BE SEALED

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

RACHEL CONDRY, JANCE HOY, CHRISTINE ENDICOTT, LAURA BISHOP, FELICITY BARBER, and RACHEL CARROLL, on behalf of themselves and all others similarly situated,

Plaintiffs,

VS.

UNITEDHEALTH GROUP INC., UNITEDHEALTHCARE, INC., UNITEDHEALTHCARE INSURANCE COMPANY, UNITED HEALTHCARE SERVICES, INC., and UMR, INC.,

Defendants.

Case No.: 3:17-cv-00183-VC

****

ORAL AND VIDEOTAPED DEPOSITION OF
LAURA HIPPLE
OCTOBER 10, 2017

****

spoke with the pediatrician about those things because I wanted to make sure that I was doing the right thing. And for the most part I felt like pediatricians were pretty supportive of the options -- or the decisions that I was making with regards to his -- his nutrition.

Q. Did you ask questions about breastfeeding of your pediatrician during these post-birth visits?

A. I do know that I specifically spoke with them about breast milk because [redacted]

[redacted]

[redacted] Did the pediatrician talk about positioning during breastfeeding?

A. No. Not that I recall.

Q. Would it surprise you to find that in the notes of the visit?

A. What was that?

Q. Would it surprise to you find that in the notes of one of the visits with the pediatrician?

A. I don't think it would surprise me only because there are a lot of notes and I am not capable of memorizing all of them, so I don't think it would necessarily surprise me, but I know that I spoke about babies' positioning with [redacted]

Q. Okay. And do you -- if there is a note in the pediatrician's records that says that she discussed positioning with you, would you question that?

A. Would I -- what would I question?

dates and times are wrong in my e-mails. Like I said, I did not do any tailoring or anything. I just forwarded them on. So I'm not for certain right now if there's something maybe even wrong with the medical records. I really don't know.

Q. Did you keep any notes of your pediatrician visits?

A. I think that they normally gave out these little forms like -- but I think those were only for well -- well visits. I don't -- and I believe I still have maybe copies of well visit notes, but I don't -- they don't normally give a summary of care of the appointment. I think she may have given just the prescription [redacted], but I don't recall specifically a form from that appointment or notes.

Q. Do you keep those well visit notes you're talking about?

A. Normally I would. I don't have a specific amount of time. Sometimes I keep them just for keepsakes. A lot of the times, though, those are just like, oh, he's this tall or this -- he weighs this much. It's usually not more than where he stands percentage-wise.

Q. Did you schedule -- I'm talking about the

EXHIBIT 72

Kangos Pediatrics
(512) 250-1997

Search

- Breast Feeding
- Asthma in Children
- ADHD
- Traveling with Children
- Child Health Topics
- Center for Disease Control and Prevention
- Car Seat Recommendations
- Product Recalls
- Immunizations

healthychildren.org
Powered by pediatricians. Trusted by parents.
learn more

Austin, TX Pediatric Office
Kangos Pediatrics
12411 Hymeadow Dr., Suite 3F
Austin, TX
<spanitemprop="postalCode">78750
(512) 250-1997
find us

- Our Philosophy
- Patient Forms
- FAQs
- Dr. Kangos' Blog

Our Blog

Like Us

We understand many women may be apprehensive or unsure at first about breastfeeding vs. bottle-feeding their baby. It's normal to have many questions related to breastfeeding. We are here to support you.

Central Texas Healthy Mothers, Healthy Babies Coalition (KeepAustinBreastfeeding.com) provides excellent support and information on breastfeeding. **Midwives**, in the Austin area, utilizing birthing centers, hospitals and home delivery are highlighted.

Attachment Parenting International, Central Texas Chapter
Extended breastfeeding, cosleeping, gentle discipline and mindfulness are among the areas emphasized.

United States Breastfeeding Coalition is a nonprofit coalition of 40 organizations to support breastfeeding. It is the most comprehensive source of accurate information and links.

La Leche League was founded to give information and encouragement, mainly through personal help, to all mothers who want to breastfeed their babies. Visit their amazing website serving mothers in over 70 countries.

The mission of La Leche League is to help mothers worldwide to breastfeed through mother-to-mother support, encouragement, information, and education, and to promote a better understanding of breastfeeding as an important element in the healthy development of the baby and mother.


Follow Us

EXHIBIT 73

REDACTED VERSION OF DOCUMENT(S) SOUGHT TO BE SEALED

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

RACHEL CONDRY, JANCE HOY, CHRISTINE ENDICOTT, LAURA BISHOP, FELICITY BARBER, and RACHEL CARROLL, on behalf of themselves and all others similarly situated,

Plaintiffs,

vs.

Case No.: 3:17-cv-00183-VC

UNITEDHEALTH GROUP INC., UNITEDHEALTHCARE, INC., UNITEDHEALTHCARE INSURANCE COMPANY, UNITED HEALTHCARE SERVICES, INC., and UMR, INC.,

Defendants.

CONFIDENTIAL

VIDEOTAPED DEPOSITION OF FELICITY H. BARBER

San Francisco, California
Friday, October 20, 2017
Volume I

Reported by: SUZANNE F. GUDELJ
CSR No. 5111
Job No. 2712857
PAGES 1 - 224

including this type of thing, that's what we're looking for. So --

And did you -- before you saw -- well, so after you saw [redacted], at some point in time you went on to UHC's website and did a search for lactation providers?

A Yes.

Q And when did you do that?

A I don't recall.

Q Okay. Was it after you had decided to be part of this lawsuit?

A It was before.

Q And how -- how much before?

A Around the time I placed the appeal.

Q Okay. So in 2017?

A Yes.

Q Okay. And when you did that search, did you decide what the mile radius should be?

A Yes.

Q Okay. And what -- what did you decide the mile radius should be for that search?

A I -- I don't recall exactly.

Q Okay. Did you try other radiuses?

A Yes.

Q And did you try more than 20 miles?

A I don't recall.
Q Okay. Do you recall -- what did you search?
A Lactation consultant.
Q Okay. And -- well, let's take a look at it.
(Deposition Exhibit 47 marked by the court reporter.)
BY MS. HANSON:
Q I'm going to hand you what's been marked as Exhibit 47. And can you tell me what Exhibit 47 is?
A It's a screenshot of a search on UnitedHealthcare's website for a lactation specialist within a 20-mile radius of my ZIP Code.
Q Okay. And you said you tried different mile radiuses. So did you use that -- that drop down box where it says 20 miles?
A Yes.
Q Okay. And for the record, Exhibit 47 is PL_FB 16 through 17.
And what -- what other mile radiuses do you recall using?
A As far as I recall, when I went on, there was like an automated number of miles.
Q So preset choices?

A Yeah, which I think -- I think the preset choice was smaller than that. And then I tried I guess up to 20. I don't recall if I tried more or less, but there wasn't anyone anywhere near me that could provide the support.

Q So you thought that 20 miles was the highest that it went?

A I don't know how high it goes.

Q Did you search 30 miles from your home?

A I don't recall.

Q Okay. Do you know that there are lactation specialists within 30 miles of your home that are in United's network?

A I don't know.

Q And did you do any search on UHC's website prior to 2017?

A No.

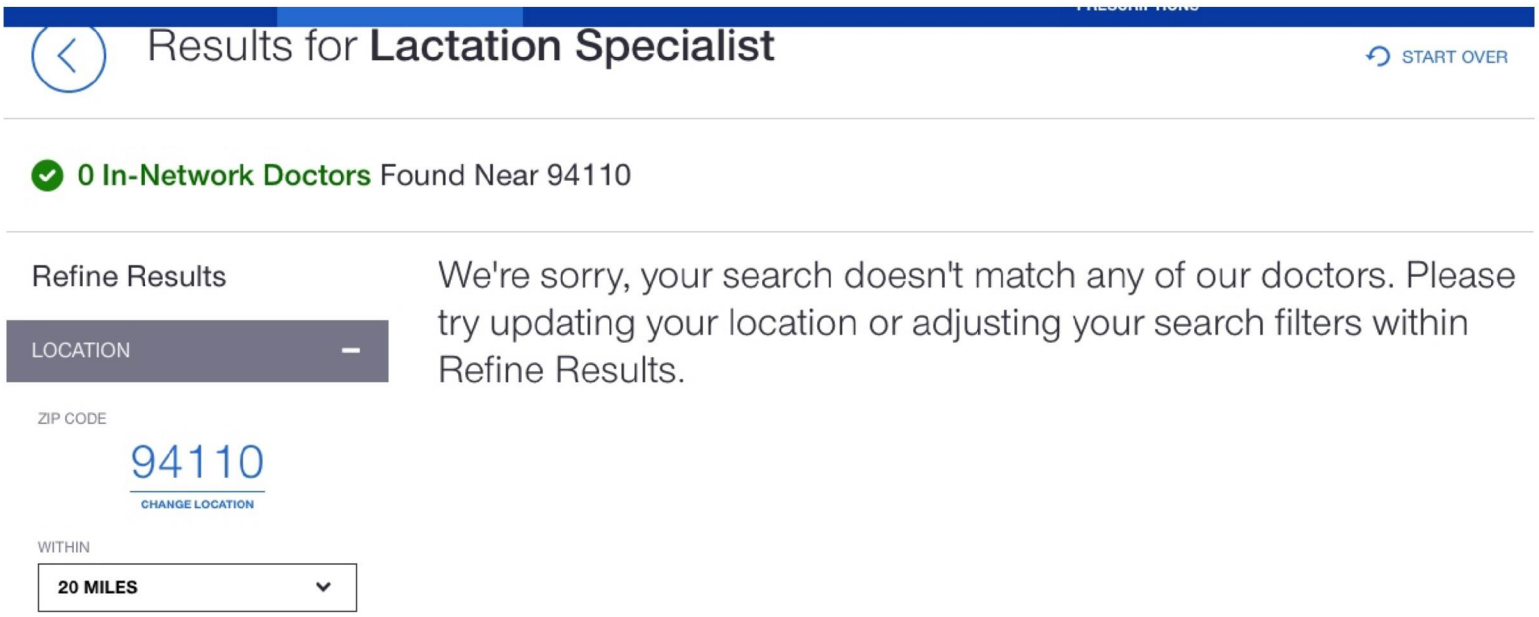
Q Okay.

(Deposition Exhibit 48 marked by the court reporter.)

BY MS. HANSON:

Q I'm going to ask that you take a look at what's being marked as Exhibit 48. And once you've had a chance to look at it, if you could let me know what Exhibit 48 is.

EXHIBIT 74


Results for Lactation Specialist
START OVER
0 In-Network Doctors Found Near 94110
Refine Results
LOCATION
ZIP CODE
94110
CHANGE LOCATION
WITHIN
20 MILES
We're sorry, your search doesn't match any of our doctors. Please try updating your location or adjusting your search filters within Refine Results.

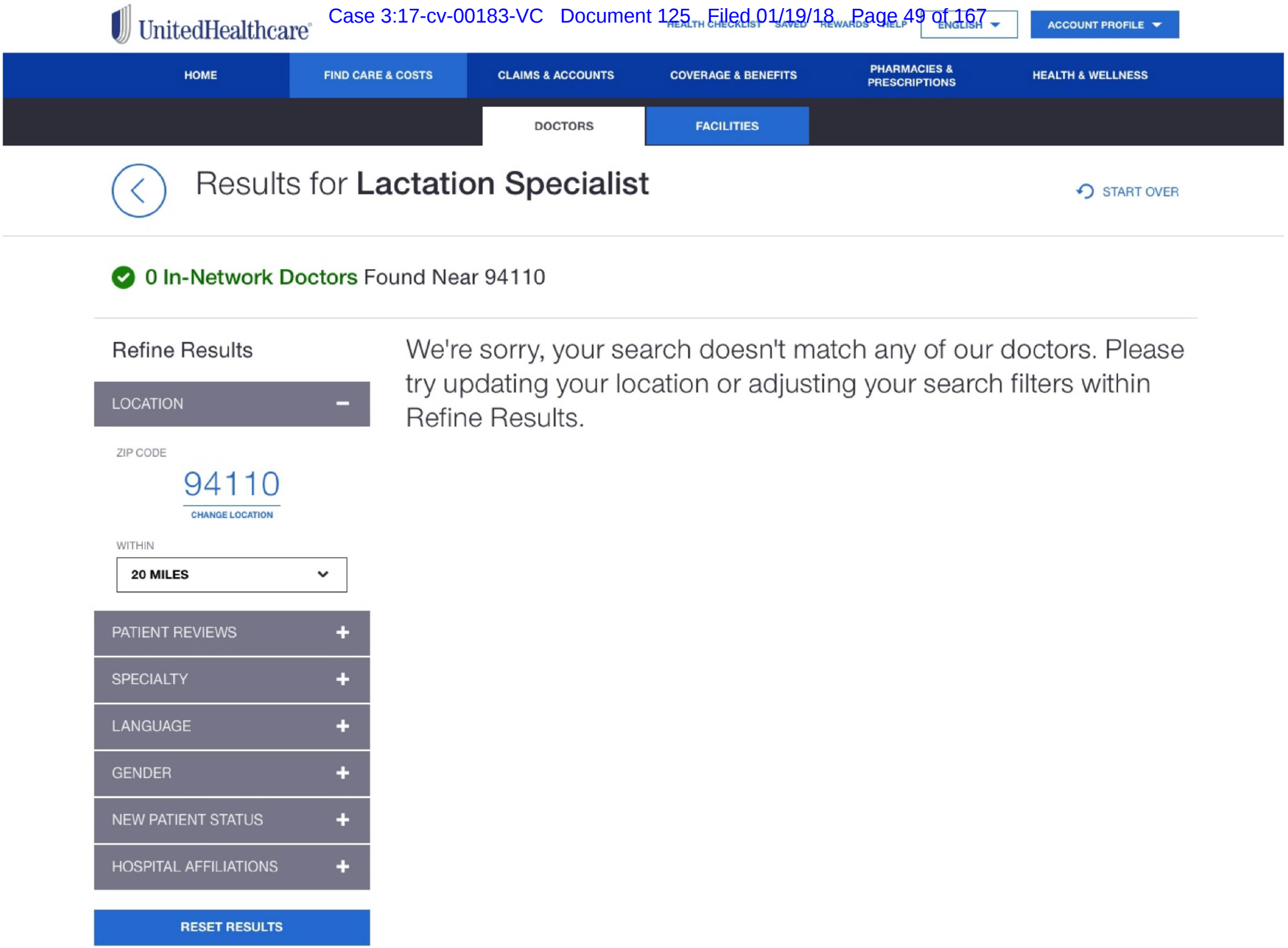

UnitedHealthcare
HEALTH CHECKLIST
SAVED
REWARDS
HELP
ENGLISH
ACCOUNT PROFILE
HOME
FIND CARE & COSTS
CLAIMS & ACCOUNTS
COVERAGE & BENEFITS
PHARMACIES & PRESCRIPTIONS
HEALTH & WELLNESS
DOCTORS
FACILITIES
Results for Lactation Specialist
START OVER
0 In-Network Doctors Found Near 94110
Refine Results
We're sorry, your search doesn't match any of our doctors. Please try updating your location or adjusting your search filters within Refine Results.
LOCATION
ZIP CODE
94110
CHANGE LOCATION
WITHIN
20 MILES
PATIENT REVIEWS
SPECIALTY
LANGUAGE
GENDER
NEW PATIENT STATUS
HOSPITAL AFFILIATIONS
RESET RESULTS

EXHIBIT 75

REDACTED VERSION OF DOCUMENT(S) SOUGHT TO BE SEALED

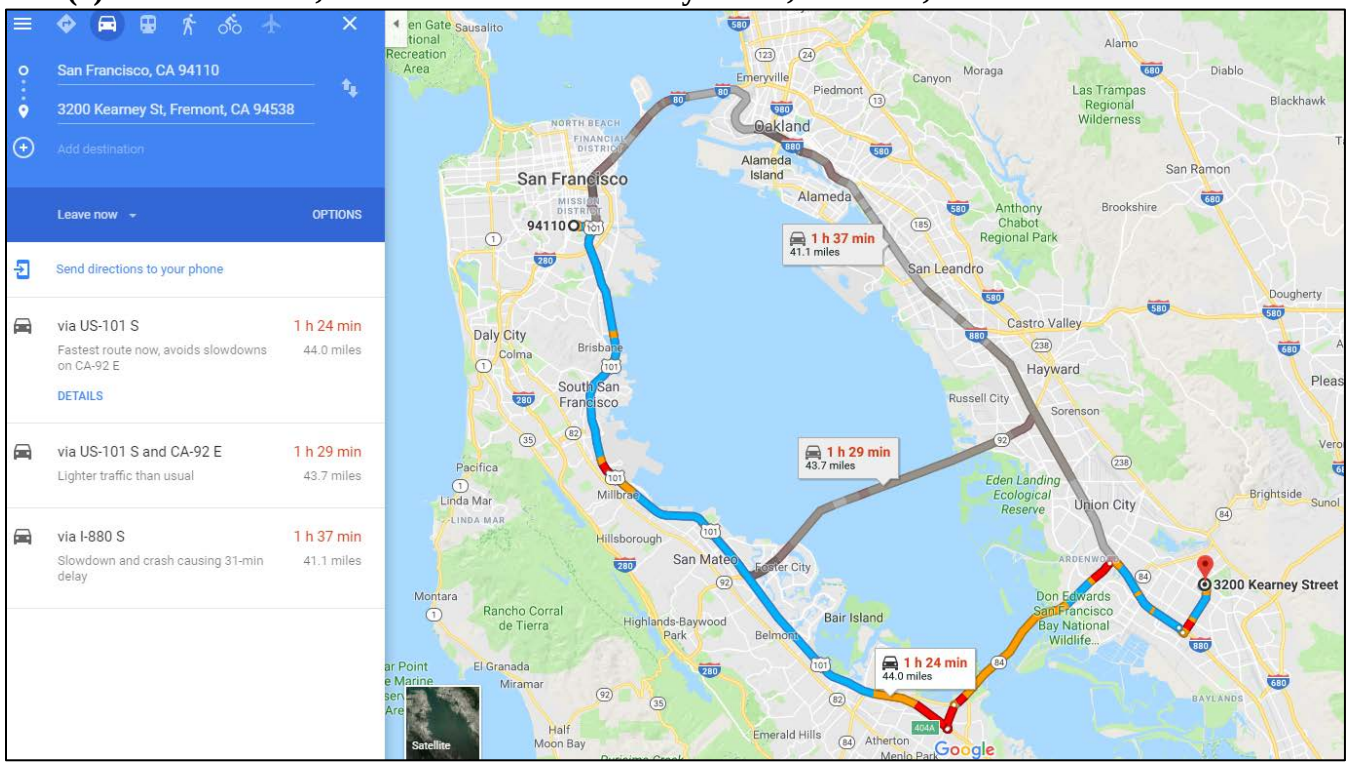
EXHIBIT 76

Smith Reply Decl., Ex. 76

Distance from Barber's Zip Code (San Francisco, CA 94110) and "Lactation Specialists" Purported to be in UHC's Network During February 2016

1. Maree E. Makins, Cheryl M. Dronkers and Jennifer P. Scales, places of service included:
   a. 3200 Kearney Street, Fremont, CA 94538 – shortest driving distance: 41.1 miles
   b. 4050 Dublin Blvd., Dublin CA 94568 – shortest driving distance: 39.5 miles
   c. 301 Old San Francisco Road, Sunnyvale, CA 94086 – shortest driving distance: 40 miles
   d. 795 El Camino Real, Palo Alto, CA 94301 – shortest driving distance: 32.7 miles

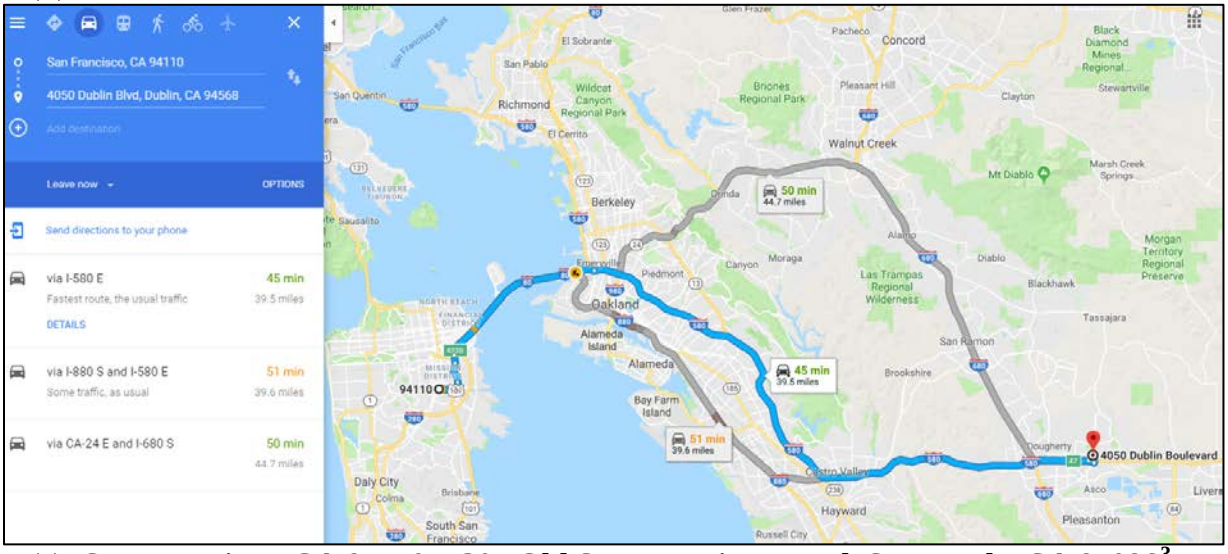
1(a): San Francisco, CA 94110 to 3200 Kearney Street, Fremont, CA 94538[1]



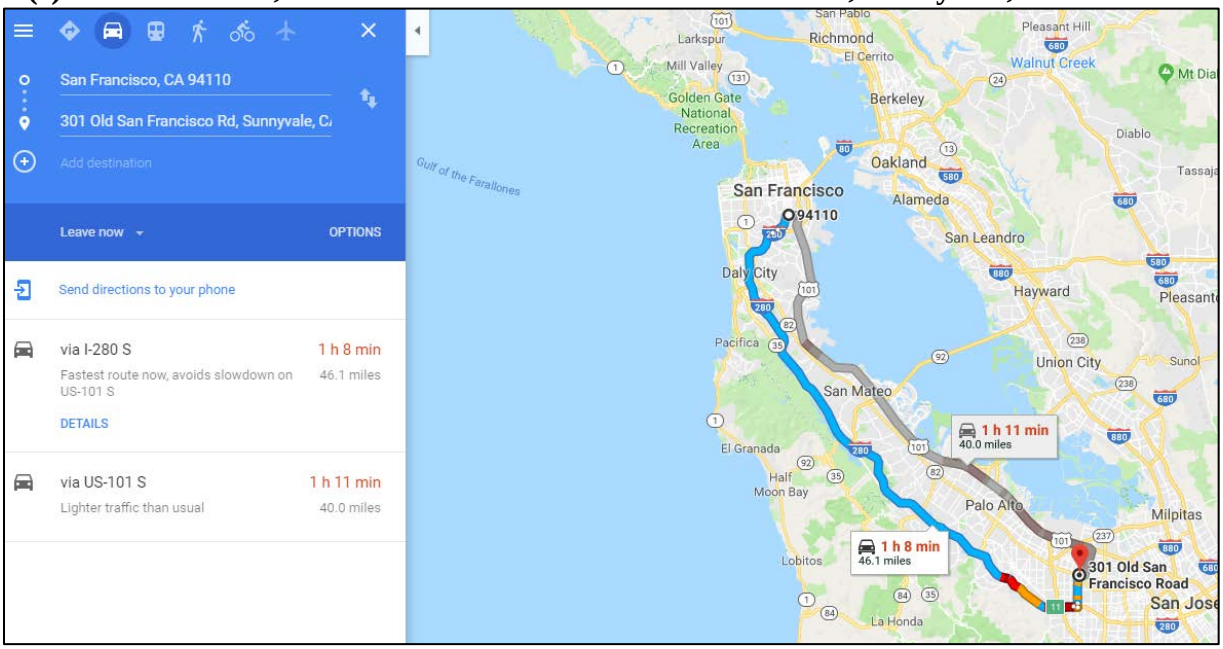
1 https://www.google.com/maps/dir/San+Francisco,+CA+94110/3200+Kearney+St,+Fremont,+CA+94538/@37.6463212,-122.3354788,11z/data=!3m1!4b1!4m14!4m13!1m5!1m1!1s0x808f7e41001c148f:0xf8e22a1c5445037a!2m2!1d-122.4184108!2d37.7485824!1m5!1m1!1s0x808fc0940d5abb53:0x8095ce2941e225ee!2m2!1d-121.9735679!2d37.5485576!3e0 (as of Jan. 16, 2018).

Smith Reply Decl., Ex. 76

1(b): San Francisco, CA 94110 to 4050 Dublin Blvd., Dublin, CA 94568[2]



1(c): San Francisco, CA 94110 to301 Old San Francisco Road, Sunnyvale, CA 94086[3]

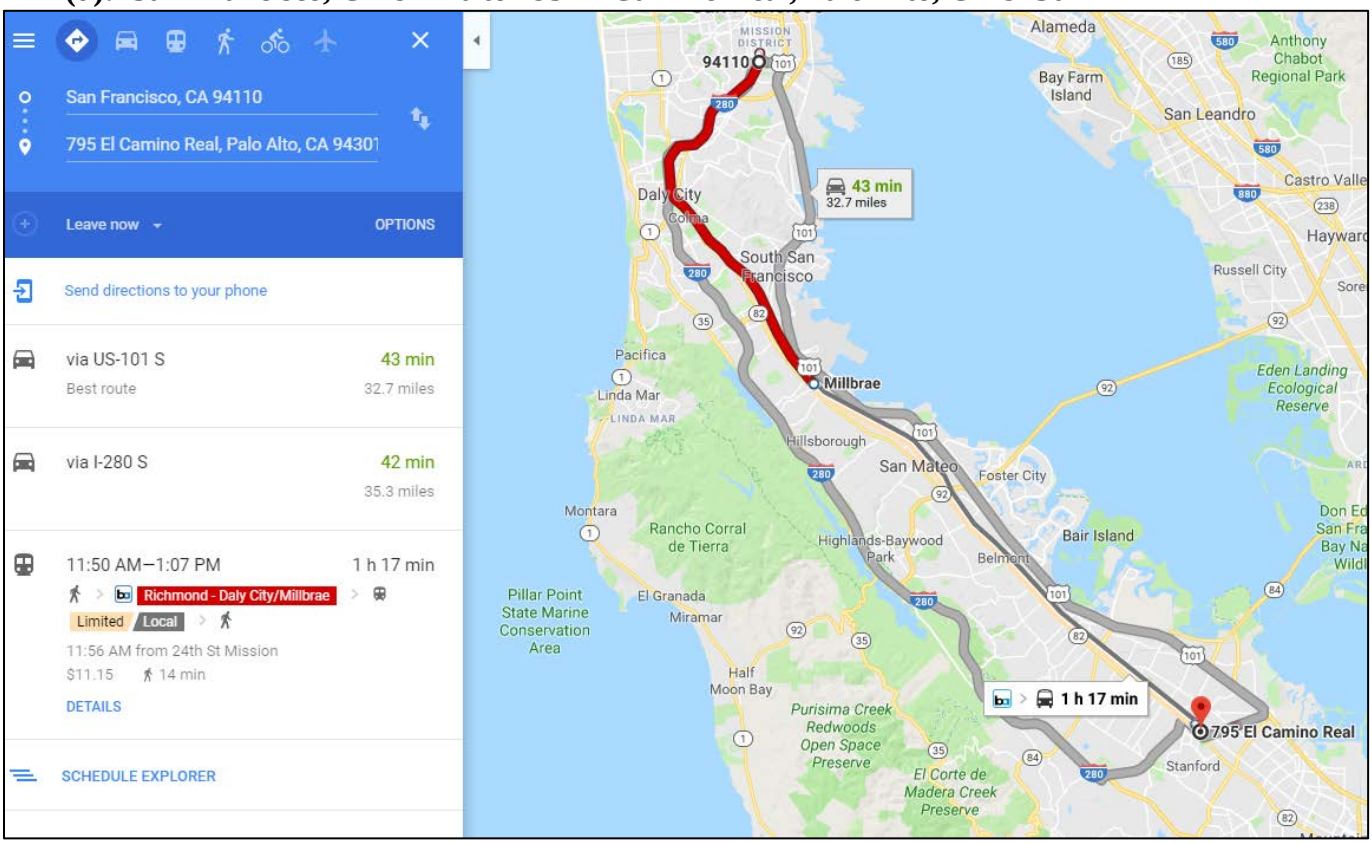


2 https://www.google.com/maps/dir/San+Francisco,+CA+94110/4050+Dublin+Blvd,+Dublin,+CA+94568/@37.7819427,-122.2852619,11z/data=!3m1!4b1!4m14!4m13!1m5!1m1!1s0x808f7e41001c148f:0xf8e22a1c5445037a!2m2!1d-122.4184108!2d37.7485824!1m5!1m1!1s0x808fe933f112810b:0x96494c64e7cb27d7!2m2!1d-121.8729756!2d37.7051736!3e0 (as of Jan. 16, 2018).

3 https://www.google.com/maps/dir/San+Francisco,+CA+94110/301+Old+San+Francisco+Rd,+Sunnyvale,+CA+94086/@37.5386038,-122.3925141,10z/data=!4m14!4m13!1m5!1m1!1s0x808f7e41001c148f:0xf8e22a1c5445037a!2m2!1d-122.4184108!2d37.7485824!1m5!1m1!1s0x808fb665c7ae2183:0xd46a2cbceccbd22b!2m2!1d-122.02973!2d37.3683413!3e0 (as of Jan. 16, 2018).

Smith Reply Decl., Ex. 76

1(d): San Francisco, CA 94110 to 795 El Camino Real, Palo Alto, CA 94301[4]



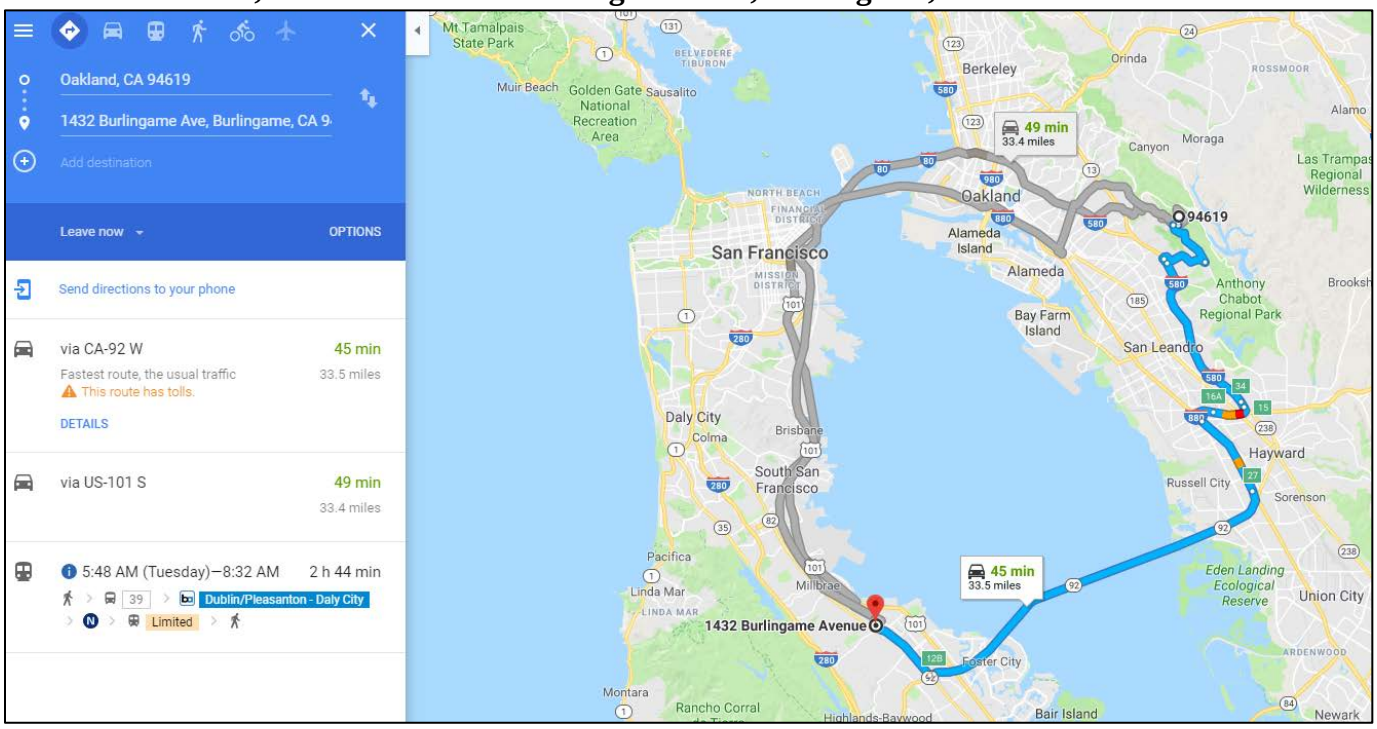
4 https://www.google.com/maps/dir/San+Francisco,+CA+94110/795+El+Camino+Real,+Palo+Alto,+CA+94301/@37.5559067,-122.321776,11z/data=!4m14!4m13!1m5!1m1!1s0x808f7e41001c148f:0xf8e22a1c5445037a!2m2!1d-122.4184108!2d37.7485824!1m5!1m1!1s0x808fbb3acd917773:0x5236a35aa24e4bb0!2m2!1d-122.1617036!2d37.4399863!5i2 (as of Jan. 16, 2018).

Smith Reply Decl., Ex. 76

Distance from Condry's Zip Code (Oakland, California 94619) and "Lactation Specialists" Purported to be in UHC's Network during March and April 2015

1. Shelia Dukas-Janakos, place of service included:
    a. 1432 Burlingame Ave., Burlingame, CA 94010– shortest driving distance: 33.5 miles

San Francisco, CA 94110 to 1432 Burlingame Ave., Burlingame, CA 94010[5]

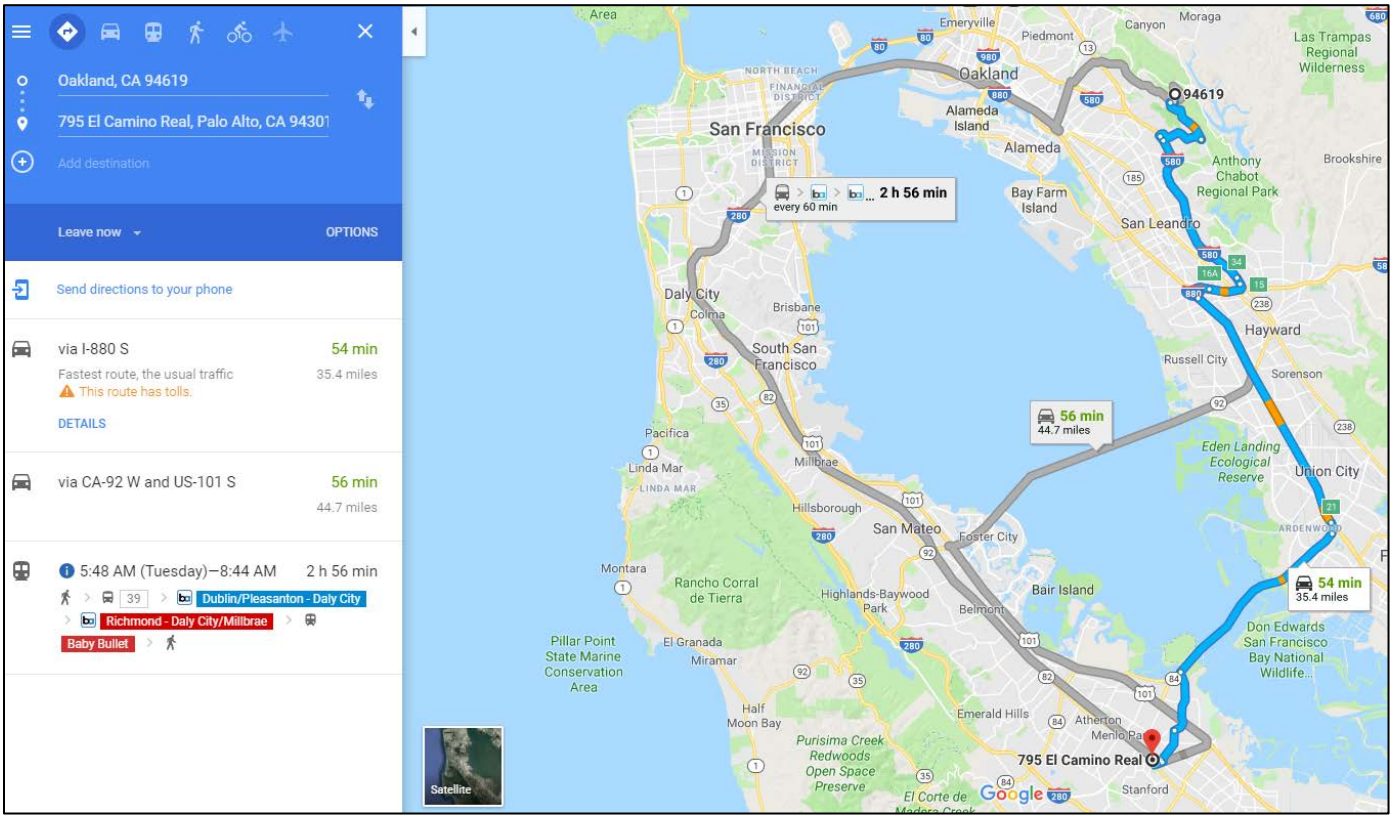


[5]https://www.google.com/maps/dir/Oakland,+CA+94619/1432+Burlingame+Ave,+Burlingame,+CA+94010/@37.6897783,-122.394006,11z/data=!4m13!4m12!1m5!1m1!1s0x808f88a4f8b1a0c9:0x4e19a04a30407eb1!2m2!1d-122.1462193!2d37.7936811!1m5!1m1!1s0x808f9df116fc6565:0x7247a09df79fad77!2m2!1d-122.3488039!2d37.5773804 (lasted visited Jan. 15, 2018).

Smith Reply Decl., Ex. 76

2. Jennifer Scales, place of service included:
    a. 795 El Camino Real, Palo Alto, CA 94301– shortest driving distance: 35.4 miles

San Francisco, CA 94110 to 795 El Camino Real, Palo Alto, CA 94301[6]



6 https://www.google.com/maps/dir/Oakland,+CA+94619/795+El+Camino+Real,+Palo+Alto,+CA/@37.6243923,-122.3955761,11z/data=!3m1!4b1!4m13!4m12!1m5!1m1!1s0x808f88a4f8b1a0c9:0x4e19a04a30407eb1!2m2!1d-122.1462193!2d37.7936811!1m5!1m1!1s0x808fbb3acd917773:0x5236a35aa24e4bb0!2m2!1d-122.1617036!2d37.4399863 (lasted visited Jan. 15, 2018).

EXHIBIT 77

The American College of Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

COMMITTEE OPINION

Number 658 • February 2016 (Replaces Committee Opinion Number 361, February 2007)

Committee on Obstetric Practice

This Committee Opinion was developed by the American College of Obstetricians and Gynecologists' Committee on Obstetric Practice and Breastfeeding Expert Work Group. Member contributors included Alison Stuebe, MD. This document reflects emerging clinical and scientific advances as of the date issued and is subject to change. This information should not be construed as dictating an exclusive course of treatment or procedure to be followed.

Optimizing Support for Breastfeeding as Part of Obstetric Practice

ABSTRACT: Although most women in the United States initiate breastfeeding, more than one half wean earlier than they desire. As reproductive health experts and advocates for women's health who work in conjunction with other obstetric and pediatric health care providers, obstetrician–gynecologists are uniquely positioned to enable women to achieve their infant feeding goals. The American College of Obstetricians and Gynecologists recommends exclusive breastfeeding for the first 6 months of life, with continued breastfeeding as complementary foods are introduced through the infant's first year of life, or longer as mutually desired by the woman and her infant. Because lactation is an integral part of reproductive physiology, all obstetrician–gynecologists and other obstetric care providers should develop and maintain knowledge and skills in anticipatory guidance, physical assessment and support for normal breastfeeding physiology, and management of common complications of lactation. Obstetrician–gynecologists and other obstetric care providers should support each woman's informed decision about whether to initiate or continue breastfeeding, recognizing that she is uniquely qualified to decide whether exclusive breastfeeding, mixed feeding, or formula feeding is optimal for her and her infant. Obstetrician–gynecologists and other obstetric care providers should support women in integrating breastfeeding into their daily lives in the community and in the workplace. The offices of obstetrician–gynecologists and other obstetric care providers should be a resource for breastfeeding women through the infant's first year of life, and for those who continue beyond the first year.

Recommendations

Education

- Clinical management of lactation is a core component of reproductive health care.
- Because lactation is an integral part of reproductive physiology, all obstetrician–gynecologists and other obstetric care providers should develop and maintain knowledge and skills in anticipatory guidance, physical assessment and support for normal breastfeeding physiology, and management of common complications of lactation.

Support for Breastfeeding Women

- The American College of Obstetricians and Gynecologists (the College) strongly encourages women to breastfeed and supports each woman's right to breastfeed. The College recommends exclusive breastfeeding for the first 6 months of life, with continued breastfeeding as complementary foods are introduced through the infant's first year of life.
- Obstetrician–gynecologists and other obstetric care providers should support each woman's informed decision about whether to initiate or continue breastfeeding, recognizing that she is uniquely qualified to decide whether exclusive breastfeeding, mixed feeding, or formula feeding is optimal for her and her infant.
- A breastfeeding history should be obtained as part of prenatal care, and identified concerns and risk factors for breastfeeding difficulties should be communicated to the infant's health care provider.

- All obstetrician–gynecologists and other obstetric care providers should support women who have given birth to preterm and other vulnerable infants to establish a full supply of milk by providing anticipatory guidance, support, and education for women. Obstetrician–gynecologists and other obstetric care providers should work with hospital staff to facilitate early, frequent milk expression.
- Women who experience breastfeeding difficulties are at higher risk of postpartum depression, and should be screened, treated, and referred appropriately.
- Obstetrician–gynecologists and other obstetric care providers should support women in integrating breastfeeding into their daily lives in the community and in the workplace.
- The offices of obstetrician–gynecologists and other obstetric care providers should be a resource for breastfeeding women through the infant's first year of life, and for those who continue to breastfeed beyond the first year.

Policy

- Obstetrician–gynecologists and other obstetric care providers should be in the forefront of policy efforts to enable women to breastfeed, whether through individual patient education, change in hospital practices, community efforts, or supportive legislation.
- The World Health Organization's "Ten Steps to Successful Breastfeeding" should be integrated into maternity care to increase the likelihood that a woman achieves her personal breastfeeding goals.
- Policies that protect the right of a woman and her child to breastfeed and that accommodate milk expression, such as paid maternity leave, onsite childcare, break time for expressing milk, and a location other than a bathroom for expressing milk, are essential to sustaining breastfeeding.

Introduction

Although most women in the United States initiate breastfeeding, more than one half wean earlier than they desire (1). In addition, substantial disparities persist in initiation and duration of breastfeeding that affect population health (2). Maternity care policies and practices that support breastfeeding are improving nationally; however, more work is needed to ensure all women receive optimal breastfeeding support during their maternity stay (3). Given this mismatch between women's intentions for and experience of breastfeeding, the previous version of this Committee Opinion was revised to address how obstetrician–gynecologists and other obstetric care providers can enable women to achieve their infant feeding intentions. As reproductive health experts and advocates for women's health who work in conjunction with other obstetric and pediatric health care providers, obstetrician–gynecologists are uniquely positioned to enable women to achieve their infant feeding goals.

Benefits of Breastfeeding

Clinical management of lactation is a core component of reproductive health care. Enabling women to breastfeed is also a public health priority because, on a population level, interruption of lactation is associated with adverse health outcomes for the woman and her child, including higher maternal risks of breast cancer, ovarian cancer, diabetes, hypertension, and heart disease, and greater infant risks of infectious disease, sudden infant death syndrome, and metabolic disease (2, 4).

Although lactation is the physiologic norm, cultural norms for infant feeding have changed dramatically in the past century. In 1971, only 24.7% of women left the hospital breastfeeding. Since then, breastfeeding initiation rates have progressively increased. In 2011, 79% of women in the United States initiated breastfeeding, 49% were breastfeeding at 6 months, and 27% were breastfeeding at 1 year postpartum (5). Exclusive breastfeeding rates are lower (Table 1).

Breastfeeding is optimal and appropriate for most women. Contraindications to breastfeeding are few and include those women who have an infant with galactosemia, are infected with human immunodeficiency virus (HIV) or human T-cell lymphotropic virus type I or type II, and have active untreated tuberculosis or varicella or active herpes simplex virus lesions on the nipple. Most medications are safe in breastfeeding, with rare exceptions such as cytotoxic chemotherapy drugs. Use of drugs or illicit substances or treatment for such may not be a contraindication to breastfeeding. For example, women on stable doses of methadone should be encouraged to breastfeed (6, 7). There are insufficient data to evaluate the effects of marijuana use on infants during lactation and breastfeeding, and in the absence of such data, marijuana use is discouraged (8).

The Role of Obstetrician–Gynecologists and Other Obstetric Care Providers in Supporting Breastfeeding

The American College of Obstetricians and Gynecologists (the College) strongly encourages women to breastfeed and supports each woman's right to breastfeed. The College recommends exclusive breastfeeding for the first 6 months of life, with continued breastfeeding as complementary foods are introduced through the infant's first year of life, or longer as mutually desired by the woman and her infant. This recommendation is consistent with those of other medical and nursing organizations, such as the American Academy of Pediatrics (9) and the Association of Women's Health, Obstetric and Neonatal Nurses (10). The College further supports public health and policy efforts to enable more women to breastfeed, including Healthy People 2020 targets for increasing

Table 1. Healthy People 2020 Goals for Breastfeeding ⇦

	Healthy People 2020 Goals (%)	Current Data (%)
Increase the proportion of infants who are breastfed at the following stages:		
Ever breastfed	81.9	79.2 ± 1.2*
Breastfed at 6 months	60.6	49.4 ± 1.5*
Breastfed at 1 year	34.1	26.7 ± 1.3*
Breastfed exclusively through 3 months	46.2	40.7 ± 1.5*
Breastfed exclusively through 6 months	25.5	18.8 ± 1.2*
Increase the proportion of employers that have worksite lactation support programs	38	28†‡
Reduce the proportion of breastfed newborns who receive formula supplementation within the first 2 days of life	14.2	19.4 ± 1.3*
Increase the proportion of live births that occur in facilities that provide recommended care for lactating mothers and their babies	8.1	7.79§

*2011 births (Centers for Disease Control and Prevention. Breastfeeding among U.S. children born 2002–2012, CDC National Immunization Surveys. Available at: http://www.cdc.gov/breastfeeding/data/nis_data/index.htm. Retrieved September 2, 2015.)

†Society for Human Resource Management. 2014 employee benefits: an overview of employee benefits offerings in the U.S. Alexandria (VA): SHRM; 2014. Available at: http://www.shrm.org/Research/SurveyFindings/Documents/14-0301%20Benefits_Report_TEXT_FNL.pdf. Retrieved September 2, 2015.

‡Offer onsite lactation/mother's room, defined as a separate room that goes above and beyond the The Patient Protection and Affordable Care Act law, which requires that employees be "shielded from view" and "free from intrusion" during their break. Six percent offer lactation support services.

§Centers for Disease Control and Prevention. Breastfeeding report card: United States/2014. Atlanta (GA): CDC; 2014. Available at: http://www.cdc.gov/breastfeeding/pdf/2014breastfeedingreportcard.pdf. Retrieved September 2, 2015.

worksite lactation programs, reducing formula supplementation of breastfed infants in the first 2 days of life, and increasing the proportion of births that occur in facilities that provide recommended care for lactating women and their infants (Table 1).

Because lactation is an integral part of reproductive physiology, all obstetrician–gynecologists and other obstetric care providers should develop and maintain skills in anticipatory guidance, support for normal breastfeeding physiology, and management of common complications of lactation. Obstetrician–gynecologists and other obstetric care providers should be in the forefront of policy efforts to enable women to breastfeed, whether through individual patient education, change in hospital practices, community efforts, or supportive legislation.

Prenatal Care

The advice and encouragement of the obstetrician–gynecologist and other obstetric care providers are critical in assisting women to make an informed infant feeding decision. As when discussing any health behavior, the obstetrician–gynecologist is obligated to ensure patient comprehension of the relevant information and to be certain that the conversation is free from coercion, pressure, or undue influence (11). Families should receive noncommercial, accurate, and unbiased information so that they can make informed decisions about their health care (12). Obstetric care providers should be aware that personal experiences with infant feeding may affect their counseling. In addition, pervasive direct-to-consumer marketing of infant formula adversely affects patient and health care provider perception of the risks and benefits of breastfeeding.

Beginning conversations about lactation early in prenatal care by asking the patient and her family, "What have you heard about breastfeeding?" sets the stage for a patient-centered discussion. When taking an obstetric history, obstetrician–gynecologists and other obstetric care providers should specifically ask about any breast surgeries, prior breastfeeding duration, and any previous breastfeeding difficulties. Prior problems leading to earlier-than-desired weaning should be discussed, anticipatory guidance should be provided, and appropriate lactation support resources should be identified. The breast examination can identify surgical scars indicating prior surgery, as well as widely spaced, tubular breasts that may indicate insufficient glandular tissue (4). A breast assessment and breastfeeding history should be obtained as part of prenatal care, and identified concerns and risk factors for breastfeeding difficulties should be discussed with the woman, and communicated to the infant's health care provider, either directly or as part of shared records. Obstetrician–gynecologist and other obstetric care providers should engage the patient's partner and other family members in discussions about infant feeding and address any questions and concerns. This

patient-centered approach allows the health care provider, the patient, and her family to anticipate challenges, develop strategies to address them, and collaborate to develop a feeding plan that is compatible with the family's individual values, circumstances, and concerns. Obstetrician–gynecologists and other obstetric care providers should support each woman's informed decision about whether to initiate or continue breastfeeding, recognizing that she is uniquely qualified to decide whether exclusive breastfeeding, mixed feeding, or formula feeding is optimal for her and her infant.

Intrapartum Care

Maternity care practices affect breastfeeding outcomes. The World Health Organization's "Ten Steps to Successful Breastfeeding" is an evidence-based set of health care practices that support breastfeeding physiology, including early skin-to-skin care, rooming-in, and feeding on demand (see Box 1) (2). In a meta-analysis of randomized controlled trials, skin-to-skin care in the first hour of life increased breastfeeding duration by 42.6 days (95% CI, −1.7 to 86.8) (13). The Ten Steps should be integrated into maternity care to increase the likelihood that a woman will initiate and sustain breastfeeding and achieve her personal breastfeeding goals (14). Cesarean birth is associated with lower breastfeeding rates, and women who undergo cesarean delivery may need extra support to establish and sustain breastfeeding. Skin-to-skin contact is feasible in the operating room and is associated with reduced need for formula supplementation (15).

Healthy People 2020 and the Joint Commission have targeted unindicated formula supplementation as a barrier to establishing breastfeeding, and maternity care providers can provide anticipatory guidance for families regarding the rationale for avoiding early introduction of formula. Distribution of formula marketing packs reduces breastfeeding initiation and duration (16) and implies that formula is a recommended feeding method. Moreover, provision of samples implies the health care provider's endorsement of a specific brand, which encourages families to purchase more expensive brand-name products, rather than generic equivalents (17). Such marketing should not occur in inpatient or outpatient health care settings.

For preterm infants, human milk feeding, in particular the woman's own milk, is associated with a reduced risk of necrotizing enterocolitis (18) and other infectious morbidity. Sharing this information with women who have given birth to preterm infants and who intended to formula feed increases breastfeeding initiation and does not increase maternal anxiety (19). The obstetrician–gynecologist and other obstetric care providers should collaborate with the pediatric care provider to share this information as soon as a preterm birth is anticipated because initiation of milk expression within 6 hours of birth is associated with improved milk production (20). Drops of colostrum obtained from early expression can be used for oral care as well as for initial feedings of even the smallest preterm infant. All obstetrician–gynecologists and other obstetric care providers should support women who have given birth to preterm infants to establish a full supply of milk by providing anticipatory guidance and working with hospital staff to facilitate early, frequent milk expression.

Box 1. Ten Hospital Practices to Encourage and Support Breastfeeding*

1. Have a written breastfeeding policy that is routinely communicated to all health care staff.
2. Train all health care staff in the skills necessary to implement this policy.
3. Inform all pregnant women about the benefits and management of breastfeeding.
4. Help women initiate breastfeeding within 1 hour of birth.
5. Show women how to breastfeed and how to maintain lactation, even if they are separated from their newborns.
6. Give newborns no food or drink other than breast milk, unless medically indicated.
7. Practice rooming-in—allow mothers and newborns to remain together 24 hours a day.
8. Encourage breastfeeding on demand.
9. Give no pacifiers or artificial nipples to breastfeeding infants.†
10. Foster the establishment of breastfeeding support groups and refer to them on discharge from the hospital or birth center.

Data from Baby-Friendly USA. Guidelines and evaluation criteria for facilities seeking baby-friendly designation. Sandwich (MA): Baby-Friendly USA; 2010. Available at: https://www.baby-friendlyusa.org/get-started/the-guidelines-evaluation-criteria. Retrieved October 29, 2015.

*The 1994 report of the Healthy Mothers, Healthy Babies National Coalition Expert Work Group recommended that the UNICEF-WHO Baby Friendly Hospital Initiative be adapted for use in the United States as the United States Breastfeeding Health Initiative, using the adapted 10 steps above.

†The American Academy of Pediatrics endorsed the UNICEF-WHO Ten Steps to Successful Breastfeeding but does not support a categorical ban on pacifiers because of their role in reducing the risk of sudden infant death syndrome and their analgesic benefit during painful procedures when breastfeeding cannot provide the analgesia.

Clinical Management of the Breastfeeding Dyad

The offices of obstetrician–gynecologists and other obstetric care providers should be a resource for breastfeeding assistance through the first year of life, and for those women who continue to breastfeed beyond the first

year because many of the health benefits associated with breastfeeding increase with longer duration of breastfeeding. Lactation is a two-person activity, and evaluation of breastfeeding problems requires assessment of the woman and her infant, as well as the active engagement and support of her partner, extended family, or other identified support. Management of issues such as pain, low milk supply, breast infections, and maternal medication safety should, therefore, be coordinated with the infant's care provider as appropriate. Office staff should be prepared to triage common breastfeeding concerns and to refer women, as needed, to certified lactation professionals in the community, such as an International Board Certified Lactation Consultant or Certified Lactation Counselor. Embedding lactation consultants within the offices of an obstetrician–gynecologist or other obstetric care provider may be feasible now that coverage of lactation services is included as preventive care under the Affordable Care Act (21).

Most medications are safe for use during breastfeeding. Obstetrician–gynecologists and other health care providers should consult lactation pharmacology resources, such as LactMed (22), for up-to-date information on individual medications (6) because inappropriate advice often can lead women to discontinue breastfeeding unnecessarily. Information about drug safety in pregnancy should not be extrapolated to breastfeeding, as the physiology of the placenta and breast are not the same. For example, warfarin crosses the placenta and can cause embryopathy, but minimal amounts enter breast milk, so it is considered to be safe during lactation (22). Counseling regarding medication use during lactation should address the risks of drug exposure through breast milk and the risks of interrupting lactation. After anesthesia for surgical procedures, women who have given birth to healthy infants generally may breastfeed as soon as they are stable, awake, and alert enough to hold the infant (23). Breastfeeding can be continued without interruption after the use of iodinated contrast or gadolinium (6).

Low milk supply is a common concern and may reflect misinterpretation of normal infant feeding behaviors, low production, or inadequate milk transfer (4). The most common cause of low milk supply is inadequate breast stimulation. Careful evaluation by a certified lactation professional to ensure frequent breast stimulation and milk removal is the most effective strategy to increase milk production. There is limited evidence for medications and herbal galactagogues to increase milk supply (24).

Disrupted lactation is common, with one in eight women reporting early, undesired cessation of breastfeeding because of multiple problems with pain, low milk supply, and the infant being able to latch on to the breast (25). Obstetric care providers should collaborate with certified lactation professionals and the infant's health care provider to evaluate and manage breastfeeding problems. Even with comprehensive support, some mother–infant dyads are unable to establish sustained, exclusive breastfeeding. Women who are not able to achieve their breastfeeding intentions report considerable distress, and obstetrician–gynecologists and other health care providers should validate each woman's efforts and experience (4). Women who experience breastfeeding difficulties are at higher risk of postpartum depression and should be screened, treated, and referred appropriately.

Although breastfeeding without introducing any complementary solids or formula will in most cases prevent ovulation and, thus, pregnancy for up to 6 months postpartum, it will do so only when women are fully or nearly fully breastfeeding and there is continued amenorrhea. Contraception is an important topic for all women, and discussion of other methods should not be delayed in breastfeeding women. Contraceptive options should be explained in detail and include nonhormonal methods (copper intrauterine devices, condoms, diaphragms) and hormonal methods (levonorgestrel intrauterine device, etonogestrel implants, medroxyprogesterone acetate injection, progestin-only pills, and combined hormonal contraceptive pills). Immediate postpartum initiation of hormonal methods is controversial (26). The Centers for Disease Control and Prevention states that the advantages outweigh the risks of progestin-only contraception immediately after birth and for combined hormonal methods at 1 month postpartum (27). Data are limited, however, and theoretical concerns exist because progesterone withdrawal after delivery of the placenta is thought to trigger onset of lactogenesis, so exogenous progesterone could prevent onset of milk production (25). Obstetric care providers should discuss these limitations and concerns within the context of each woman's desire to breastfeed and her risk of unplanned pregnancy, so that she can make an autonomous and informed decision.

Breastfeeding in the Community

Obstetrician–gynecologists and other obstetric care providers should support women in integrating breastfeeding into their daily lives in the community and in the workplace. Before discharge from the maternity center, women should be provided with contact information for community-based lactation support. Maintaining milk supply depends largely on frequency of milk removal through breastfeeding and through expressing milk (breast pumping or manual expression) when the woman and her infant are separated. Policies that protect the right of the woman and her child to breastfeed and that accommodate milk expression, such as paid maternity leave (28), on-site childcare, break time, and a location other than a bathroom for expressing milk (29), are essential to sustaining breastfeeding. Obstetric care provider offices and hospitals can set an example through supportive policies for lactating staff, accommodations for nursing patients, awareness and educational materials, and staff training (10, 30).

For More Information

These resources are for information only and are not meant to be comprehensive. Referral to these resources does not imply the American College of Obstetricians and Gynecologists' endorsement of the organization, the organization's web site, or the content of the resource. The resources may change without notice.

ACOG has identified additional resources on topics related to this document that may be helpful for ob-gyns, other health care providers, and patients. You may view these resources at www.acog.org/More-Info/ObBreastfeedingSupport.

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EXHIBIT 78

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

RACHEL CONDRY, JANCE HOY, CHRISTINE ENDICOTT, LAURA BISHOP, FELICITY BARBER, and RACHEL CARROLL, on behalf of themselves and all others similarly situated,

Plaintiffs,

vs.

UNITEDHEALTH GROUP INC., UNITEDHEALTHCARE, INC., UNITEDHEALTHCARE INSURANCE COMPANY, UNITED HEALTHCARE SERVICES, INC., and UMR, INC.,

Defendants.

Case No.:
3:17-cv-00183-VC

VIDEOTAPED DEPOSITION OF JANE MORTON, M.D.
San Francisco, California
Tuesday, November 14, 2017

Reported by: SUZANNE F. GUDELJ
CSR No. 5111
Job No. 2733634

around the country, around the world, and the participants are primarily lactation consultants, nurses, very few physicians. I might say that next week or two I will give the annual breastfeeding discussion to the Stanford residents for one hour.

Q So from 2002 to 2014, you were an adjunct clinical professor of pediatrics at Stanford. During that time period, who were you teaching? Was that medical students, residents?

A Yes, primarily residents.

Q Okay. And I'm just trying to understand, because your resume seems to indicate -- it indicates that you've been some level of professor at Stanford for all these many years, but then in your answer you said, well, primarily you teach at conferences, and so I'm trying to understand really what --

A Let me clarify.

MR. KRAVITZ: What's the question? I'm not sure.

MS. WYRICK: I'm trying to understand if she --

BY MS. WYRICK:

Q Did you teach classes to residents at Stanford, teach -- I'm trying -- let me say this

again.

MS. WYRICK: I'm just trying to understand who her audience was as teacher. Is it lactation consultants? Is it med students? It's not clear to me.

THE WITNESS: In the '70s, there were no lactation consultants. So my teaching at Stanford was primarily focused in the care of my patients. I would be attending on the ward at times, the clinical attending. And the other common part of teaching was when I would have residents come to my office for a month. They would stay in my office and work with me for a month. And that was the extent -- and it was general pediatrics that I was teaching.

BY MS. WYRICK:

Q Okay. That was the '70s or --

A When -- when I was at the Palo Alto Clinic, the entire time my teaching has primarily focused on general pediatrics.

Q And in teaching general pediatrics during that time period, did you -- did the curriculum that you taught include breastfeeding issues?

A Yes. In fact, that would be why people would come to my office was because -- be because

they would like to learn something about it.

Q So that was part of the curriculum for Stanford medical students?

A It was never a part of the curriculum; it was part of my agenda of what they needed to learn.

Q Okay. Is it part of the curriculum at Stanford today?

A A small part. For example, I asked if they have core competencies for the residents in breastfeeding, and the answer is no.

Q At Stanford?

A (Nods head.) I don't know if that's the case all over.

Q Have you asked that question of any other medical schools?

A I have not asked that question specifically, but in discussing this with my colleagues around the country at conferences that I participate in, I think that it's unusual to have much teaching of physicians in breastfeeding.

Q And that's just from conversations you've had with other physicians?

A It's -- can you -- can you ask that question one more time?

Q Do you come to that opinion based on

A Perhaps if a mother comes in with a mass in her breast and needs a diagnostic imaging, that would be more -- it's easier to parse that out in my opinion.

Q And I think you've already told us that you think that anything that would help enable breastfeeding would be preventive. Is there any other area of medicine where you would think that the term "preventive" would cover all services?

MR. KRAVITZ: Okay. Vague. Overbroad.

BY MS. WYRICK:

Q Well, you just said that you think that that --

A Mm-hmm.

Q -- distinction applies in some arenas but not others.

A Mm-hmm.

Q And I understand that you think it doesn't apply in the area of breastfeeding, correct?

A I think it's -- that's right.

Q Is there any other area where that distinction would not apply?

A I think the distinction starts falling down in the arena of behavioral care. That might be one example.

Q Can you explain that further to me?
A Normal growth and development of babies. Do you want an example?
Q Yes, please.
A If a mother comes in, and she's exhausted because she can't sleep, and her baby eats all day -- all night and sleeps all day, you could call that a sleeping problem, but the truth is, it's a well mother and a well baby, and in trying to help that mother, I don't see anybody is sick. I'm not making a diagnosis, I'm just giving anticipatory guidance to help her change the schedule so that parenting is more fun.
So that distinction of nobody is sick, there's no morbidity that I'm thinking of, I'm simply offering some suggestions in the realm of behavioral care.
Q When you were in private practice, did you ever submit -- do any coding of your claims that were submitted to insurance companies, you personally?
A Yes.
Q And you understand that insurance companies make a different -- a distinction between preventive and diagnostic care, correct?

A It's been many years since I had to worry about coding, so I'd have to say I don't recall. I'm not an expert in coding.

Q In your most recent years of practice, did you have an office staff that handled that?

A The office practice that I designed did not take insurance. It was a -- what you might call concierge practice, and families paid a monthly amount, and I would be available for them at any time at any place.

Q This was in the Burgess Pediatrics?

A That's correct.

Q So you didn't have to deal with insurance at all?

A It was lovely.

Q So you would agree, taking your example of a mammogram, there's preventive mammogram screenings, which women over a certain age are recommended to have every year, correct?

A Correct.

Q And then you would distinguish that from a diagnostic mammogram where a women may need a mammogram because a lump was detected, correct?

A I think you could make that distinction.

Q Are you aware if insurance companies do?

EXHIBIT 79

Clinical Preventive Services for Women

Closing the Gaps

Committee on Preventive Services for Women

Board on Population Health and Public Health Practice

INSTITUTE OF MEDICINE
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1

Introduction

The passage of the Patient Protection and Affordable Care Act of 2010 (ACA) provides the United States with an opportunity to offer an unprecedented level of population health care coverage and dramatically reduce existing health disparities. The expansion of coverage to millions of uninsured Americans and the new standards for coverage of preventive services that are included in the ACA have the potential to increase the use of preventive health care services and screenings and in turn improve the health and well-being of individuals across the United States.

SPECIFICS OF THE LEGISLATION

The approaches to prevention and wellness offered within the Act are broad based and range from new coverage requirements and incentives to expand workplace wellness activities to new investments. Among these are prohibition of the imposition of cost-sharing requirements for recommended preventive services (an overview of the Act is provided in Box 1-1, and the preventive services are listed and described in detail in Chapter 2), the requirement to link health insurance premiums to participation in health promotion programs, public health workforce development (the ACA authorizes new training and placement programs for public health workers), and community-based prevention activities.

This report focuses on the preventive services for women specified in Section 2713 of the Public Health Service Act. These services were added by the ACA and are detailed in the last bulleted item in Box 1-1 (HHS, 2010; *Federal Register,* 2010).

BOX 1-1
Overview of Regulations in Section 2713 of the Public Health Service Act

Section 2713 of the Public Health Service Act, Coverage of Preventive Health Services, which was added by the Affordable Care Act, and the interim final regulations (26 CFR 54.9815–2713T, 29 CFR 2590.715–2713, 45 CFR 147.130) require that group health plans and health insurance issuers offering health insurance coverage for groups or individuals provide benefits and prohibit the imposition of cost-sharing requirements for

- Medical devices or services that are evidence based and that have, in effect, a rating of Grade A or B in the current recommendations of the United States Preventive Services Task Force (USPSTF) for the individual involved.
- Immunizations for routine use in children, adolescents, and adults that have, in effect, a recommendation from the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) for the individual involved. A recommended ACIP immunization is considered to be "in effect" after it has been adopted by the CDC director. A recommended immunization is considered to be for routine use if it appears on the immunization schedules of the Centers for Disease Control and Prevention.
- Preventive health care and screenings for infants, children, and adolescents informed by scientific evidence and provided for in the comprehensive guidelines supported by the Health Resources and Services Administration (HRSA).
- Preventive health care and screenings for women informed by scientific evidence and provided for in comprehensive guidelines supported by HRSA (not otherwise addressed by the recommendations of the USPSTF). The U.S. Department of Health and Human Services is developing these guidelines and expects to issue them no later than August 1, 2011.

The complete list of recommendations and guidelines that these interim final regulations are required to cover can be found at http://www.HealthCare.gov/center/regulations/prevention.html.

ROLE OF PREVENTION IN ADDRESSING HEALTH AND WELL-BEING

Prevention is a well-recognized, effective tool in improving health and well-being and has been shown to be cost-effective in addressing many conditions early (Maciosek et al., 2010). Prevention goes beyond the use of disease prevention measures. For example, interventions to prevent injuries and binge drinking can increase positive health outcomes and reduce harm.

Historically, the many disparate components of the U.S. health care system have relied more on responding to acute problems and the urgent

needs of patients than on prevention. Although these functions are appropriate for acute and episodic health problems, a notable disparity occurs when this model of care is applied to the prevention and management of chronic conditions. The provision of preventive health care services is thus inherently different from the treatment of acute problems, but the U.S. health care system has fallen short in the provision of such services. Compared with a system that prevents avoidable conditions early, a system that responds to the acute health care needs of patients can be inefficient and costly, and a focus on response instead of prevention is a major barrier to the achievement of optimal health and well-being by Americans.

Nearly half of all deaths in the United States are caused by modifiable health behaviors (McGinnis and Foege, 1993). Maciosek and colleagues found that an increase in the use of clinical preventive services in the United States could result in the saving of more than 2 million life-years annually (Maciosek et al., 2010). Because of the numbers of diseases and conditions that are preventable, inclusion of support for prevention has become more routine during clinical health care visits (Sussman et al., 2006). When patients are systematically provided with the tools and information that they need to reduce their health risks, the likelihood that they will take steps to, for example, reduce substance use, stop using tobacco products, practice safe sex, eat healthful foods, and engage in physical activity increases (WHO, 2002). Therefore, physicians who routinely educate patients on risk-reducing behaviors may reduce the long-term burden and health care demands of chronic conditions. Stimulating the commitment and action of patients, families, and health care teams is also necessary to promote prevention and improve overall population well-being.

Evidence-based testing, diagnosis, and relief of symptoms are also hallmarks of contemporary health care, but these services are often underutilized. A well-cited reason for this underutilization is, for example, the high cost of prescription copayments, with the result being that patients do not fill their prescribed medications, resulting in the loss of lives and dollars (Shrank et al., 2010). Moreover, a recent study by The Commonwealth Fund that analyzed the responses of U.S. adults to a questionnaire indicated that U.S. adults were significantly less likely than adults in all other countries studied to have confidence in their ability to afford health care (Schoen et al., 2009).

About 51 million Americans lacked health insurance in 2009 (DeNavas-Walt et al., 2010). This is in addition to the millions of underinsured Americans who lack access to the appropriate screenings and services needed to detect and address preventable health conditions and diseases. Furthermore, health care workers have often failed to seize patient interactions as opportunities to promote health and well-being and to inform patients about disease prevention strategies (WHO, 2002). This failure to

inform patients has been found to be due to time constraints in the clinical setting, a lack of reimbursement for provision of these services, and a lack of consensus and provider knowledge about what services to prioritize for their patients. The ACA intends to mitigate these issues.

WHY WOMEN?

The ACA has the potential to transform the way in which the U.S. health care system addresses women's health issues in many ways. It expands access to coverage to millions of uninsured women, ends discriminatory practices such as gender rating in the insurance market, eliminates exclusions for preexisting conditions, and improves women's access to affordable, necessary care. The Women's Health Amendment (*Federal Register,* 2010), which was introduced by Senator Barbara Mikulski and which was added to the ACA, expands on these improvements by requiring that all private health plans cover—with no cost-sharing requirements—a newly identified set of preventive health care services for women. Defining appropriate preventive services for women and ensuring that those services can be accessed without cost sharing are important strategies to improve women's health and well-being (Bernstein et al., 2010; Blustein, 1995).

Many reasons exist for expanding the list of preventive care and screening services for women beyond those included in the guidelines of the United States Preventive Services Task Force (USPSTF) Grade A and B guidelines, the Advisory Committee on Immunization Practices (ACIP), and Bright Futures (for adolescents) stipulated in the ACA (USPSTF, ACIP, and Bright Futures and their guidelines are described in detail in Chapter 2). Even though women have longer life expectancies than men, women suffer from chronic disease and disability at rates disproportionate to those of men, with consequences for their own health and the health of their families (Wood et al., 2010). Furthermore, mounting evidence suggests that women not only have different health care needs than men (because of reproductive differences) but also manifest different symptoms and responses to treatment modalities (IOM, 2010). Behavioral factors that are shown to contribute to morbidity and mortality in women, include smoking, eating habits, physical activity, sexual risk-taking, and alcohol use (IOM, 2010). Pregnancy and childbirth also carry risks to women's health including maternal mortality (CDC, 2008). Figure 1-1 illustrates preventable mortality in women.

Health outcomes occur because of multiple factors including biology, behavior, and the social, cultural, and environmental contexts in which women live. Smoking, eating habits, physical activity, and other health-related behaviors are shaped by cultural and social contexts, including factors associated with social disadvantage. The marked differences in

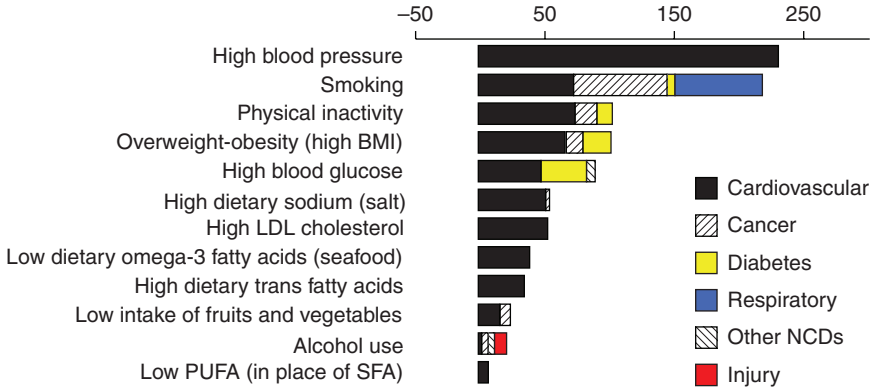

FIGURE 1-1 Deaths in women attributable to total effects of individual risk factors (in thousands), by disease.
ABBREVIATIONS: BMI, body-mass index; LDL, low-density lipoproteins; NCD, non-communicable disease; PUFA, polyunsaturated fatty acid; SFA, saturated fatty acid.
SOURCE: Danaei et al. (2009).

condition prevalence and mortality in women who experience social disadvantage are associated with minority race/ethnicity, lower education, low income, and differential exposure to stressors such as domestic violence. Such exposures are related to outcomes as varied as injury and trauma, depression, asthma, heart disease, human immunodeficiency virus (HIV) infection, and other sexually transmitted infections (Campbell et al., 2002; Coker et al., 2000; Ozer and Weinstein, 2004; Tjaden and Thoennes, 1998).

On average, women need to use more preventive care than men (Asch et al., 2006; HHS, 2001), owing to reproductive and gender-specific conditions, causing significant out-of-pocket expenditures for women (Bertakis et al., 2000; Kjerulff et al., 2007). This creates a particular challenge to women, who typically earn less than men and who disproportionately have low incomes. Indeed, women are consistently more likely than men to report a wide range of cost-related barriers to receiving or delaying medical tests and treatments and to filling prescriptions for themselves and their families (KFF, 2010). For example, women have been shown to be more likely than men to forgo preventive services such as cancer screenings and dental examinations because of cost (Rustgi et al., 2009). Studies have also shown that even moderate copayments for preventive services such as mammograms and Pap smears deter patients from receiving those services (Solanki et al., 2000; Trivedi et al., 2010). A 2010 Commonwealth Fund

survey found that 44 percent of adult women (compared with 35 percent of adult men) either reported that they had a problem paying medical bills or indicated that they were paying off medical debt over time, an increase from 38 percent in 2005 (Robertson and Collins, 2011). The same survey indicated that less than half of women are up to date with recommended preventive care screenings and services (Robertson and Collins, 2011).

Most women and men in the United States are covered by insurance obtained through the workplace. However, women with employer-based insurance are almost twice as likely as men to be covered as dependents, increasing their vulnerability to losing their insurance if they divorce, their partners lose their jobs, or they become widowed (KFF, 2010). Even though results of studies indicate that evidence-based preventive care services lower the burden of disease, are often cost-effective, increase the efficiency of health care spending, and contribute to the creation of a more productive and prosperous America, many financial barriers exist that prevent women from achieving health and well-being for themselves and their families.

PREVENTIVE SERVICES FOR WOMEN

Preventive services for women are services that prevent conditions harmful to women's health and well-being. "Conditions" are considered diseases, disabilities, injuries, behaviors, and functional states that have direct implications for women's health and well-being. These conditions may be specific to women, such as gynecologic infections and unintended pregnancy; they may be more common or more serious in women, such as autoimmune diseases and depression; they may have distinct causes or manifestations in women, such as alcohol abuse, obesity, and interpersonal violence-related posttraumatic stress disorder; or they may have different outcomes in women or different treatments, such as cardiovascular disease and diabetes (IOM, 2010). To "prevent" is to forestall the onset of a condition; detect a condition at an early stage, when it is more treatable; or slow the progress of a condition that may worsen or result in additional harm. Preventive services may therefore include the provision of immunizations, screening tests, counseling and education, Food and Drug Administration-approved medications and devices, procedures, and over-the-counter medications and devices.

COMMITTEE ON PREVENTIVE SERVICES FOR WOMEN

The Office of the Assistant Secretary for Planning and Evaluation (ASPE) of the U.S. Department of Health and Human Services (HHS) asked the Institute of Medicine to convene a diverse committee of experts in disease prevention, women's health issues, adolescent health issues, and

evidence-based guidelines to review existing guidelines, identify existing coverage gaps, and recommend services and screenings for HHS to consider in order to fill those gaps (Box 1-2). A 16-member committee was selected to complete the statement of task.

In subsequent guidance to the committee, HHS sponsors at ASPE directed the committee to limit its focus to females between the ages of 10 and 65 years.

BOX 1-2
Statement of Task to the Committee on Preventive Services for Women

The Institute of Medicine will convene an expert committee to review what preventive services are necessary for women's health and well-being and should be considered in the development of comprehensive guidelines for preventive services for women. The committee will also provide guidance on a process for regularly updating the preventive screenings and services to be considered. In conducting its work, the committee will: conduct a series of meetings to examine existing prevention guidelines, obtain input from stakeholders, identify gaps that may exist in recommended preventive services for USPSTF Grade A and B preventive services guidelines for women and in Bright Futures and USPSTF Grade A and B guidelines for adolescents, and highlight specific services and screenings that could supplement currently recommended preventive services for women. Specifically, the committee will consider the following questions:

- What is the scope of preventive services for women not included in those graded A and B by the USPSTF?
- What additional screenings and preventive services have been shown to be effective for women? Consideration may be given to those services shown to be effective but not well utilized among women disproportionately affected by preventable chronic illnesses.
- What services and screenings are needed to fill gaps in recommended preventive services for women?
- What models could HHS and its agencies use to coordinate regular updates of the comprehensive guidelines for preventive services and screenings for women and adolescent girls?

The Office of the Assistant Secretary for Planning and Evaluation (ASPE) on behalf of the U.S. Department of Health and Human Services (HHS) has been charged to examine recommendations for women's preventive services. ASPE will use the information and recommendations from the committee's report to guide policy and program development related to provisions in the Affordable Care Act addressing preventive services for women.

The ACA defines the current USPSTF recommendations regarding breast cancer screening, mammography, and breast cancer prevention to be "the most current other than those issued in or around November 2009." Thus, coverage for screening mammography is guided by the 2002 USPSTF guideline, which specifies that such screenings be performed every one to two years for women aged 40 years and older.

Furthermore, for consistency in approach with the other three guidelines used by the ACA and given the time limitations for this study, the committee was restricted from considering cost-effectiveness in its process for identifying gaps in current recommendations. Finally, despite the potential health and well-being benefits to some women, abortion services were considered to be outside of the project's scope, given the restrictions contained in the ACA.

The committee received clarification from ASPE that its work was not intended to duplicate the processes used by the USPSTF or Bright Futures. Thus, the committee interpreted this guidance to indicate that evidence ranging from systematic reviews of the evidence to other bodies of evidence could be considered. This appears to be consistent with the process that led to the current preventive services within the ACA.

The committee was also directed to limit its work to identifying clinical preventive service coverage gaps and not to make recommendations regarding community-based prevention activities.

The committee recognizes that many factors that shape the health and well-being of women fall outside the realm of clinical services. These include, for example, changes to the environment and the workplace to promote health, changes in women's concept of self-efficacy to promote health, and changes in women's self-empowerment to address their own health and wellness. These factors and determinants of health are elements of models such as the Whitehead and Dahlgren (1991) determinants-of-health model and encompass biological, behavioral, and social factors. Nevertheless, evaluation of these factors and determinants of health were outside of the committee's purview.

HHS will consider the committee's recommendations as it develops guidelines to support the delivery of effective preventive services for women. If they are enacted, the recommendations from this study, along with the other coverage requirements in the ACA, will provide a comprehensive package of clinical preventive services for women.

COMMITTEE PROCESS

To meet its charge, the committee held three information-gathering meetings on preventive services for women and reviewed the relevant literature. Before the first meeting and throughout the committee's delibera-

tions, the committee gathered extensive information on numerous topics related to health and health care services for women, including chronic and mental health conditions, cancers, sexually transmitted infections, bone diseases, breastfeeding, interpersonal violence, unintended pregnancy, and a variety of behavioral health issues. During the public forums, representatives from women's health organizations, national health interest groups, health coverage providers, employer interest groups, and other experts presented statements to the committee on the latest status and developments in their respective fields (see Appendix B for the meeting agendas). Committee members questioned the speakers to address additional concerns that they did not cover in their statements. The committee also invited comments (both written and oral) from the general public and representatives from numerous organizations with interest in women's preventive services.

The committee first met in November 2010 and held its last meeting in May 2011. Within that time frame, it should be noted that the committee did not have adequate time or resources to conduct its own meta-analyses or comprehensive systematic review for each preventive service or for every special population group that may have different health needs or benefit from different preventive services, such as minority populations, disabled women, recent immigrants, lesbians, prisoners, and those employed in high-risk environments.

Box 1-3 details the committee's definition of preventive health services, which was used as a starting point for the study.

This definition of preventive health services is primarily derived from a blend of definitions from multiple health care organizations and agencies, including the USPSTF and the World Health Organization, with the text regarding well-being possessing the most original phrasing by the committee and stems from the statement of task. In addition, other key definitions are included in Box 1-4. These definitions were adapted from the Five Major Steps to Intervention of the Agency for Healthcare Research

BOX 1-3
Definition of Preventive Health Services

For the purposes of this study, the Committee on Preventive Services for Women defines preventive health services to be measures—including medications, procedures, devices, tests, education, and counseling—shown to improve well-being and/or decrease the likelihood or delay the onset of a targeted disease or condition.

BOX 1-4
Key Definitions: Preventive Interventions

Preventive interventions come in several forms: screening, testing, counseling, immunization, preventive medication, and preventive treatment.

- **Screening** is best described as tests that assess the likelihood of the presence of a disease or condition in an apparently healthy individual. Screening methods use, for example, laboratory analyses and X rays and similar technologies. Screening also includes questions from clinicians. Screening may be targeted to people at increased risk because of age, gender, family or personal history, and other factors. Each screening tool is different in design and method, affecting the sensitivity (ability to correctly identify those with the disease), specificity (ability to correctly identify those without the disease), and positive and negative predictive values of the tool. Ideally, screening tests are rapid, simple, and safe. Screening is not a definitive diagnostic test, and a positive result on a screening test merely indicates that the screened individual has a higher likelihood of having the disease or condition for which the individual is being screened. Individuals who screen positive on such tests should have confirmatory diagnostic tests to ensure an accurate diagnosis.
- **Testing** refers to any process used to determine whether a condition is present or to assess the status of a condition. Testing may involve questioning patients (e.g., asking a patient about tobacco use), physical examination (e.g., mammography screening to detect potential breast cancers), or examining blood, body fluids, or tissues (e.g., to see if a cancer is present in a biopsy sample). Testing may also require the use of sophisticated technology, such as computed tomography and magnetic resonance imaging scans and other X rays, or invasive procedures, such as heart catheterization to detect blockage of coronary arteries. Tests may be used to

    1. Screen individuals who have risk factors but no indication of having the condition,
    2. Diagnose a disease or condition in individuals who have symptoms and signs but for whom a test will add certainty about the diagnosis, or
    3. Monitor the progress of an individual who is being treated or being considered for treatment, such as monitoring blood pressure over time.

- **Counseling** refers to a discussion between a clinician and patient about ways that changes in personal behavior can reduce the risk of illness or injury. The goal of counseling is for clinicians to educate patients about their health risks as well as to provide them with the skills, motivation, and knowledge that they need to address their risk behaviors (e.g., the "5 A" framework for tobacco cessation: **a**sk, **a**dvise, **a**ssess, **a**ssist, **a**rrange). A special kind of counseling, informed decision making, recognizes that different people will make different decisions, even though their situations may seem to be similar. Informed decision making is structured to give an individual all the information needed

BOX 1-4 Continued

to choose from among different clinical options, such as whether to undergo genetic testing.

- **Immunization** protects an individual from a specific communicable disease (e.g., hepatitis) by exposing the individual to an antigen or a trace amount of an inactivated disease-causing agent, spurring the development of natural immunity.
- **Preventive medications** are used to prevent the onset of a disease or a condition (e.g., aspirin therapy to prevent cardiovascular events).
- **Preventive treatment** involves a procedure intended to prevent the occurrence of a disease or condition or to prevent the progression of a disease from one stage to another. Preventive treatments usually refer to the use of prescription or nonprescription (over-the-counter) medications, but they may also involve the use of prescriptions for lifestyle changes (e.g., exercise or diet change) or other interventions. Some surgical procedures may be considered preventive treatment, such as removal of polyps in the colon identified during a screening colonoscopy to prevent their progression to cancer lesions.

SOURCES: AHRQ, 2011; NBGH, 2005.

and Quality (AHRQ, 2011) and the National Business Group on Health's *Purchaser's Guide to Clinical Preventive Services: Moving Science into Coverage* (NBGH, 2005).

The report that follows is organized into seven chapters, summarized below.

- In Chapter 2, the report reviews the three existing guidelines used in the ACA to determine coverage.
- Chapter 3 details the existing practices of national, state, and selected private health plans.
- In Chapter 4, the committee discusses its framework for identifying gaps in existing preventive services and its process for selecting how to fill those gaps.
- Chapter 5 provides a description of the gaps identified through the committee's work.
- The committee's recommendations for updating guidelines for preventive services are proposed in Chapter 6.
- Chapter 7 includes committee conclusions and summarizes committee recommendations while identifying the limitations under which the committee performed its work.

The evidence provided to support a recommendation related to increasing detection of and counseling for interpersonal and domestic violence is based on peer-reviewed studies and federal and international policies, in addition to clinical professional guidelines from organizations, such as the AMA and ACOG.

Recommendation 5.7: The committee recommends for consideration as a preventive service for women: screening and counseling for interpersonal and domestic violence. Screening and counseling involve elicitation of information from women and adolescents about current and past violence and abuse in a culturally sensitive and supportive manner to address current health concerns about safety and other current or future health problems.

WELL-WOMAN PREVENTIVE VISITS

Provision of Preventive Services

The committee examined existing guidelines, available evidence, and current clinical best practices to identify effective provision of services that, when provided to women through dedicated clinical encounters, have been shown to promote optimal well-being. Primary care office visits that are dedicated to preventive care may facilitate increased access to health care services that are shown to identify chronic disease risk factors, promote well-being, and/or decrease the likelihood or delay the onset of a targeted disease or condition. Box 5-2 contains examples of terms that are commonly used to label the prevention-oriented clinical encounter; this report

BOX 5-2
Common Terms Used for Well Visits

Preventive pediatric health care visit (AAP/Bright Futures)
Well-child checkup (Early Periodic Screening, Diagnosis, and Treatment program and Medicaid)
Well-adult checkup (Medicaid)
Health risk assessment (Medicaid)
"Welcome to Medicare" visit (Medicare)
Annual wellness examination (Medicare)
Health maintenance visit (MHQP)

uses the term "well-woman preventive visit" to describe the provision of prevention services in an office visit or clinical encounter.

Target Populations

Well-woman preventive care visits apply to women of all ages (and according to the committee's charge, women from 10 through 64 years) and stages of life. Stages of womanhood are defined by age groupings, which are in general alignment with published frameworks and practice guidelines (AAP, 2008). These include adolescence (subdivided into two subgroups ages 10 to 14 years and 15 to 19 years), early adulthood (ages 20 to 24 years), middle adulthood (ages 25 to 49 years), and later adulthood (after age 50 years).

Justification of Well-Woman Visits for Provision of Preventive Services

Women's Preventive Care Is Fragmented

Although "well" visits for adults are not explicitly recommended by the USPSTF, they provide an opportunity for delivering prevention services recommended by a number of government and nongovernment health care agencies (GAO, 2009). In the U.S. health care system, for women, the tendency is to separate reproductive health care services from other components of primary care (Weisman, 1998). Because many preventive services for women are for reproductive health (e.g., screening for cervical cancer and sexually transmitted infections and contraception services), many women may see obstetrician-gynecologists for those services and a generalist physician (a family physician or a general internist) for other components of their routine health care. For example, a national survey of the U.S. female population in 1998 showed that 29 to 49 percent of women, depending of type of health plan, see both a generalist and an obstetrician-gynecologist for their regular health care (Weisman and Henderson, 2001). In another study of women aged 18 to 64 years, 58 percent of women in all stages of life saw an obstetrician-gynecologist in addition to a generalist physician (Henderson et al., 2002). In the 2008 Kaiser Women's Health Survey, 44 percent of women aged 18 to 64 years reported seeing two or more regular providers (Ranji and Salganicoff, 2011). Given these patterns of physician use, it is likely that women make more than one visit and use more than a single provider to attain needed preventive services in a given year. Thus, no single type of provider can be identified as the sole primary care provider for women.

Women have greater health care needs than men and require a broader array of health services, but not all providers are equipped or able to

provide the full range of preventive services for women. A consequence of women obtaining preventive health care from more than one provider is that women's primary care is often fragmented.

Cost as a Major Barrier to Services and Visits

Although the preventive services detailed in Table 5-6 will be covered with no cost sharing under the ACA, insurance plans are permitted to require copayments for office visits (*Federal Register,* 2010). Increased health care costs, combined with the fact that most Americans have seen too little or no gains in income in recent years, can be seen as a threat to the health and financial status of women across the country (Collins et al., 2011). Furthermore, evidence suggests that these issues are adversely affecting women disproportionately compared to men. In 2010, for example, 44 percent of women but only 35 percent of men indicated that they were experiencing difficulty paying medical bills or were paying off medical debt. Furthermore, almost a third of women stated that they did not visit a doctor or clinic when they were faced with a medical problem because of cost, whereas less than a quarter of men reported the same experience (Robertson and Collins, 2011).

Gaps in Well Visits for Women

Clinical guidelines and mandated coverage for well visits exist for children and adolescents (until age 21 years), for some adults, and into maturity (for individuals aged 65 years and older) in public-sector health plans (Medicaid and Medicare) as well as some private-sector health plans (see below and Chapter 3). However, public programs may be incomplete in providing coverage in early, middle, and later adulthood. According to a Government Accountability Office analysis of responses to a survey of state Medicaid directors conducted between October 2008 and February 2009, only 39 states cover health maintenance visits to adults under their Medicaid programs (GAO, 2009). This significant gap in coverage places a disproportionate burden on women of childbearing age, putting them at a greater risk for disease and illness in their most active reproductive years.

Existing Guidelines and Recommendations

Adolescence

Clinical preventive services guidelines for adolescents issued by governmental agencies and nonprofit medical organizations (e.g., HRSA, the Maternal and Child Health Bureau, AAP, AMA, and AAFP) have long

TABLE 5-6 List of Preventive Services to Be Obtained During Well-Woman Preventive Visits Under Recommendation 8

Topic	Description	Grade
USPSTF Grade A and B Recommended Services		
Alcohol misuse counseling	The USPSTF recommends screening and behavioral counseling interventions to reduce alcohol misuse by adults, including pregnant women, in primary care settings.	B
Anemia screening: pregnant women	The USPSTF recommends routine screening for iron deficiency anemia in asymptomatic pregnant women.	B
Bacteriuria screening: pregnant women	The USPSTF recommends screening for asymptomatic bacteriuria with urine culture for pregnant women at 12 to 16 weeks' gestation or at the first prenatal visit, if later.	A
Blood pressure screening	The USPSTF recommends screening for high blood pressure in adults aged 18 and older.	A
BRCA screening, counseling about	The USPSTF recommends that women whose family history is associated with an increased risk for deleterious mutations in *BRCA1* or *BRCA2* genes be referred for genetic counseling and evaluation for *BRCA* testing.	B
Breast cancer preventive medication	The USPSTF recommends that clinicians discuss chemoprevention with women at high risk for breast cancer and at low risk for adverse effects of chemoprevention. Clinicians should inform patients of the potential benefits and harms of chemoprevention.	B
Breast cancer screening	The USPSTF recommends screening mammography for women, with or without clinical breast examination, every 1–2 years for women aged 40 and older.	B
Breastfeeding counseling	The USPSTF recommends interventions during pregnancy and after birth to promote and support breastfeeding.	B
Cervical cancer screening	The USPSTF strongly recommends screening for cervical cancer in women who have been sexually active and have a cervix.	A
Chlamydial infection screening: non-pregnant women	The USPSTF recommends screening for chlamydial infection for all sexually active nonpregnant young women aged 24 and younger and for older nonpregnant women who are at increased risk.	A
Chlamydial infection screening: pregnant women	The USPSTF recommends screening for chlamydial infection for all pregnant women aged 24 and younger and for older pregnant women who are at increased risk.	B
Cholesterol abnormalities screening: women 45 and older	The USPSTF strongly recommends screening women aged 45 and older for lipid disorders if they are at increased risk for coronary heart disease.	A

EXHIBIT 80

FINAL REPORT

WPSI

Women's Preventive Services Initiative

Recommendations for Preventive Services for Women
Final Report to the U.S. Department of Health and Human Services, Health Resources & Services Administration
December 2016

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Recommendations for Preventive Services for Women was developed by the Multidisciplinary Steering Committee of the Women's Preventive Services Initiative. The information in *Recommendations for Preventive Services for Women* should not be viewed as a rigid body of rules. The recommendations are general and intended to be adapted to many different situations, taking into account the needs and resources particular to the locality, the institution, or the type of practice. Variations and innovations that improve the quality of patient care are encouraged rather than restricted. The purpose of these guidelines will be well served if they provide a firm basis on which local norms may be built.

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STATEMENTS OF SUPPORT

Members of the Advisory Panel support the Women's Preventive Services Initiative:

The American College of Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

NPWH
NURSE PRACTITIONERS IN WOMEN'S HEALTH
Caring for Women

ACP
American College of Physicians
Leading Internal Medicine, Improving Lives

AMERICAN ACADEMY OF FAMILY PHYSICIANS
STRONG MEDICINE FOR AMERICA

The organizations comprising the Multidisciplinary Steering Committee endorse the collaborative and consensus process of the Women's Preventive Services Initiative:

Conflict of Interest Disclosures

The following Advisory Panel and Multidisciplinary Steering Committee members reported no financial relationships or potential conflicts of interest to disclose: Jeanne Conry, MD, PhD; Pelin Batur, MD, FACP, NCMP, CCD; Therese Bevers, MD; Gale R. Burstein, MD, MPH, FAAP, FSAHM; Octavia Cannon, DO; David Chelmow, MD; Stamatia Destounis, MD, FACR, FSBI; Susan C. Dimock, PhD; Jennifer Frost, MD; Janel George, JD; Kimberly D. Gregory, MD, MPH; Linda Humphrey, MD, MPH; Susan M. Kendig, JD, WHNP-BC; Jeanette Kowalik, PhD, MPH, MCHES; Melissa McNeil, MD, MPH; Edith P. Mitchell, MD, FACP; Susan Peck, RNC, MSN, APN; Maureen Phipps, MD, MPH; Amir Qaseem, MD, PhD, MHA, FACP; Alina Salganicoff, PhD; Maureen Sayres Van Niel, MD; Robert Smith, PhD; James Stevermer, MD, MSPH, FAAFP; Annamarie Streilein, MHS, PA-C; Jessi Leigh Swenson, JD and Stacy Tessler Lindau, MD, MAPP, FACOG.

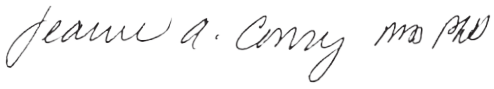
Michelle Collins, PhD, CNM, FACNM in 2015, served as an expert witness for a law firm that represents Bayer pharmaceuticals in the class action suit against Bayer re: Mirena IUDs. She may be called upon again for testimony, though there is doubt that it will go to trial. Susan Hoffstetter, PhD, WHNP-BC, FAANP is a Nexplanon Trainer. Rachel Urrutia, MD receives salary support from KNDR Healthcare management group. KNDR Healthcare management group works to improve access to fertility awareness methods of family planning.

FOREWORD

The American College of Obstetricians and Gynecologists is pleased to submit our report "Recommendations for Preventive Services for Women" to the U.S. Department of Health and Human Services Administration. The Women's Preventive Services Initiative is a collaborative effort between health professional societies and consumer organizations that are experts in women's health. This report is the first in a 5-year effort to develop, review, update, and disseminate recommendations for women's preventive health care services and identifies needs across a woman's life span, from adolescence through adulthood into maturity. The goal of the Women's Preventive Services Initiative is to promote health over the course of a woman's lifetime through disease prevention and preventive health care.

In order to ensure that women of all ages receive appropriate preventive health screenings, both health care providers and patients need uniform, established guidelines. The Women's Preventive Services Initiative recognizes that women may seek guidance for preventive services from a diverse set of experts in women's health, including family physicians and internists, obstetrician–gynecologists, physician assistants, nurse practitioners, certified nurse-midwives, and certified midwives. It will take the collaborative effort of the Women's Preventive Services Initiative, with its broad membership of specialty societies providing women's health care, to share guidelines and to hold all accountable for optimizing the health and well-being of women. Efficient, effective guidelines established with evidence-based processes and vetted by women's health experts will optimize health care delivery and outcomes.

The American College of Obstetricians and Gynecologists thanks the Health Resources and Services Administration for the opportunity to undertake this rewarding and satisfying project. We represent more than 58,000 obstetrician–gynecologists and, more importantly, the women we serve. Over the next 4 years, we look forward to the prospect of identifying and developing more topic-specific recommendations and building an implementation strategy so that the health of all women is improved in this generation and generations to come!



Jeanne Ann Conry, MD, PhD, FACOG
ACOG Past President
Chairperson, Women's Preventive Services Initiative

EXECUTIVE SUMMARY

On March 1, 2016, the American College of Obstetricians and Gynecologists (ACOG) launched the Women's Preventive Services Initiative (WPSI), a close collaboration of national health professional societies and consumer organizations, all with important contributions to improving women's health. Through a 5-year cooperative agreement with the U.S. Department of Health and Human Services, Health Resources and Services Administration (HRSA), ACOG will coordinate the WPSI effort to develop, review, update, and disseminate recommendations for women's preventive health care services.

The WPSI Advisory Panel provides oversight to the Initiative and is made up of representatives from ACOG and three other major professional organizations representing the majority of women's health care providers: the American Academy of Family Physicians, the American College of Physicians, and the National Association of Nurse Practitioners in Women's Health. The Multidisciplinary Steering Committee, which develops the preventive health care recommendations, includes representatives from medical specialty societies that oversee the majority of women's primary care services and chronic disease management care, public health professionals, and patients and consumers (**see the box**).

2016 Multidisciplinary Steering Committee Participating Organizations

American Academy of Family Physicians

American College of Obstetricians and Gynecologists

American College of Physicians

National Association of Nurse Practitioners in Women's Health

Academy of Women's Health

American Academy of Pediatrics

American Academy of Physician Assistants

American Cancer Society

American College of Nurse–Midwives

American College of Preventive Medicine

American College of Radiology

American Osteopathic Association

American Psychiatric Association

American Geriatrics Society

Association of Reproductive Health Professionals

Association of Women's Health, Obstetric and Neonatal Nurses

National Comprehensive Cancer Network

National Medical Association

Association of Maternal & Child Health Programs

National Partnership for Women & Families

National Women's Law Center

Patient Representative

Federal Partners

Centers for Disease Control and Prevention

Health Resources and Services Administration

Office of Health Reform

Office of Minority Health

Office of Population Affairs

Office on Women's Health

In addition, the WPSI incorporates a strong evidence-based structure that follows the criteria specified by the Institute of Medicine (IOM, now the National Academies of Sciences, Engineering, and Medicine) for trustworthy guidelines[1] combined with the in-depth knowledge and expertise of the WPSI members. The recommendations will help ensure that women receive a comprehensive set of preventive services. In its first year, the WPSI updated eight topics addressed by the 2011 IOM report, *Clinical Preventive Services for Women: Closing the Gap*.[2] Because of the confusion caused by contradictory recommendations around breast cancer screening, the WPSI also addressed breast cancer screening for women at average risk. Additional topics will be determined by WPSI members with input from the public and addressed in subsequent years.

The benefits to women of preventive health services throughout the life course are well documented in the literature. Evidence-based preventive health care has been shown to identify risk factors for disease and to promote early detection of disease and infection, allowing more effective management and prevention of further complications.[3] Preventive care—including reproductive life planning, optimization of nutrition and exercise, screening for and management of chronic diseases, immunizations, management of infectious diseases, and attention to psychological and behavioral health—contributes to women's overall health.

To ensure women of all ages receive appropriate preventive health screenings, health care providers and patients need uniform, established guidelines for recommended preventive services for women. The availability of various and sometimes inconsistent guidelines fuels provider uncertainty and patient confusion. Efficient and effective guidelines established by the WPSI's strong evidence-based process and vetted by experts in women's health will impact patient preventive care delivery, patient safety, and quality of care by increasing the consistency of behavior and replacing individual preferences with best practices. Because the WPSI recommendations represent the consensus of the members, the participating organizations will work together to adopt and widely promote the recommendations to help ensure that all women receive a comprehensive set of preventive services.

The WPSI partnered with physician scientists from the Pacific Northwest Evidence-based Practice Center (EPC) at Oregon Health & Science University to review and update the evidence for each topic under consideration. The WPSI methodology and process were designed to promote thorough consideration of the best available evidence, ensure transparency, minimize the impact of individual bias and conflicts of interest, and drive members to reach consensus on recommendations. The process allows for public input and periodic updating of recommendations. When evidence was lacking, the WPSI also took into account members' clinical expertise and judgment as well as current best practices and patient perspectives.

Overall, the recommendations presented here (see page 23) apply to the general population of U.S. women at average risk for the conditions addressed. The final WPSI preventive services recommendations are presented in a single website, WomensPreventiveHealth.org, that is easily accessible by both health care providers and their patients. The recommendations contained in this report represent the conclusions of the WPSI and are not necessarily endorsed by individual organizations that participated in the Multidisciplinary Steering Committee that created them.

These WPSI recommendations are the culmination of a multidisciplinary effort to identify needed services and to improve the uptake of women's preventive services that will contribute to overall improved health. These recommendations take into account the most current evidence available, yet research gaps remain. In particular, more research is needed to address the preventive health needs of racial and ethnic minority women and underserved populations.

With the WPSI recommendations approved by HRSA, the WPSI will convene stakeholders with broad national networks for outreach and proven success in reaching their targeted audiences to promote the recommendations and increase consumer awareness of the need for and benefits of preventive care. As a result, more women will get the services they need and avoid unnecessary services as well. As the IOM stated, "Trustworthy guidelines hold the promise of improving health care quality and outcomes."[3] At the same time, ensuring that more women have access to recommended preventive health services will improve the health of women, their families, and their communities.

References

[1] Institute of Medicine. Clinical Practice Guidelines We Can Trust. Washington, DC: National Academies Press; 2011.

[2] Institute of Medicine. Clinical Preventive Services for Women: Closing the Gaps. Washington, DC: National Academies Press; 2013.

[3] Maciosek MV. Greater Use of Preventive Services in U.S. Health Care Could Save Lives at Little or No Cost. Health Aff (Millwood) 2010;29(9):1656–60.

Introduction

On March 1, 2016, the American College of Obstetricians and Gynecologists (ACOG) launched the Women's Preventive Services Initiative (WPSI). The WPSI is a close collaboration of national health professional societies and consumer organizations that recognizes important contributions of these stakeholders to improved women's healthcare. Through a 5-year cooperative agreement with the U.S. Department of Health and Human Services, Health Resources and Services Administration (HRSA), ACOG will coordinate the WPSI effort to develop, review, update, and disseminate recommendations for women's preventive health care services, including the HRSA-sponsored Women's Preventive Services Guidelines.

The WPSI incorporates a strong evidence-based structure aligned with Institute of Medicine (IOM, now National Academics of Sciences, Engineering, and Medicine)-specified criteria for trustworthy guidelines, combined with the women's health expertise of the WPSI's members. Because the WPSI recommendations represent the consensus of the members, these participating organizations will work together to adopt and to widely promote the recommendations to help ensure that all women receive a comprehensive set of preventive services. ACOG has a track record of coalition-building and recommendation development, with notable success in synthesizing a wide range of information and opinions and arriving at strong consensus-based outcomes accepted across broad audiences nationwide.

In its first year, in keeping with HRSA priorities, the WPSI focused on updating eight topics addressed by the IOM in its 2001 report, *Clinical Preventive Services for Women: Closing the Gap.*[1] Because of the confusion caused by contradictory recommendations from multiple entities around breast cancer screening, the WPSI also addressed breast cancer screening for women at average risk. Additional topics will be determined by WPSI members with input from the public and addressed in subsequent years.

This document presents the following recommendations from the WPSI:

- Breast cancer screening for average-risk women
- Breastfeeding services and supplies
- Screening for cervical cancer
- Contraception
- Screening for gestational diabetes mellitus
- Screening for human immunodeficiency virus
- Screening for interpersonal and domestic violence
- Counseling for sexually transmitted infections
- Well-woman preventive visits

Preventive Health Care Improves Health

The benefits to women of preventive health visits throughout the life course are well documented in the literature. Evidence-based preventive health care has been shown to identify risk factors for disease and to promote early detection of disease and infection, allowing more effective management and prevention of further complications.[2] Preventive care—including reproductive life planning, optimization of nutrition and exercise, screening for and management of chronic diseases, immunizations, management of infectious diseases, and attention to psychological and behavioral health—contributes to women's overall health.

The role of preventive health care services, particularly in conjunction with early treatment of symptoms that may lead to worsening conditions, is the foundation of well-woman care.[3] In its Fifth Annual Report to Congress, *High-Priority Evidence Gaps for Clinical Preventive Services: Improving the Health of Women Through Research*, the U.S. Preventive Services Task Force (USPSTF) acknowledged the larger impact of preventive interventions that improve the health and well-being of women and girls. It noted that "the experience of disease and disability among women has unique transgenerational implications not only for themselves but for their children, their parents, their spouses, and even their communities."[4]

Uniform Guidelines Needed

To ensure women of all ages receive appropriate preventive health screenings, health care providers and patients need uniform, established guidelines for recommended preventive services for women. The development, updating, and maintenance of recommendations for women's preventive health services across the lifespan are not the purview of any one entity or institution. Governmental organizations and agencies may conduct high-quality, systematic reviews of existing evidence and develop recommendations. At the same time, clinical specialty societies create clinical practice guidelines, sometimes with contributions from organizations with disease-specific or population-specific interests. The availability of various guidelines, which may be inconsistent or even contradictory, leads to provider uncertainty and patient confusion about needed preventive services.

In addition, clinicians may not know that guidelines exist, may find them complex with unclear or difficult to implement recommendations, or lack the time and resources to fully adhere to recommended practice. Health care providers are more likely to use preventive health guidelines if they are evidenced-based. Therefore, efficient and effective guidelines established by a strong evidence-based process, vetted by experts in women's health, will impact patient preventive care delivery, patient safety, and quality by increasing the consistency of behavior and replacing individual preferences with best practices.

Women must also be engaged partners in the effort to follow consistent, well-vetted recommendations on prevention. In addition, guidelines need to be updated regularly to reflect the latest scientific evidence available and address any inconsistencies between medical and specialty organizations so that providers can give women clear messages on which to base informed decision making.

The development of consistent, evidence-based guidelines is sometimes hampered by limitations of supporting evidence. For the nine topics addressed in its first year, the WPSI found insufficient evidence for use in tailoring recommendations for preventive services for underserved or special populations of women, such as racial and ethnic minorities and those at high risk to certain conditions. These populations may have different needs for routine preventive health screening and intervention, and the WPSI fully supports development of additional data and resources to clarify these needs. When evidence was lacking, the WPSI also took into account its Multidisciplinary Steering Committee members' clinical expertise and judgment as well as current best practices and patient perspectives. Overall, the recommendations presented here apply to the general population of U.S. women at average risk for the conditions addressed; where relevant data were available, the recommendations address women at increased risk.

Overcoming Barriers to Preventive Care Uptake

More must be done by those working in preventive women's health to improve awareness and adoption of preventive measures. Providers need to be aware of and endorse evidenced-based guidelines and implement them in their practices. The Patient Protection and Affordable Care Act (ACA) provides expanded access to and coverage for preventive services for all women; an estimated 55.6 million women have received no-cost coverage for preventive services since the policy went into effect.[5] For both insured and uninsured women, affordability of care remains a significant concern.[6] Despite clear recognition of the benefits of preventive health services—such as improved long-term health outcomes and more efficient utilization of health services—disparities persist in the use of screening procedures among racial and ethnic minorities, those with lower health literacy, and the poor.[7,8] Coordination of care among providers is also required. High-quality care for women throughout the lifespan depends on use of consistent evidence-based guidelines across specialties, open communication and transparency, and patient education.

Collaborative, Multidisciplinary Approach

The WPSI is a collaboration among national professional societies and consumer organizations all with important contributions to improved women's health. The WPSI provides a forum for reviewing evidence and reaching consensus on recommendations for preventive women's care. The specific aims of the WPSI are as follows:

1. Establish a process for developing and regularly recommending updates to guidelines for women's preventive service.
2. Obtain participation from health professional organizations in developing recommended guidelines for women's preventive services.
3. Review and synthesize existing guidelines and new scientific evidence for women's preventive services.
4. Develop recommended guidelines for women's preventive services.
5. Disseminate HRSA-supported comprehensive guidelines for use in clinical practice.

The WPSI consists of an Advisory Panel made up of representatives from ACOG and three other major professional organizations representing the majority of women's health care providers: the American Academy of Family Physicians, the American College of Physicians, and the National Association of Nurse Practitioners in Women's Health. In addition, three individuals who were members of the IOM's 2011 Committee on Preventive Services for Women serve as Advisory Panel members.

The Advisory Panel oversees two standing committees—the Multidisciplinary Steering Committee (MSC) and the Implementation Steering Committee—and any future work groups formed. The WPSI instituted a strong evidence-based structure, tailored to the IOM standards for trustworthy guidelines, to create widely accepted recommendations that apply nationwide to women at various life stages. The methodology is detailed below.

The WPSI is chaired by Jeanne A. Conry, MD, PhD, Past President of ACOG. The Advisory Panel is chaired by Maureen Phipps, MD, MPH. Members of the MSC include representatives from medical specialty societies that oversee the majority of women's primary care services and chronic disease management care, public health professionals, and patients and consumers (see the box). The MSC also includes federal agency liaisons. In years 2–5, the MSC membership will be adjusted also to include expertise relevant to a specific topic selected. The WPSI partnered with physician scientists from the Pacific Northwest Evidence-based Practice Center (EPC) at Oregon Health & Science University to conduct reviews and updates of the evidence for each topic under consideration. Additional methodological, clinical, policy, and academic expertise came from three members of the 2011 IOM Clinical Preventive Services for Women panel. The WPSI is coordinated by ACOG staff members. Appendix 1 lists the WPSI members and staff.

2016 Multidisciplinary Steering Committee Participating Organizations

American Academy of Family Physicians

American College of Obstetricians and Gynecologists

American College of Physicians

National Association of Nurse Practitioners in Women's Health

Academy of Women's Health

American Academy of Pediatrics

American Academy of Physician Assistants

American Cancer Society

American College of Nurse–Midwives

American College of Preventive Medicine

American College of Radiology

American Osteopathic Association

American Psychiatric Association

American Geriatrics Society

Association of Reproductive Health Professionals

Association of Women's Health, Obstetric and Neonatal Nurses

National Comprehensive Cancer Network

National Medical Association

Association of Maternal & Child Health Programs

National Partnership for Women & Families

National Women's Law Center

Patient Representative

Federal Partners

Centers for Disease Control and Prevention

Health Resources and Services Administration

Office of Health Reform

Office of Minority Health

Office of Population Affairs

Office on Women's Health

METHODOLOGY

The IOM's July 2011 report, *Clinical Practice Guidelines We Can Trust*, noted a perceived lack of transparency in the derivation of some clinical practice recommendations and in managing conflicts of interest.[9] It cites variations in guidelines development processes as one fundamental cause of a lack of consistent guidelines across specialties and groups, which contributes to provider uncertainty and patient confusion about needed preventive services. The WPSI methodology is predicated on the belief that a strong evidence-based process will improve compliance with preventive service guidelines. The WPSI process was designed to ensure a strong evidence foundation, transparency, and to minimize the impact of individual bias and conflicts of interest.

In keeping with its aim to review and synthesize existing guidelines and new scientific evidence as it develops new recommendations, the WPSI avoids duplicating or contradicting recommendations of the USPSTF; the American Academy of Pediatrics (AAP) Bright Futures Initiative for infants, children, and adolescents; and the CDC's Advisory Committee on Immunization Practices. These sources reflect comprehensive reviews

of evidence conducted in a rigorous, transparent way. Topics considered by the WPSI require targeted systematic reviews that focus on specific evidence gaps not covered by existing recommendations from these bodies and new recommendations not addressed by these groups.

The methodology for the WPSI recommendations is based on the criteria for evidence-based clinical practice guideline development articulated in the IOM report, *Clinical Practice Guidelines We Can Trust*. These criteria are intended to support the accuracy, integrity, and clinical relevance of the recommendations, and they provide the framework for their development.

Ensuring Transparency

The MSC is made up of health care professionals from national organizations involved in the provision of women's preventive health services across the lifespan. This broad representation of experienced clinicians and experts increases transparency to the public by ensuring that multiple perspectives and approaches are included. It also minimizes the impact of individual biases and opinions on the recommendations.

The MSC also includes members representing patient and consumer perspectives. These members serve as full MSC committee and subcommittee members and are involved in all aspects of recommendation development, including topic selection, defining the scope of the recommendation, reviewing the evidence provided by the EPC, and participating in the development and dissemination of the HRSA-supported recommendations. These members serve an important role in ensuring that the recommendations are made with patients' perspectives in mind. Patient and consumer members will also be involved in dissemination efforts, including development of patient education materials, in future years.

In addition, the WPSI provided opportunity for broad public input through a public comment period that increased transparency of the process and improved balance, comprehensiveness, and quality. The dispensation of public comment responses, including changes to the recommendation or no action, was documented and retained by WPSI project staff.

Mitigating Conflict of Interest

All WPSI participants and project staff followed ACOG's formal Conflict of Interest Policy and submitted the standard organizational disclosure form prior to appointment to the initiative and will do so annually thereafter. Any disclosures were shared with the MSC at each meeting. Members of the Advisory Panel, the WPSI Chair, Subcommittee Chairs, and project staff were not permitted to have any financial conflicts of interest. All disclosed conflicts of interest are listed in Appendix I.

Broad Range of Perspectives and Experience

Members of the MSC are multispecialty, multidisciplinary representatives from national health professional organizations with expertise in women's health care across the lifespan, including obstetricians and gynecologists, family physicians, internal medicine physicians, nurse practitioners, nurse–midwives, women's health nurses, women's health researchers, public health professionals, and patient representatives. They are experts in the fields of women's health, primary care, chronic disease management, mental health, and gerontology, among others. Members were assigned to subcommittees based on clinical and methodological expertise. In coming years, subcommittees will be tasked with developing recommendations on one to two new topics each year.

Rigorous, Thorough Evidence Review

Physician scientists from the EPC at Oregon Health & Science University with extensive experience in systematic review methodology and clinical guideline development conducted reviews and updates of the evidence for each topic under consideration. Focused updates of evidence reviewed for the nine topics considered for revision included overviews of recent systematic reviews for the USPSTF published since the last recommendations were issued by the IOM Committee in 2011, as well as summaries of additional relevant studies published since the systematic reviews.

MSC members provided input to the EPC to refine the scope of the update based on criteria from the Populations, Interventions, Comparators, Outcomes, Timing, and Setting/Study Design (PICOTS) format, a well-established protocol for clearly articulating the topic of interest. In future years, key questions will be developed for each new topic based on the PICOTS format, and the EPC will work with the MSC to refine inclusion and exclusion criteria for the literature searches.

For the updates to the IOM's 2011 recommendations presented in this report, a research librarian conducted searches in Ovid MEDLINE, the Cochrane Central Register of Controlled Trials, and the Cochrane Database of Systematic Reviews through August 2016 for all topics. For topics on counseling for sexual transmitted infections, interpersonal and domestic violence, and well-woman visits, searches were also conducted in PsycINFO through March 2016. Investigators also manually reviewed reference lists of relevant articles.

A best evidence approach was applied when reviewing abstracts and selecting studies to include for the updates that involves using the most relevant studies with the strongest methodologies.[10,11,12] For most topics, systematic reviews and key studies published since the most recent systematic review for the USPSTF were included. For well-woman visits and contraceptive methods and counseling, there are no USPSTF reviews or recommendations. Therefore, other systematic reviews and studies published since the 2011 IOM recommendations for these topics were included.

Randomized, controlled trials and large (ie, more than 100 subjects) prospective cohort studies were included if they provided relevant information for a specific topic. Other study designs, such as case-control and modeling studies, were included when evidence was lacking or when they demonstrated new findings. Studies conducted in settings

applicable to the United States were particularly targeted. Findings relevant to population subgroups were specifically included when available. The focus of each review was on gaps identified in the 2011 IOM recommendations and any new evidence that could change or additionally inform the recommendations where evidence was not previously available. Selection criteria specific to each topic were developed to address issues specific to the WPSI.

Applicability is defined as the extent to which the effects observed in published studies are likely to reflect the expected results when an intervention is applied to the population of interest under "real-world" conditions.[12] It is an indicator of the extent to which research included in a review might be useful for informing clinical decisions in specific situations. Factors important for understanding the applicability of studies were considered, including differences in the interventions and comparators, populations, and settings.

No new or revised statistical meta-analyses were conducted. Studies were qualitatively synthesized according to interventions, populations, and outcomes measured. Studies and their findings were summarized in a narrative, descriptive format to provide an overview of the new evidence for each topic.

Establishing the Strength of Recommendations

As recommendations were developed by the MSC members, EPC investigators created evidence maps to provide a descriptive summary of supporting evidence for each component of the recommendation. Evidence maps for the WPSI updates were adapted from methods of the 2011 IOM panel. Current systematic reviews and research studies, epidemiologic data, USPSTF and AAP Bright Futures recommendations, clinical best practices, and other relevant sources were included. In addition, like the 2011 IOM Panel, the MSC considered multiple levels of evidence when developing recommendations and permitted recommendations to be based on varying levels of evidence, expert consensus, or standard best practices.

Reaching Consensus Around Evidence-Based Recommendations

A summary of the evidence for each topic was presented to the full MSC and served as the basis for recommendation development. A subcommittee of the MSC considered the evidence in depth and formulated a draft recommendation. Draft recommendations were presented and discussed by the full MSC and revised as needed. To build consensus, the foundation for the recommendation must be transparent and clearly articulated to provide an understanding of the volume and quality of the supporting evidence and an accurate assessment of the benefits and harms for each topic. Although the recommendations were based on the evidence reviewed, some components lacked sufficient evidence. In such cases, recommendations were supplemented with the expert consensus of the over 20 multidisciplinary women's health experts of the MSC, taking into consideration standards of best practice, risk-benefit analysis, and expert opinion.

Once the MSC discussion concluded, the proposed draft recommendation was put forth for a vote by the full MSC. Votes were taken by hand, without secret ballots, and recorded as "approve," "do not approve," or "abstain." The MSC is required to reach at least 75% agreement from voting members for the recommendation

to be adopted. If 75% agreement was not reached after one round of voting, further discussion was permitted, and an email vote outside of the meeting was permitted if additional time was needed. Although not required for these first nine topics, if after discussion and a second round of voting 75% agreement was not reached, the recommendation would have been returned to the subcommittee for reconsideration, at the discretion of the MSC chair. The subcommittee would then determine whether the recommendation should be reconsidered after a reevaluation of the supporting evidence and information. These steps will be considered for future topics that require additional discussion to reach consensus agreement.

Inviting Public Comment and External Review

A draft of each recommendation was released online for public comment for a one-month period, based on a process mirroring that of AAP Bright Futures. Input during the public comment period was solicited from all interested organizations and individuals. Commenters represented a broad array of perspectives and expertise on women's preventive health care. All comments were reviewed and summarized by project staff and provided to the MSC. Comments were reviewed and addressed by the corresponding subcommittee or full MSC as needed. For future recommendations, a process for in-person public comment addressed directly to the MSC will be considered as time permits.

Continual Updating of Recommendations

Recommendations will be reviewed for currency and accuracy at least every 24 months after submission to and adoption by HRSA. For each recommendation, the literature search dates, along with the proposed date for review, will be reported. The EPC and ACOG project staff will scan the horizon continuously to identify emerging evidence, assess current validity of each recommendation, and identify or clarify associated benefits and harms. Recommendations identified for updates will be included on the list of next topics to be addressed by the MSC.

WPSI RECOMMENDATIONS

Each WPSI recommendation is made up of clinical considerations and implementation considerations. The clinical considerations describe the overarching clinical recommendation based on the best available evidence and clinical expertise. The implementation considerations address clinical and practical aspects of applying the recommendation for patient care.

The WPSI recommendations recognize that decisions about preventive health services should be based on a periodic shared decision-making process involving the woman and her health care provider. The shared decision-making process assists women in making an informed decision and includes, but is not limited to, a discussion about benefits and harms, an assessment of the woman's values and preferences, and consideration of factors such as life expectancy, comorbidities, and health status.

ADDITIONAL CONSIDERATIONS

These WPSI recommendations are the culmination of a multidisciplinary effort to identify needed services and to improve the uptake of women's preventive services that will contribute to overall improved health. These recommendations take into account the most current evidence available, yet research gaps remain. In particular, more research is needed to address the preventive health needs of racial and ethnic minority women and underserved populations. For example, current evidence does not sufficiently address screening strategies to eliminate disparities in breast cancer detection, treatment, and mortality for minority women.

Although access to preventive health services has expanded, coverage of important preventive services differs across payers and may be incomplete. The implementation considerations included in each WPSI

recommendation not only address practical aspects of implementation but also offer guidance to payers about what is included in preventive services based on the best interpretation of evidence.

The process established by the WPSI for developing and updating recommendations seeks to address the shortcomings noted by the IOM by ensuring transparency, mitigating conflicts of interest, incorporating multiple perspectives, and relying on evidence. However, the WPSI has opportunities to improve:

Needs of Minority Women: Some have been critical of the WPSI for the extent to which the needs of minority women were considered. As part of the commitment to ensuring broad representation of providers, patient representative organizations, and consumers, the MSC included individuals from ethnic and minority groups. Despite the diversity of perspective, the WPSI acknowledges the lack of sufficient scientific evidence for tailoring many of the recommendations to specific needs of racial and ethnic minority women. The WPSI recognizes the importance of addressing the needs of these often underserved women and will continue to seek relevant information to develop recommendations that are tailored to diverse populations. As the WPSI progresses in years 2–5, it will work with HRSA to determine high-priority new topics based on the availability of evidence, the identified gaps in preventive services for women, and the likelihood of impact on a broad population of women.

Public Participation: Although highly desirable, the timeframe for the WPSI's first year did not allow for in-person public input into topic refinement or recommendations. The WPSI will work with HRSA to ensure that staff can plan and promote public comment opportunities with broad and meaningful outreach. These opportunities are vital to ensure transparency in the guideline development process and to give the public an opportunity to voice issues they would like the MSC to consider when developing new or updating recommendations. For future recommendations, a process for in-person public comment addressed directly to the MSC will be incorporated as time permits.

NEXT STEPS

With the WPSI recommendations approved by HRSA, stakeholders with broad national networks for outreach and proven success in reaching their targeted audiences will be convened. The second standing committee, the Implementation Steering Committee, will be convened in year 2 by engaging supporting partners from the MSC and other groups active in community and provider outreach and patient awareness activities with capabilities to reach a wide audience of women, including adolescents; reproductive-aged, mature, and older women; and those from underserved communities. The Implementation Steering Committee will work to promote the recommendations from the MSC and increase consumer awareness of the need for and benefits of preventive care.

The final WPSI preventive services recommendations are presented in a single website, WomensPreventiveHealth.org, that is easily accessible by both health care providers and their patients. All messaging surrounding the WPSI's outreach will involve directing patients and providers to the website for consistent, up-to-date information, interactive tools, and resources for provider recommendations and patient preventive care awareness.

CONCLUSION

The WPSI is a unique collaboration of experts and advocates representing national organizations whose constituencies reflect the full spectrum of the health and well-being of adolescents and adult women in the United States. These recommendations are the result of a rigorous, transparent, and well-structured process informed by clinical and patient perspectives. They are based on the best available current evidence. The MSC members dedicated numerous hours to discussion, debate, evidence review, and draft revisions to develop recommendations that represent a consensus among clinical experts in women's health, patient and consumer health advocates, and public health policymakers. As such, they represent the kind of reliable and trustworthy recommendations the IOM called for in its 2011 report, *Clinical Practice Guidelines We Can Trust*. Implementing uniform recommendations such as these for preventive services will provide clarity for clinicians and their patients. As a result, more women will get the services they need and avoid unnecessary services as well. As the IOM stated, "Trustworthy guidelines hold the promise of improving health care quality and outcomes."[1] At the same time, ensuring that more women have access to recommended preventive health services will improve the health of women, their families, and their communities.

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Final Recommendations: Preventive Services for Women
Women's Preventive Services Initiative Multidisciplinary Steering Committee*
December 2016

Breast Cancer Screening for Average-Risk Women

Clinical Recommendations

The Women's Preventive Services Initiative recommends that average-risk women initiate mammography screening no earlier than age 40 and no later than age 50. Screening mammography should occur at least biennially and as frequently as annually. Screening should continue through at least age 74 and age alone should not be the basis to discontinue screening.

These screening recommendations are for women at average risk of breast cancer. Women at increased risk should also undergo periodic mammography screening, however, recommendations for additional services are beyond the scope of this recommendation.

Implementation Considerations

The Women's Preventive Services Initiative recommends, as a preventive service, that women initiate mammography screening no earlier than age 40 and no later than age 50 and continue through at least age 74. Screening mammography should occur at least biennially and as frequently as annually.

Decisions regarding when to initiate screening, how often to screen, and when to stop screening should be based on a periodic shared decision-making process involving the woman and her health care provider. The shared decision-making process assists women in making an informed decision and includes, but is not limited to, a discussion about the benefits and harms of screening, an assessment of the woman's values and preferences, and consideration of factors such as life expectancy, comorbidities, and health status.

Breastfeeding Services and Supplies

Clinical Recommendations

The Women's Preventive Services Initiative recommends comprehensive lactation support services (including counseling, education, and breastfeeding equipment and supplies) during the antenatal, perinatal, and postpartum periods to ensure the successful initiation and maintenance of breastfeeding.

Implementation Considerations

Lactation support services include counseling, education, and breastfeeding equipment and supplies. A lactation care provider should deliver lactation support and provide services across the antenatal, perinatal, and postpartum periods to ensure successful preparation, initiation, and continuation of breastfeeding. Lactation care providers include, but are not limited to, lactation consultants, breastfeeding counselors, certified

midwives, certified nurse-midwives, certified professional midwives, nurses, advanced practice providers (eg, physician assistants and nurse practitioners), and physicians. Breastfeeding equipment and supplies, as agreed upon by the woman and her lactation care provider, include, but are not limited to, double electric breast pumps (including pump parts and maintenance) and breast milk storage supplies. Access to double electric pumps should be based on optimization of breastfeeding, and not predicated on prior failure of a manual pump.

Screening for Cervical Cancer

Clinical Recommendations

The Women's Preventive Services Initiative recommends cervical cancer screening for average-risk women aged 21 to 65 years. For women aged 21 to 29 years, the Women's Preventive Services Initiative recommends cervical cancer screening using cervical cytology (Pap test) every 3 years. Cotesting with cytology and human papillomavirus testing is not recommended for women younger than 30 years. Women aged 30 to 65 years should be screened with cytology and human papillomavirus testing every 5 years or cytology alone every 3 years. Women who are at average risk should not be screened more than once every 3 years.

Implementation Considerations

The Women's Preventive Services Initiative recommends as a preventive service, cervical cancer screening for average-risk women aged 21 to 65 years. For average-risk women aged 30 to 65 years, informed shared decision-making between the patient and her clinician regarding the preferred screening strategy is recommended.

Women who have received the human papillomavirus vaccine should be screened according to the same guidelines as women who have not received the vaccine.

These recommendations are for routine screening in average-risk women and do not apply to women infected with human immunodeficiency virus, women who are immunocompromised because of another etiology (such as those who have received solid organ transplantation), women exposed to diethylstilbestrol in utero, or women treated for cervical intraepithelial neoplasia grade 2 or higher within the past 20 years. Screening strategies for high-risk women are outside the scope of these recommendations.

Cervical cancer screening is not recommended for women younger than 21 years or those older than 65 years who have had adequate prior screening and are not otherwise at high risk for cervical cancer. Adequate prior negative screening is defined as documentation (or a reliable patient report) of three consecutive negative cytology results or two consecutive negative cotest results within the previous 10 years with the most recent test within the past 5 years. Cervical cancer screening is also not recommended for women who have had a hysterectomy with removal of the cervix and who do not have a history of a high-grade precancerous lesions (eg, cervical intraepithelial neoplasia grade 2 or grade 3 or cervical cancer within the past 20 years).

Breastfeeding Services and Supplies

Clinical Recommendations

The Women's Preventive Services Initiative recommends comprehensive lactation support services (including counseling, education, and breastfeeding equipment and supplies) during the antenatal, perinatal, and postpartum periods to ensure the successful initiation and maintenance of breastfeeding.

Implementation Considerations

Lactation support services include counseling, education, and breastfeeding equipment and supplies. A lactation care provider should deliver lactation support and provide services across the antenatal, perinatal, and postpartum periods to ensure successful preparation, initiation, and continuation of breastfeeding. Lactation care providers include, but are not limited to, lactation consultants, breastfeeding counselors, certified midwives, certified nurse-midwives, certified professional midwives, nurses, advanced practice providers (e.g., physician assistants and nurse practitioners), and physicians. Breastfeeding equipment and supplies, as agreed upon by the woman and her lactation care provider, include, but are not limited to, double electric breast pumps (including pump parts and maintenance) and breast milk storage supplies. Access to double electric pumps should be based on optimization of breastfeeding, and not predicated on prior failure of a manual pump.

EVIDENCE MAP

Comprehensive lactation support services, including counseling, education, and breastfeeding equipment and supplies.		
Systematic Reviews	**Additional Studies**	**USPSTF[1]**
2016 USPSTF review of 52 studies reported increased rates of any and exclusive breastfeeding at <3 months and at 3-6 months, and exclusive breastfeeding at 6 months for women enrolled in individual-level breastfeeding interventions versus usual care.[2]	None	For pregnant women, new mothers, and their children, the USPSTF recommends providing interventions during pregnancy and after birth to support breastfeeding (Level B; 2016)
A lactation care provider should deliver lactation support and provide services across the antenatal, perinatal, and postpartum periods to ensure successful preparation, initiation, and continuation of breastfeeding.		
Systematic Reviews	**Additional Studies**	**USPSTF[1]**
2016 USPSTF review of studies evaluating the timing of breastfeeding interventions (intervention during only one period [prenatal, perinatal, or postpartum] vs. across multiple periods). Results indicated increased breastfeeding when interventions occurred across multiple periods.	Two good-quality trials of effective breast feeding interventions in the U.S. included 5 in-person visits with a lactation consultant (two during prenatal clinic visits, one in the hospital, and one or two voluntary postpartum home visits).[3] These were supplemented by phone calls and EHR alerts.	For pregnant women, new mothers, and their children, the USPSTF recommends providing interventions during pregnancy and after birth to support breastfeeding (Level B; 2016)
Efficiency of double electric pumps.		
Systematic Reviews	**Additional Studies**	**USPSTF[1]**
Compared to other methods, double electric breast pumps more closely mimic the sucking actions of an infant, result in a greater volume of expressed milk, and come the closest to matching the milk removal efficiency of a healthy infant (85% of milk removed in 15 minutes versus 80% of milk removed in 5 minutes).[4]	None	Not addressed

Abbreviations: EHR=electronic health record; USPSTF=U.S. Preventive Services Task Force

SUMMARY OF EVIDENCE

Introduction

Breastfeeding is the process of feeding infants with human milk from a woman's breast, either directly from the breast or by expressing (pumping) the milk from the breast and bottle-feeding.[5] Breastfeeding counseling and support includes maternity care practices, such as discussions with healthcare professionals about breastfeeding; structured breastfeeding education, such as information and resources provided during the prenatal and intrapartum periods; employee benefits and services, such as designated private space and time for breastfeeding or expressing milk (now included under a provision of the ACA);[6] peer support, such as individual counseling and mother-to-mother support groups; professional support, such as lactation consultations; and marketing initiatives.[7]

Current Recommendations and Coverage of Service

The gap in services provided under the provisions of the Patient Protection and Affordable Health Care Act of 2010 previously identified by the Institute of Medicine (IOM) Committee was that comprehensive prenatal and postnatal lactation support, counseling, and supplies were not included.[8] Health insurance plans are now required to provide breastfeeding support, counseling, and equipment for the duration of breastfeeding including the purchase or rental cost of breast pumps (**Table 1**).[9] The IOM recommendation includes an explicit description of a more comprehensive set of services than the U.S. Preventive Services Task Force (USPSTF).

Table 1. Summary of Recommendations Currently Covered by the Affordable Care Act

IOM Committee[8]	Comprehensive lactation support and counseling and costs of renting breastfeeding equipment. A trained provider should provide counseling services to all pregnant women and to those in the postpartum period to ensure the successful initiation and duration of breastfeeding.
USPSTF[10]	Provide interventions during pregnancy and after birth to support breastfeeding (Level B; 2016). Interventions may include more than one component and be delivered over prenatal, perinatal, and postpartum periods.

Abbreviations: IOM=Institute of Medicine; USPSTF=U.S. Preventive Services Task Force

Background

Breastfeeding is associated with several health benefits for infants including reduced risk of acute otitis media, non-specific gastroenteritis, severe lower respiratory tract infections, atopic dermatitis, asthma (young children), obesity, type 1 and 2 diabetes, childhood leukemia, sudden infant death syndrome (SIDS), and necrotizing enterocolitis.[11] Breastfeeding is not recommended in specific situations involving mothers who have been infected with human immunodeficiency virus (HIV) or human T-cell lymphotropic virus type I or type II; who are prescribed cancer chemotherapy agents, taking antiretroviral therapy or drugs, undergoing radiation therapies; using or dependent upon illicit drugs; or have untreated, active tuberculosis.[12]

The Surgeon General's call to action to support breastfeeding identified several barriers to breastfeeding in the United States.[13] These include lack of knowledge, social norms, poor family and social support, embarrassment, lactation problems, employment and child care issues, and lack of access to health services.

The Centers for Disease Control and Prevention (CDC) reported in 2012 that 80.0% of newborn infants started breastfeeding at birth, 51.4% were still breastfeeding at 6 months, and 29.2% at 12 months; 43.3% were exclusively breastfeeding at 3 months and 21.9% exclusively breastfeeding at 6 months.[14] These rates are close to the goals set by Healthy People 2020[15] (**Table 2**).

Breastfeeding rates vary greatly and are higher with increasing maternal age, education, and income, and among mothers who do not receive supplemental nutrition assistance (WIC).[16] Rates differ across racial/ethnic groups, with 83.2% of Asian/Pacific Islanders reporting initiating breastfeeding in 2012, 83.0% of whites, 82.4% of Hispanics, 71.5% of American Indian/Alaska Natives, and 66.4% of blacks. These differences are most apparent in the southern United States, with differences between whites and blacks ranging from 9% in Florida to 32 in Alabama.

Table 2. Rates and Goals of Breastfeeding Practices in the United States

Breastfeeding practice	Prevalence in 2012[14]	Healthy People 2020 goals[15]
Initiation	80.0%	81.9%
At 6 months	51.4%	60.6%
At 12 months	29.2%	34.1%
Exclusively at 3 months	43.3%	46.2%
Exclusively at 6 months	21.9%	25.5%

The American Congress of Obstetricians and Gynecologists (ACOG), the American Academy of Family Physicians (AAFP), the American Academy of Pediatrics (AAP), the American College of Nurse-Midwives (ACNM), and the World Health Organization (WHO) all recommend exclusive breastfeeding for the first 6 months, with continued breastfeeding along with appropriate complementary foods up to age 2 years or beyond. Most groups emphasize breastfeeding through the first year of life and then continuing as long as mutually desired (**Table 3**).

Table 3. Recommendations of Professional Organizations

Organization	Recommendation
American Academy of Family Physicians (AAFP)[17,18]	All babies, with rare exceptions, be breastfed and/or receive expressed human milk exclusively for the first 6 months of life. Breastfeeding should continue with the addition of complementary foods throughout the second half of the first year.
American Congress of Obstetricians and Gynecologists (ACOG)[19]	Exclusive breastfeeding is recommended for the first 6 months of a baby's life. Breastfeeding should continue up to the baby's first birthday as new foods are introduced. Continue breastfeeding after the baby's first birthday for as long as mother and baby would like.
American Academy of Pediatricians (AAP)[20]	Exclusive breastfeeding for about 6 months, followed by continued breastfeeding as complementary foods are introduced, with continuation of breastfeeding for 1 year or longer as mutually desired by mother and infant. Medical contraindications to breastfeeding are rare.
American College of Nurse-Midwives (ACNM)[21]	Exclusive breastfeeding for the first 6 months provides complete nutrition for growth and development, and ideally breastfeeding should continue throughout the first year of life.
American College of Nurse-Midwives (ACNM)[21]	Exclusive breastfeeding for the first 6 months provides complete nutrition for growth and development, and ideally breastfeeding should continue throughout the first year of life.
The World Health Organization (WHO)[22]	Exclusive breastfeeding is recommended up to 6 months of age, with continued breastfeeding along with appropriate complementary foods up to 2 years of age or beyond.

Recommendations provide additional guidance on how to promote and support breastfeeding. Several recommendations suggest the adoption of the WHO/The United Nations Children's Emergency Fund (UNICEF) Ten Steps to Successful Breastfeeding (**Table 4**).[23]

Table 4. The 10 Steps to Successful Breastfeeding[23]

1. Have a written breastfeeding policy that is routinely communicated to all health care staff.
2. Train all health care staff in the skills necessary to implement this policy.
3. Inform all pregnant women about the benefits and management of breastfeeding.
4. Help mothers initiate breastfeeding within one hour of birth.
5. Show mothers how to breastfeed and how to maintain lactation, even if they are separated from their infants.
6. Give infants no food or drink other than breast-milk, unless medically indicated.
7. Practice rooming in, allow mothers and infants to remain together 24 hours a day.
8. Encourage breastfeeding on demand.
9. Give no pacifiers or artificial nipples to breastfeeding infants.
10. Foster the establishment of breastfeeding support groups and refer mothers to them on discharge from the hospital or birth center.

UPDATE OF EVIDENCE

Interventions to Support Breastfeeding Initiation and Duration

A systematic review[2,24] was recently published to support the 2016 USPSTF recommendation[1] on breastfeeding. The review is an update of a prior review published in 2008, and includes new studies and re-evaluation of studies included in the prior review.

The review includes 52 studies assessing the effectiveness of breastfeeding support interventions in increasing initiation of breastfeeding and prolonging breastfeeding, either exclusively or with supplementation. The review included only randomized controlled trials (RCTs) for individual-level interventions, and controlled before and after studies and prospective cohort studies for system-level interventions. Studies were conducted in either the prenatal, peripartum, or postpartum phase, or a combination of phases.

Of the 52 studies, 43 provided data about individual level interventions,[3,25-71] while the other nine studies provided data on system level interventions.[72-80] Individual-level interventions include professional support (one-to-one support during hospital stay or outpatient visits, home visits, or telephone support from health professionals); peer support (counseling or social support from peers or lay persons); and formal or structured education (structured education sessions or classes directed at mothers or other family members, typically provided in group sessions). System-level interventions include policies, programs, and staff training (Baby-Friendly Hospital Initiative [BFHI], implementation of a new policy or protocol, or training of health professionals); and other maternity care practices (encouragement of skin-to-skin contact, rooming-in, restricted pacifier use, or distribution of breast pumps).

Individual-Level Interventions

Meta-analyses of trials of individual-level interventions to promote and support breastfeeding reported in the 2016 USPSTF review indicate statistically significantly higher rates of any breastfeeding at less than 3 months (RR 1.07; 95% CI, 1.03 to 1.11; 26 trials) and at 3 to 6 months (RR 1.11; 95% CI, 1.04 to 1.18; 23 trials), but not on initiation of breastfeeding or breastfeeding at 6 months (Table 5).[2] The review also reported statistically significantly higher rates of exclusive breastfeeding at less than 3 months (RR 1.21; 95% CI, 1.11 to 1.33; 22 trials), 3 to 6 months (RR 1.20; 95% CI, 1.05 to 1.38; 18 trials), and at 6 months (RR 1.20; 95% CI, 1.05 to 1.38; 17 trials).

Table 5. Summary of Results of Meta-analysis of Trials of Individual-level Interventions to Promote and Support Breastfeeding[2]

Breastfeeding practice	Time Point (months)	Studies, n	Mothers, n	RR (95% CI)	I^2 (%)
Any	Initiation	14	9,428	1.00 (0.99 to 1.02)	22.8
	<3	26	11,588	1.07 (1.03 to 1.11)	72.0
	3 to <6	23	8,942	1.11 (1.04 to 1.18)	46.5
	6	20	9,715	1.07 (0.98 to 1.16)	57.5
Exclusive	<3	22	8,246	1.21 (1.11 to 1.33)	52.4
	3 to <6	18	7,027	1.20 (1.05 to 1.38)	44.6
	6	17	7,690	1.16 (1.02 to 1.32)	14.3

Number of Individual-level Intervention Sessions. The USPSTF review did not specifically assess the optimal number of sessions required for successful breastfeeding.[2] Results from individual studies are mixed, although higher numbers of professional intervention sessions generally increased breastfeeding rates at less than 3 months, 3 to 6 months, and 6 months. For example, among seven studies of single-session interventions, none showed statistically significant effects on breastfeeding rates at less than 3 months. In comparison, in six studies of 2 to 10 intervention sessions, the intervention was consistently associated with higher rates of breastfeeding, although only three studies reported statistically significant differences. Results were similar for 10 or more intervention sessions, based on 3 studies.

Providing breastfeeding interventions during the prenatal, peri-, and postpartum time points was more effective than interventions provided at one or two time points. Of 10 studies of interventions provided at all three time points, all found higher rates or breastfeeding relative to control at <3, 3 to <6 and 6 month measures, although for three of these studies the risk estimate was not statistically significant.

A best evidence approach that examines the most effective and most relevant studies provides an estimate of the number of intervention visits needed for effective breastfeeding in the United States. Of the eight studies conducted in the U.S.,[3,27,31,48,60,67] only three studies reported statistically significantly increased breastfeeding rates at any of the follow-up time points,[3,27] and one[48] reported rates with borderline statistical significance at one time point (**Table 6**). The Bonuck 2014 studies (two trials reported in one publication) are among the largest studies, and the only U.S. studies with statistically significant results that met criteria for good study quality. Results showed consistently increased rates of breastfeeding at less than 3, 3 to 6, and 6 month follow-up times. Although the interventions in both trials required 20 sessions, only 5 of these sessions were in-person visits with a lactation consultant (two during prenatal clinic visits, one in the hospital, and one or two voluntary postpartum home visits). The prenatal visits averaged 1 hour, hospital visits 40 to 50 minutes, and postpartum

contacts greater than 1 hour. The other sessions included prompts in the EMR at prenatal visits or regular phone calls postpartum. In comparison, the fair-quality Bonuck 2006 trial included 4 intervention sessions, and achieved statistically significant rates at <3 and 3 to 6 months, but not at 6 months follow-up.

Table 6. U.S. Based Studies of Individual-level Interventions to Promote and Support Breastfeeding – Effectiveness According to Number of Sessions[2]

Author, year N; Quality	Number of sessions	Timing of intervention	Intervention type	Risk estimate (RR; 95% CI) Intervention vs. Control
Outcome: any breastfeeding, <3 months				
Bonuck 2014a[3] N=666; *Good*	20	Pre; Peri; Post	Lactation support and brief education	1.26 (1.03 to 1.54)
Bonuck 2014b[3] N=275; *Good*	20	Pre; Peri; Post	Lactation support and brief education	1.23 (1.08 to 1.40)
Bonuck 2006[27] N=382; *Fair*	4	Pre; Peri; Post	Lactation support	1.32 (1.10 to 1.57)
Pollard 2011[67] N=86; *Good*	4	Peri; Post	Self-monitoring	1.21 (0.89 to 1.64)
Paul 2012[48] N=1154; *Fair*	2	Peri	Home visits	1.09 (1.00 to 1.18)
Hopkinson 2009[60] N=552; *Good*	1	Post	Lactation support	0.99 (0.93 to 1.05)
Outcome: any breastfeeding, 3 to 6 months				
Edwards 2013[31] N=248; *Fair*	23	Pre; Peri; Post	Lactation support	1.88 (0.65 to 1.20)
Bonuck 2014a[3] N=666; *Good*	20	Pre; Peri; Post	Lactation support and brief education	1.49 (1.09 to 2.03)
Bonuck 2014b[3] N=275; *Good*	20	Pre; Peri; Post	Lactation support and brief education	1.37 (1.07 to 1.73)
Pollard 2011[67] N=86; *Good*	4	Peri; Post	Self-monitoring	1.11 (0.65 to 1.90)
Outcome: any breastfeeding, 6 months				
Bonuck 2014a[3] N=666; *Good*	20	Pre; Peri; Post	Lactation support and brief education	1.28 (0.85 to 1.94)
Bonuck 2014b[3] N=275; *Good*	20	Pre; Peri; Post	Lactation support and brief education	1.48 (1.01 to 2.17)
Bonuck 2006[27] N=382; *Fair*	4	Pre; Peri; Post	Lactation support	1.34 (0.98 to 1.84)
Pollard 2011[67] N=86; *Good*	4	Peri; Post	Self-monitoring	1.12 (0.62 to 2.03)

Subgroup Differences. Seven trials provided direct comparisons of the effect of the intervention based on characteristics of the mother (age, education, insurance status, country of origin, primary language spoken, delivery type, parity, prior breastfeeding experience, and breastfeeding intentions). Maternal country of origin and language spoken were the only significant findings. Breastfeeding rates were lower among women in the U.S.-born control groups than in the U.S.-born intervention group and all foreign-born participants[28] at 13 and 52 weeks; and Spanish-speaking women at 4, 12, and 26 weeks, but not English-speaking women at 4 weeks.[68]

Adolescents and Young Adults. Four trials[31,44,49,69] were limited to adolescents or young adults. The three U.S. trials reported statistically significant differences between intervention and usual care groups, while the trial conducted in Australia showed no effect.[49] A U.S. trial[81] provided mothers with support by a community doula during the prenatal, peripartum, and postpartum phases. Mothers in the intervention group were more likely to initiate breastfeeding than the usual care group (63.9% vs. 49.6%; p=0.02) and to breastfeed for at least 6 weeks (28.7% vs. 16.8%; p=0.04), but there was no difference in breastfeeding between groups at 16 weeks (8.3% vs. 4.4%). Another U.S. trial[69] of mothers receiving group prenatal education and given electric breast pumps beginning in the second trimester and through postpartum reported higher rates of breastfeeding initiation compared with usual care (79% vs. 63%) and longer median duration of any breastfeeding (177 days vs. 61 days). The third U.S. trial[44] provided mothers with postpartum peer telephone support, and reported statistically significant longer durations of exclusive breastfeeding than those receiving usual care (median 35 days vs. 10 days; p=0.004).

System-Level Interventions

Three good-quality studies[74,79,80] reported the effects of hospital policies or BFHI accreditation on breastfeeding rates. One study found that women with lower education (≤12 years) who delivered at a BFHI accredited hospital had higher rates of exclusive breastfeeding at 4 weeks or more by 4.5 percentage points compared with women who delivered at non-BFHI accredited hospitals (effect estimate 0.045; 95% CI, 0.01 to 0.08; p=0.02).[79] No effects were found in other studies.

Three fair-quality trials[72,73,78] of the effects of maintaining mother and baby contact following delivery reported mixed results with only one trial demonstrating an effect. The trial included women scheduled for cesarean section deliveries who were randomized to either a new protocol for minimizing maternal-infant separation following birth or usual peripartum care (infants were removed immediately from the operating room and transferred to the obstetric recovery room with brief or no physical contact with their mother).[78] Women in the intervention group reported higher rates of breastfeeding at hospital discharge (76.0% vs. 52.0%) and at 4 weeks (72.7% vs. 33.3%) compared with usual care (unadjusted RR 2.18; 95% CI, 1.17 to 4.06). Three good-quality trials[75-77] reported no differences in breastfeeding rates between mothers instructed to delay or restrict pacifier use and those not given these instructions.

Efficiency of Different Breast Pumps

Over 80% of mothers need to express breast milk during the first 4 months postpartum.[82] Breast milk can be expressed by hand or through the use of a breast pump. Breast pumps fall into three general categories: manual, battery-operated, and electric. In addition, breast pumps can be single (expressing milk from one breast at a time) or double (expressing milk from both breasts simultaneously) action pumps. Manual and battery-operated breast pumps tend to be single action while electric pumps can be either single or double action.[83]

Reviews of breast milk expression methods have found little direct evidence on which type of breast pump is ideal, and have concluded that the best method of milk expression is likely dependent on individual factors.[84,85] For example, a recent Cochrane review of breast milk expression methods found few differences between breast pump type and maternal satisfaction, adverse events (including milk contamination and breast pain or damage), or volume of milk expressed.[85] The milk expressed by both hand expression and electric pumps had a higher protein content than that expressed by battery-operated pumps, but there were no differences between pump type and other nutrient levels. Only one study included in the review compared electric and manual pumps and the effect on time spent pumping, finding that woman using an electric breast pump spent 20 minutes less per day pumping milk compared to manual pump users.[86] The studies included in the review were heterogeneous in terms of population (both mothers and babies) and the review ultimately concluded that the best method of breast milk expression may be dependent on individual circumstances.

A more recent review evaluated aspects of different methods of breast milk expression.[4] Using the human infant as the "gold standard" for milk expression, electric breast pumps more closely mimicked the sucking actions of an infant and were more efficient at expressing milk when compared with hand expression. The use of double electric breast pumps, particularly in situations where the breast pump is acting as a replacement for an infant unable to breastfeed, resulted in a greater volume of expressed milk.[4] In addition to volume of breast milk expressed, double electric breast pumps come the closest to matching the milk removal efficiency of a healthy infant (85% of milk removed in 15 minutes versus 80% of milk removed in 5 minutes).[4] The efficiency of milk expression is an important factor in breast pump choice for working mothers who may have limited time to pump or mothers of infants unable to breastfeed (e.g. neonatal intensive care unit infants) who must pump many times a day.

Related to breast pump volume and efficiency, is the mother's level of dependence on milk expression. For women who are completely dependent on a breast pump to regulate their lactation level, the review concluded that hospital-grade electric pumps are the best choice because of their efficiency and convenience.[4]

For mothers unable to breastfeed during the first days postpartum, electric breast pumps are also important in order to avoid subsequent lactation failure, and their use remains important once lactation has been established.[4] For mothers of healthy breastfeeding infants with established lactation, who are partially or minimally dependent on breast pumps, convenience may be the most important factor in pump choice. Electric pumps may be the best choice for these women.

Harms of Interventions to Promote or Support Breastfeeding

Two trials[29,33] reported harms related to breastfeeding. In one trial,[29] mothers in the intervention group expressed feelings of anxiety, decreased confidence, or concerns about confidentiality, while the other trial[33] reported no statistically significant differences between the intervention and usual care groups on the State-Trait Anxiety Inventory at 2 weeks.

Relevant Studies Published Since the USPSTF Draft Systematic Review

Other Reviews

A recent systematic review included observational studies as well as trials of interventions to improve breastfeeding outcomes (initiation of breastfeeding, exclusive breastfeeding, continued breastfeeding, and any breastfeeding) and reported similar pooled results as the USPSTF report (**Table 7**).[87]

Table 7. Meta-analysis of Trials and Observational Studies[87]

Breastfeeding practice	Studies, n	OR (95% CI)	I^2
Initiation	49	1.25 (1.19 to 1.32)	90.6
Exclusive up to 6 months	130	1.44 (1.38 to 1.51)	91.0
Continued past 6 months	18	1.61 (1.17 to 2.20)	92.0
Any breastfeeding	118	1.30 (1.23 to 1.37)	92.1

Abbreviations: CI=confidence interval; OR=odds ratio

Ongoing Studies

Ten randomized controlled trials of interventions to promote or support breastfeeding initiation and prolong breastfeeding are currently in progress.2 Three trials include telephone support; two focus on earlier versus later (usual care) timing of the intervention; one assesses lay person support; one targets low-income mothers; and another targets populations at risk for childhood obesity. Two Cochrane systematic reviews of interventions for promoting and supporting breastfeeding among overweight or obese women[88] or among women with multiple pregnancies[89] are currently in progress.

CONCLUSIONS

Breastfeeding is associated with health benefits, and clinical guidelines encourage women to breastfeed exclusively for 6 months and breastfeed with solid food supplementation up to 1 year. However, multiple barriers discourage breastfeeding including lack of knowledge, inadequate support, lactation problems, constraints of employment, and limited access to appropriate health services and lactation supplies. Randomized controlled trials of individual-level interventions administered by professionals, peers, or lay persons, provided during prenatal, peripartum, or postpartum phases indicate higher rates of breastfeeding initiation and duration than women not receiving interventions. This includes increased rates of any and exclusive breastfeeding at less than 3 months and at 3 to 6 months, and exclusive breastfeeding at 6 months.

Trials evaluating the timing of breastfeeding interventions (intervention during only one period [prenatal, perinatal, or postpartum] versus across multiple periods) indicate increased breastfeeding when interventions occurred across multiple periods. Two good-quality trials of effective breast feeding interventions in the United States included five in-person visits with a lactation consultant (two during prenatal clinic visits, one in the hospital, and one or two voluntary postpartum home visits). These were supplemented by phone calls and alerts in the electronic health record. A review of breast pump methods indicates that double electric breast pumps more closely mimic the sucking actions of an infant, result in a greater volume of expressed milk, and come the closest to matching the milk removal efficiency of a healthy infant.

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Women's Preventive Services Initiative

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EXHIBIT 81

Code Chart

Summary UHC Service Codes re: Breastfeeding Support & Counseling (Well Examinations) and Breastfeeding Support, Supplies and Counseling

CDG Listed Codes Remaining After Eliminating Codes Listed in NP Policy, excluding codes re: breast pump equipment and supplies (*see* fn. 1 below)

HCPCS (*see* fn. 2 below)	**CMS Long Description**	**CMS Short Description**
G0402	Initial preventive physical examination; face-to-face visit, services limited to new beneficiary during the first 12 months of medicare enrollment	Initial preventive exam
G0438	Annual wellness visit; includes a personalized prevention plan of service (pps), initial visit	Ppps, initial visit
G0439	Annual wellness visit, includes a personalized prevention plan of service (pps), subsequent visit	Ppps, subseq visit
G0445	High intensity behavioral counseling to prevent sexually transmitted infection; face-to-face, individual, includes: education, skills training and guidance on how to change sexual behavior; performed semi-annually, 30 minutes	High inten beh couns std 30m
S0610	Annual gynecological examination, new patient	Annual gynecological examina
S0612	Annual gynecological examination, established patient	Annual gynecological examina
S0613	Annual gynecological examination; clinical breast examination without pelvic evaluation	Ann breast exam
S9443	Lactation classes, non-physician provider, per session	Lactation class

FOOTNOTES

(1)	**CDG Coding re: Breastfeeding Support & Counseling (Well Examinations); Breastfeeding Support, Supplies and Counseling** Effective Date(s): 02-15-2015 (H-1), 4-01-2015 (H-2), 07-01-2015 (H-3),09-01-2015 (H-4), 01-01-2016 (H-5)		Huckaby SJ Decl. (Dkt. 105), Exs. H-1 (Dkt. 105-1) through H-5 (105-5)
	CDG Codes Eliminated by NP Policy	**Remaining Codes**	
	Well Examinations: 99381-387, 99391-397, 99401-404, 99411-412, 99461	G0402, G0438, G0439, G0445, S0610, S0612, S0613	Ex. H-1 (Dkt. 105-1) at UHC_149646 Ex. H-2 (Dkt. 105-2) at UHC_149760 Ex. H-3 (Dkt. 105-3) at UHC_150146 Ex. H-4 (Dkt. 105-4) at UHC_150278 Ex. H-5 (Dkt. 105-5) at UHC_149510-511
	Breastfeeding Support, Supplies and Counseling: 99241-245, 99341-345, 99347-350	S9443	Ex. H-1 (Dkt. 105-1) at UHC_149674 Ex. H-2 (Dkt. 105-2) at UHC_149788 Ex. H-3 (Dkt. 105-3) at UHC_150178 Ex. H-4 (Dkt. 105-2) at UHC_150308
	NP Policy - Codes not applicable to Nonphysicians - 99201-99499		Huckaby Reply Decl. (Dkt. 119-1), Ex. M at ¶5, Ex. M-1 (Dkt. 119-2) at UHC_002636
(2)	CMS HCPCS 2016		
	https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS-Items/2016-Alpha-Numeric-HCPCS-File.html?DLPage=2&DLEntries=10&DLSort=0&DLSortDir=descending		last visited 1-18-2018

EXHIBIT 82

WPSI
Women's Preventive Services Initiative

The American College of Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

Women's Preventive Services Initiative
Draft Recommendations

These draft recommendations are posted for public comment from September 1st – 30th.

WPSI
Women's Preventive Services Initiative

The American College of Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

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The American College of Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

Women's Preventive Services Initiative
Draft Recommendations

Breast Cancer Screening for Average Risk Women

WPSI recommendation
WPSI recommends discussions between women in their 40s at average risk of breast cancer and their health care providers regarding potential benefits and harms of screening mammography (ACS, USPSTF, ACOG, ACR, NCCN, ACP). WPSI recommends screening mammography every 1 or 2 years for women at average risk, based on an informed decision-making process including discussion of the benefits and harms of annual and biennial screening, and incorporating patient values and preferences. Women at average risk of breast cancer who have not initiated screening in their 40s should begin screening mammography at age 50 and continue until at least age 75. Beyond age 75, the decision to discontinue screening mammography should be also based on a shared decision making process that includes the women's health status and longevity.

Clarification recommendations
Discussion about initiation and discontinuation of screening mammography should include an informed/shared decision making approach. The shared decision making process includes, but is not limited to, a discussion that communicates information about the risks and benefits of screening or not screening, elicits the woman's values and preferences, and assists the woman in making an informed decision.

Following the initial screen, the resulting sequence of follow-up imaging tests and interventions, including biopsies, necessary to complete the evaluation of breast cancer screening are also recommended.

A shared decision making process for when to discontinue screening takes into account factors such as life expectancy, comorbidities, health status, and a woman's willingness and ability to undergo additional testing (including biopsy and potential treatment), if indicated. WPSI recommends age alone should not be the basis to discontinue screening.

Implementation recommendations
Screening mammography for average risk women is recommended as a preventive service for women, beginning as early as age 40 and occurring as frequently as annually for some women. Ages to begin and end screening and intervals of screening (annual versus biennial) are based on individual considerations, although all women should be screened annually or biennially between ages 50 and 75 years. The resulting sequence of follow-up imaging tests and interventions, including biopsies, necessary to complete the evaluation of mammographic findings detected on screening is also recommended as an integral part of breast cancer screening.

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Breastfeeding Services and Supplies

WPSI Recommendation

WPSI recommends comprehensive lactation support, including counseling, education, and breastfeeding equipment and supplies. A lactation care provider should deliver lactation support and provide services for as long as determined by the woman and her health care providers. Services and equipment should be provided in the antenatal, perinatal, and postpartum periods to ensure the successful initiation and maintenance of breastfeeding.

Clarification Recommendation

Breastfeeding equipment includes, but is not limited to manual and double-electric pumps (including pump-parts and maintenance) and breast-milk storage supplies. Lactation care providers include, but are not limited to lactation consultants, breastfeeding counselors, certified midwives, certified nurse midwives, nurses, advanced practice providers (e.g. physician assistants and nurse practitioners), and physicians.

Implementation Recommendation

Lactation support services, including counseling and education by lactation care providers defined above, are recommended as a preventive service for women. Breastfeeding equipment and supplies, as agreed upon by a patient and lactation care provider, including, but not limited to double-electric breast pumps (including pump-parts and maintenance) and breast-milk storage supplies are recommended as a preventive service for women. WPSI recommends access to double-electric pumps not be predicated on prior failure of a manual pump or subject to preauthorization. Services and equipment should be provided in the antenatal, perinatal, and postpartum periods to ensure the successful initiation and maintenance of breastfeeding.

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Screening for Cervical Cancer

WPSI Recommendation

WPSI recommends cervical cancer screening for women aged 21 to 29 years using cervical cytology (Pap test) every 3 years. Co-testing with cytology and HPV testing is not recommended for women younger than 30 years. Women aged 30 to 65 years, should be screened with cytology and HPV testing every 5 years (preferred) or, if HPV testing is not available, cytology alone every 3 years (acceptable).

Cervical cancer screening is not recommended for women: younger than 21 years; older than 65 years who have had adequate prior screening and are not otherwise at high risk for cervical cancer; and who have had a hysterectomy with removal of the cervix and who do not have a history of a high-grade precancerous lesion (cervical intraepithelial neoplasia [CIN] grade 2 or grade 3, or cervical cancer within the past 20 years). Women who have received the HPV vaccine should be screened according to the same guidelines as women who have not been vaccinated.

Clarification Recommendation

These recommendations are for routine screening in average-risk women and do not apply to women infected with HIV, otherwise immunocompromised (such as those who have received solid organ transplants), exposed to diethylstilbestrol in utero, or treated for CIN 2 or higher within the past 20 years. These high-risk women may need more frequent screening. Adequate prior negative screening test results are defined as documentation or reliable patient report of three consecutive negative cytology results or two consecutive negative co-test results within the previous 10 years, with the most recent test performed within the past 5 years. Women who are average risk should not be screened more often than every three years. In appropriately counseled women 25 years and older, FDA-approved primary HPV screening tests can be considered as an acceptable alternative to current cytology-based cervical cancer screening methods.

Implementation Recommendation

For women aged 21 to 29 years, testing with cervical cytology alone and screening every 3 years is recommended as a preventive service for woman. For women aged 30 to 65 years, screening with a combination of cytology and HPV testing every 5 years, or if HPV testing is not available, cytology alone every 3 years is recommended as a preventive service for women. Screening of high-risk women and continued screening past age 65 of inadequately screened average-risk women is recommended as a preventive service for woman. In women 25 years and older, FDA-approved primary HPV screening tests can be considered as alternatives to current cytology-based cervical cancer screening methods and are recommended to be included as preventive services. The resulting sequence of tests and interventions following screening that are necessary to prevent invasive cervical cancer, including colposcopy, treatment of precancerous lesions, and follow-up testing, are recommended as an integral part of cervical cancer screening.

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Contraception and Contraceptive Counseling

WPSI Recommendation

WPSI recommends adolescent and adult women have access to the full range of family planning services to prevent unintended pregnancy and improve birth outcomes. Access should include contraceptive counseling, initiation of contraceptive use, and follow-up care (eg, management, evaluation, change in method, and removal or discontinuation of contraceptive method). WPSI recommends that the full range of Food and Drug Administration (FDA)-approved contraceptive methods, effective family planning practices, and sterilization procedures be included.

Clarification Recommendation

The full range of contraceptive and family planning services include the following:

- All contraceptive methods currently identified by the FDA, which include: (1) sterilization surgery for women and men; (2) surgical sterilization implant for women; (3) implantable rod; (4) copper intrauterine device (IUD); (5) IUD with progestin (all durations and doses); (6) shot/injection; (7) oral contraceptives (combined pill); (8) oral contraceptives (progestin only); (9) oral contraceptives (extended/continuous use); (10) patch; (11) vaginal contraceptive ring; (12) diaphragm; (13) sponge; (14) cervical cap; (15) female and male condoms; (16) spermicide; (17) emergency contraception (levonorgestrel); and (18) emergency contraception (ulipristal acetate); and additional methods as identified by the FDA.
- Instruction in fertility awareness-based methods, including the lactation amenorrhea method, for women desiring alternative, although less-effective methods
- Counseling that allows for discussion of the full range of contraceptive options and emphasizes patient-centered decision making. The most appropriate choice to prevent pregnancy for a woman might include a vasectomy for her partner or use of male condoms

Multiple visits may be necessary to identify appropriate contraceptive methods for a woman to optimize compliance and effectiveness, as determined by a woman and her healthcare provider.

Implementation Recommendation

WPSI recommends for consideration as a preventive service: the full range of FDA-identified contraceptive methods; counseling, initiation, and follow-up care (eg, for management, evaluation, change in method, and removal or discontinuation of contraceptive method) as often as needed, including postpregnancy contraception; over-the-counter contraceptive methods without a prescription; effective family planning practices; and patient-specific services or FDA-approved methods that may be required based on individual women's needs. WPSI recommends as a preventive service accommodation of an alternative contraceptive method for any individual for whom a particular drug (generic or brand name) would be medically inappropriate, as determined by the individual's health care provider.

Research indicates that delayed initiation or disruption of contraceptive use increases the risk of unintended pregnancy, therefore WPSI recommends timely authorization. Effective family planning practices that reduce the risk of unintended pregnancy are included, including, but not limited to,

dispensation of 1-year supplies of contraceptives, use of copper IUD as emergency contraceptives, and continuous or extended use of hormonal contraceptives.

Screening for Gestational Diabetes Mellitus

WPSI Recommendation

WPSI recommends screening pregnant women for gestational diabetes mellitus (GDM) after 24 weeks of gestation, preferably between 24 and 28 weeks of gestation, in order to prevent adverse birth outcomes. Screening with the 50-g oral glucose challenge test (OCT), followed by the 3-hour 100-g oral glucose tolerance test (OGTT) for women with abnormal results on the initial OCT, is preferred.

Diabetes screening before 24 weeks of gestation, ideally at the first prenatal visit, is suggested for women with risk factors for diabetes mellitus. The 50-g OCT is the recommended modality for screening prior to 24 weeks of gestation. If early screening is normal, screening with 50-g OCT should be done at 24 to 28 weeks of gestation as described above.

In women diagnosed with diabetes mellitus during pregnancy, appropriate diabetes care (including education, nutrition counseling, medications, and supplies) is recommended.

Clarification Recommendation

Risk factors for diabetes mellitus that may identify women for early screening are determined by clinical expertise, and include, but are not limited to: previous GDM, known impaired glucose metabolism, a body mass index of 30 or greater, prior fetal macrosomia, unexplained stillbirth, and strong immediate family history of type 2 diabetes or GDM. The 50-g OCT is the recommended modality for screening prior to 24 weeks of gestation; however other options for detecting glucose abnormalities in nonpregnant women may be appropriate for women in early pregnancy based on clinical expertise.

Diabetes care supplies include, but are not limited to: test strips, glucose monitors, and lancets. Diabetes education and nutrition counseling services vary by patient needs, literacy, and compliance.

Implementation Recommendation

Diabetes screening during pregnancy and appropriate diabetes care for women diagnosed with diabetes mellitus or GDM as a result of screening are recommended as a preventive service for women for the duration of the pregnancy. Counseling and education may be provided by a team and/or more than one provider type including, but not limited to, physicians, physician assistants, registered nurses, nutritionists, or other individuals trained in the management of diabetes (eg, certified diabetes educators).

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Screening for Human Immunodeficiency Virus Infection

WPSI Recommendation

WPSI recommends prevention education and risk assessment for human immunodeficiency virus (HIV) infection in adolescents and women at least annually throughout the lifespan. All patients should be tested for HIV at least once during their lifetime. Screening frequency should be based on risk, and frequent screening (annually or more frequent) may be appropriate for individuals with increased risk.

HIV screening is recommended for all pregnant women at the initiation of prenatal care, with retesting during pregnancy based on risk factors. Rapid HIV testing is recommended for pregnant women who present in active labor with unknown HIV status.

Clarification Recommendation

This recommendation refers to routine HIV screening, which is different from incident-based or exposure-based HIV testing. Risk factors for HIV infection in women include, but are not limited to, active injection drug use; unprotected vaginal or anal intercourse; multiple sexual partners; initiation of a new sexual relationship; sexual partners who are HIV-infected, bisexual, or injection drug users; exchanging sex for drugs or money; and having other sexually transmitted infections. Approximately 20–26% of infected patients are not identified by risk-based screening. Early detection and treatment improves outcomes for the patient and reduces transmission. Given these potential benefits, screening annually or more frequently may be reasonable. Screening during pregnancy enables prevention of vertical transmission.

Implementation Recommendation

After the initial HIV screen, the frequency of screening may be based on risk. More frequent screening for high-risk women, as determined by clinical judgment, is recommended as a preventive service for women.

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Screening for Interpersonal and Domestic Violence

WPSI Recommendation

WPSI recommends screening and counseling adolescents and women for interpersonal and domestic violence and when needed, provision of, and/or referrals to, intervention services.

Clarification Recommendation

Interpersonal and domestic violence includes violence, the threat of violence, abuse, and neglect. The frequency and intensity of screening may vary according to risk factors and life stage. Risk factors and vulnerable times may include, but are not limited to: pregnancy, younger and older age, periods of family stress, dependency, and institutionalization. Interventional services include, but are not limited to, counseling and education. Further information on domestic violence intervention and prevention is available at: http://www.acf.hhs.gov/fysb/programs/family-violence-prevention-services/programs/centers#1

Implementation Recommendation

Screening adolescents and women for interpersonal and domestic violence is recommended as a preventive service for women. WPSI recommends payment models be developed to cover the broad range of services that may be needed to help adolescents and women in these circumstances.

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Counseling for Sexually Transmitted Infections

WPSI Recommendation

WPSI recommends that a sexual history be incorporated into a routine wellness visit. For adolescents and adults not identified at high risk, annual counseling to reduce the risk of STIs should be considered. A periodic risk assessment is recommended to identify women at increased risk of STIs. WPSI recommends counseling by an appropriately trained individual for sexually active adolescent and adult women at increased risk.

Clarification Recommendation

A sexual history and assessment of risk factors may help identify women at increased risk of STIs. Risk factors include age younger than 25, recent history of STI, new sex partner, multiple partners, partner with concurrent partners, partner with an STI, and inconsistent condom use. For adolescents and adults not identified at high risk, annual counseling to reduce the risk of STI should be considered. In addition, providers should consult their state and local public health departments to identify populations and communities at increased risk for STI exposure to help guide counseling. More information about populations at high risk of STIs is available at:

http://www.cdc.gov/std/prevention/screeningreccs.htm

For women not identified at high risk, annual counseling to reduce the risk of STIs is recommended. More frequent and more intensive counseling may be indicated for some women, including, but not limited to the following: longer duration or multiple counseling sessions, motivational interviewing techniques, and goal setting. Some examples are available at:

http://www.cdc.gov/hiv/research/interventionresearch/compendium/index.html

Counseling is recommended regardless of whether screening for STIs takes place at the same visit and regardless of type of sexual activity or gender of partners. Counseling may be repeated over multiple encounters, ie, annually and as often as indicated. Further information on screening recommendations for specific STIs is available at:

http://www.cdc.gov/std/tg2015/screening-recommendations.htm

Implementation Recommendation

WPSI recommends as a preventive service for women: STI counseling at least annually and as often as clinically indicated, depending on risk. Individuals at increased risk are identified by the clinical provider. To be considered preventive, services need not be limited to those delivered in clinical settings and could include, for example, telephone support and care delivered in long-term care facilities and school-based clinics.

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Well Woman Preventive Visits

WPSI Recommendation

WPSI recommends at least one annual preventive care visit for women beginning in adolescence and continuing across the lifespan to ensure that women obtain recommended preventive services. The purpose of these visits should be the delivery and coordination of recommended preventive services as determined by age and risk factors. These services can be delivered by health care providers who care for adolescents or women.

Clarification Recommendation

The well-woman visit promotes health over the course of a woman's lifespan through disease prevention and preventive health care. The goal of the well-women preventive care visit(s) is to promote health and wellness. More than one visit (potentially to more than one provider) may be needed to obtain all necessary recommended preventive services. The number of visits and services provided will vary by a woman's age, health status and needs, reproductive health needs and pregnancy status, and risk factors. Visits should allow sufficient time to address and coordinate services, and a team-based approach may facilitate delivery of services. These services include, but are not limited to, assessment of physical and psychosocial function, secondary prevention/screening, risk factor assessment, immunizations, counseling, and education. Recommended services are available from USPSTF and ACIP; additional details on age-specific components of the well woman visit can be found at AAFP, ACP, ACOG, NPWH. The selection of a provider for well-woman care will be determined as much by a woman's needs and preferences as by her access to health services or health plan availability. Preconception, prenatal, and interconception care are part of well-women preventive services.

Implementation Recommendation

Preventive care visits that allow coordination and delivery of preventive services should occur at least annually and are recommended as a preventive service for women, regardless of whether any other medical problems are encountered or treated during the visit. Consideration of a well woman visit(s) as a preventive service should not preclude the management of medical issues. More than one visit, potentially to more than one provider, if needed, is recommended to achieve the full scope of recommended preventive services.

EXHIBIT 83

REDACTED VERSION OF DOCUMENT(S) SOUGHT TO BE SEALED

Claim Chart		Plaintiff Claim Summary							
		Invoice Submitted with Claim						Adjudication / EOB	
				Maternal		Infant			
Plaintiff	Note	Date(s) of Service	CPT / HCPCS; Modifier	ICD Primary	ICD Secondary	ICD Primary	ICD Secondary	Type of Service EOB	Adjudication EOB
	1							Office Visits	Denied - Your plan does not cover this non-medical service or personal item.
	2 3							Preventive Med	Denied - This is not a reimbursable service. There may be a more appropriate CPT or HCPCS code that describes the service and/or the use of the modifier or modifier combination is inappropriate. 3
	4							Medical Service	Charge(s) denied. Exceeds the usual, reasonable and customary fees. Your claim was processed at the Out of Network Level of Benefits.
	5							Medical Service	Charge(s) denied. This service is excluded by your health plan.
	6			N/A	N/A		N/A	Home Service	Charge(s) denied. This service is excluded by your health plan.
	7			N/A	N/A		N/A	Home Service	Charge(s) denied. This service is excluded by your health plan.
	8 9			none	none	none	none	Home Visit	Denied - This is not a reimbursable service. There may be a more appropriate CPT or HCPCS code that describes the service and/or the use of the modifier or modifier combination is inappropriate. 9
	8 9			none	none	none	none	Preventive Med	Denied - This is not a reimbursable service. There may be a more appropriate CPT or HCPCS code that describes the service and/or the use of the modifier or modifier combination is inappropriate. 9
	10 11 13							Home Visit	Payment for services is denied. We asked member for more information and didn't receive it on time. 13
	10 12 13							Home Visit	Payment for services is denied. We asked member for more information and didn't receive it on time. 13
	14 17 19							Preventive Med	Denied - This is not a reimbursable service. There may be a more appropriate CPT or HCPCS code that describes this service and/or the use of the modifier or modifier combination is inappropriate. 19
	15 17 19							Preventive Med	Denied - This is not a reimbursable service. There may be a more appropriate CPT or HCPCS code that describes this service and/or the use of the modifier or modifier combination is inappropriate. 19
	16 17 18							Preventive Med	Denied - This is not a reimbursable service. There may be a more appropriate CPT or HCPCS code that describes this service and/or the use of the modifier or modifier combination is inappropriate. 18

	Claim Chart
	Plaintiff Claim Summary - Footnotes
1	Provider: [redacted]; [Seay/Barber Decl. (Dkt. 109-4), Exs. E-2, E-3, E-6]
2	Provider: [redacted] [Seay/Bishop Decl. (Dkt. 108-3), Exs. B-2, B-4]
3	EOB denying claim dated [redacted] [Seay/Bishop Decl. (Dkt. 108-3), Exs. B-4, Ex B-2]. Letter from [redacted] dated [redacted] providing ICD codes [Seay/Bishop Decl. (Dkt. 108-3), Ex B-5].
3	Letter from [redacted] y dated [redacted] providing ICD codes [Seay/Bishop Decl. (Dkt. 108-3), Ex. B-5]; [redacted] EOB dated 10-30-2016 indicates that "this claim was already reviewed and processed." [Smith Reply Decl., Ex. 86 at PL_LB000006].
4	Provider: [redacted] $52.70 of the $65 amount charged applied to deductible [Seay/Carroll Decl. (Dkt. 108-3), Exs. C-2, C-4].
5	Provider: [redacted] $0 benefit received [Seay/Carroll Decl. (Dkt. 108-3), C-3, C-5].
6	Provider [redacted] [Smith Reply Decl., Ex. 86 at UHC_RAC000004 (claims), UHC_RAC000132 (EOB)].
7	Provider: [redacted]) [Smith Reply Decl., Ex. 86 at UHC_RAC000005 (claim); UHC_RAC000132 (EOB)].
8	Provider: [redacted] [Seay/Condry Decl. (Dkt. 109-4), Ex. F-2].
9	UHC separated a single charge into two components [Seay/Condry Decl. (Dkt. 109-4), Ex. F-3].
10	Provider: [redacted] [Seay/Endicott Decl. (Dkt. 109-4), Ex. D-2].
11	ICD 9 code requested for service code [redacted] [Seay/Endicott Decl. (Dkt. 109-4), Exs. D-5]; service code billed was [redacted] [Seay/Endicott Decl. (Dkt. 109-4), Ex. D-2].
12	UHC requested ICD 10 code for service [redacted] [Seay/Endicott Decl. (Dkt. 109-4), Ex. D-4]; ICD-10 code [redacted] provided with the claim [Seay/Endicott Decl. (Dkt. 109-4), Ex. D-2].
13	Initial adjudication [Seay/Endicott Decl. (Dkt. 109-4), Ex. D-7]. Following appeal to State of CT Insurance Department, the claims were reprocessed allowing $173 and $40 of eligible expense toward the non-network deductible re: claims for services on [redacted], respectively [Seay/Endicott Decl. (Dkt. 109-4), Exs. D-9, D-11].
14	Provider: [redacted] [Seay/Hoy Decl. (Dkt. 106-3), Ex. A-2 at UHC_000817-8; Seay/Hoy Decl. (Dkt. 106-3), Ex. A-10 at UHC_000839]; request for ICD 9 codes related to service code [redacted] [Seay/Hoy Decl. (Dkt. 106-3), Exs. A-5, A-6, A-7 at UHC_000864].
15	Provider: [redacted] [Seay/Hoy Decl. (Dkt. 106-3), Exs. A-2 at UHC_000815-6, A-10 at UHC_000841]; request for ICD 9 codes related to service code [redacted] [Seay/Hoy Decl. (Dkt. 106-3), Ex. A-7 at UHC_000865-6].
16	Provider: [redacted] [Seay/Hoy Decl. (Dkt. 106-3), Exs. A-2 at UHC_000819-20 and A-10 at UHC_000842-3].
17	Response to UHC inquiry specifying: (1) service code [redacted] (2) diagnosis code [redacted] [Seay/Hoy Decl. (Dkt. 106-3), Ex. A-7 at UHC_000863].
18	Seay/Hoy Decl. (Dkt. 106-3), Ex. A-8.
19	Seay/Hoy Decl. (Dkt. 106-3), Ex. A-9.

EXHIBIT 84

REDACTED VERSION OF DOCUMENT(S) SOUGHT TO BE SEALED

EXHIBIT 85

REDACTED VERSION OF DOCUMENT(S) SOUGHT TO BE SEALED

EXHIBIT 86

REDACTED VERSION OF DOCUMENT(S) SOUGHT TO BE SEALED

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October 30, 2015

303MEOBSW1002004-11158-01
[redacted]

Member/Patient Information
Member/Patient: [redacted]
Member ID: [redacted]
Relationship: [redacted]
Group Name: [redacted]
Group #: [redacted]

Explanation of Benefits Statement
This is not a bill. Do not pay. This is to notify you that we processed your claim.

Claims Summary
Detailed claim information is located on the following page(s).

Dollar Amount	Description
$130.00	**Amount Billed** This is the total amount that your provider billed for the services that were provided to you.
$130.00	**Plan Discounts** Your plan negotiates discounts with providers to save you money. This amount may also include services that you are not responsible to pay.
$0.00	**Your Plan Paid** This is the portion of the amount billed that was paid by your plan.
$0.00	**Total amount you owe the provider(s)** The portion of the Amount Billed you owe the provider(s). This amount does not reflect any payment you may have already made at the time you received care. This amount may include your deductible, co-pay, coinsurance and/or non covered charges. This amount does not include any payments made to the subscriber*. If a payment was made directly to the subscriber, you/the subscriber is responsible for paying the physician, facility or other health care professional. * When coordination of benefits applies, this amount will include payments made to the subscriber.

S WD-12174*01*056514-MO-15303-61644-AFJ 22SYMS

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ATLANTA, GA 30374-0800
Phone: 1-800-782-3740

October 30, 2015

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Claim Detail for [redacted]

Provider: [redacted] **Claim Number:** [redacted]

Date(s) of Service	Type of Service	Notes*	Amount Billed	(-)	Plan Discounts	(-)	Your Plan Paid	(=)	Your Itemized Responsibility to Provider** Deductible (+)	Copay (+)	Coinsurance (+)	Non Covered (=)	Amount You Owe
[redacted]	PREVENTIVE MED	05	$130.00		$130.00		$0.00		$0.00	$0.00	$0.00	$0.00	$0.00
Claim Total:			**$130.00**		**$130.00**		**$0.00**		**$0.00**	**$0.00**	**$0.00**	**$0.00**	**$0.00**

**This total does not reflect any payments / copays you made at the time of service.
Please wait for a provider bill before making a payment.

Notes*

05 - THIS CLAIM WAS ALREADY REVIEWED AND PROCESSED. IF THIS IS A CORRECTED CLAIM, THE PROVIDER MUST SUBMIT AND INDICATE IT IS A CORRECTED CLAIM. IT MUST SHOW THE ORIGINAL SERVICE, CHARGE AND ANY CORRECTIONS.

A review of this benefit determination may be requested by submitting your appeal to us in writing at the following address: UnitedHealthcare Appeals, P.O. Box 30573, Salt Lake City, UT 84130-0573. The request for your review must be made within 180 days from the date you receive this statement. If you request a review of your claim denial, we will complete our review not later than 30 days after we receive your request for review.

If your plan is governed by ERISA, you may have the right to file a civil action under ERISA if all required reviews of your claim have been completed.

You or your authorized representative, such as a family member or physician, may appeal the decision by submitting comments, documents or other relevant information to the appeal address referenced above.

You may request copies (free of charge) of information relevant to your claim by contacting us at the above address.

Availability of Consumer Assistance/Ombudsman Services:
There may be other resources available to help you understand the appeals process. If your plan is governed by ERISA, you can contact the Employee Benefits Security Administration at 1-866-444-EBSA (3272). If your plan is not governed by ERISA, you can contact the Department of Health and Human Services Health Insurance Assistance Team at 1-888-393-2789. Your state consumer assistance program may also be able to assist you at:
Texas Department of Insurance
Consumer Protection (111-1A)
333 Guadalupe

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Austin, TX 78714
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Web site: www.texashealthoptions.com
E-mail: ConsumerProtection@tdi.texas.gov

If we continue to deny the payment, coverage, or service requested or you do not receive a timely decision, you may be able to request an external review of your claim by an independent third party, who will review the denial and issue a final decision.

Disclosure of Provider Status
Not all physicians and providers at contracted facilities (hospital, ambulatory surgical center, etc) are contracted with your plan. If you receive health care services at or through a contracted facility and the physicians or providers who provided that care are not contracted with your plan, the services may be denied or paid at the non-network level. In those cases, you may be responsible for payment of all or part of the fees for those services. In these situations, the facility or non-contracted physician or provider can choose to bill you for the balance not paid by the health plan for non-covered or out-of-network services. Should you have a complaint regarding payments of health care services, you may contact the Texas Department of Insurance Consumer Protection Division at 1-800-252-3439.

Insurance fraud adds millions to the cost of health care. If services are listed which you did not receive or service you were told would be free, call 1-800-782-3740.

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Please call the number included in this document or on the back of your ID card if you need diagnosis and/or treatment code information regarding the services referenced in this communication.

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Para obtener asistencia en español, llame al número de teléfono que se incluye en este documento o al dorso de su tarjeta de identificación.

Account Summary

Summary of Deductible and Out of Pocket

Plan Year: 2015

[redacted] Relationship: [redacted]	Annual Amount	(-) Applied to Date	(=) Remaining Balance
IN NETWORK			
Deductible	[redacted]	[redacted]	[redacted]
Out of Pocket	[redacted]	[redacted]	[redacted]
OUT OF NETWORK			
Deductible	[redacted]	[redacted]	[redacted]
Out of Pocket	[redacted]	[redacted]	[redacted]
QUALITY/EFFICIENCY			
Out of Pocket	[redacted]	[redacted]	[redacted]

FAMILY	Annual Amount	(-) Applied to Date	(=) Remaining Balance
IN NETWORK			
Deductible	[redacted]	[redacted]	[redacted]
Out of Pocket	[redacted]	[redacted]	[redacted]
OUT OF NETWORK			
Deductible	[redacted]	[redacted]	[redacted]
Out of Pocket	[redacted]	[redacted]	[redacted]
QUALITY/EFFICIENCY			
Out of Pocket	[redacted]	[redacted]	[redacted]

Definitions of Key Terms

Applied to Date: The total amount of money applied to your deductible or out of pocket as of this EOB statement.

Deductible: The deductible is the fixed dollar amount that you pay each year toward eligible health care services before your plan benefits are payable. Once the deductible has been met, the co-payment and/or coinsurance period of your plan may begin. Please refer to your plan documents for specific information regarding what services apply to the deductible.

Out of Pocket: The out of pocket maximum is the dollar amount you pay before your plan benefit starts paying at 100% for eligible health care services. Please refer to your plan documents for specific information on what costs apply to the maximum amount.

Plan Year: The dates your plan benefit maximums are applicable.

EXHIBIT 87

REDACTED VERSION OF DOCUMENT(S) SOUGHT TO BE SEALED

UMR MEMBER CLAIM REIMBURSEMENT FORM

LARIMER COUNTY
COMMITTED TO EXCELLENCE

Larimer County Employee Benefit Plan
200 West Oak Street, Suite 3200
Ft. Collins, Colorado 80521

To be considered a valid claim, submit your receipt or itemized statement along with this completed claim form containing the required information listed below.

Submit claims to: UMR - Attn: Larimer County Team
10021 - 120th Ave, 2nd Fl, Ste 200
Bothell WA 98011 / Fax: 866-859-1112
Email: LCReimbursementClaim@umr.com

EMPLOYEE INFORMATION

EMPLOYER **LARIMER COUNTY / DEPT:**	GROUP NUMBER [redacted]
EMPLOYEE - LAST, FIRST, MI [redacted]	MEDICAL ID NUMBER WITH UMR [redacted]
STREET ADDRESS [redacted]	CITY [redacted] STATE [redacted]
ZIP [redacted] DATE OF BIRTH [redacted]	PHONE NUMBER [redacted] EMAIL [redacted]

PATIENT INFORMATION (if other than employee)

LAST NAME, FIRST, MI [redacted]	RELATIONSHIP TO EMPLOYEE: [redacted]

PROVIDER INFORMATION

PROVIDER NAME: [redacted]	PROVIDER TAX ID (9 digits): [redacted]
PROVIDER PHONE NUMBER: [redacted]	(USA only: required field-please contact provider if statement or receipt is missing information.)

TYPE OF SERVICE (check all that apply)

	VISION EXAM	DO YOU HAVE VSP COVERAGE? IF SO, ATTACH VSP EXPLANATION OF BENEFITS					
	MEDICAL		OFFICE VISIT		FLU SHOT		ACUPUNCTURE
			LAB / X-RAY		IMMUNIZATION		MASSAGE
		✓	OTHER: briefly describe services received	[redacted]			

RECEIPT MUST SHOW: Date of Service, Provider's Name, Patient Name, Diagnosis, Charge for Each Service
NOTE: Your claim may require routing to verify provider network status
VISION/MASSAGE/ACUPUNCTURE CLAIMS: Diagnosis may not apply (will not route networks)
WRITE MEMBER ID ON EVERY PAGE SUBMITTED. KEEP A COPY OF RECEIPT(S) FOR YOUR RECORDS.

SEND PAYMENT TO:

	✓	MEMBER	PROVIDER

EMPLOYEE RELEASE

Authorization to pay benefits to Employee

I hereby authorize payment of benefits directly to me for services, but not to exceed the reasonable and customary charge for said services. I understand I am financially responsible for any charges not covered by this authorization.

[redacted] _____ [redacted] _____

Covered Person Date

PATIENT OR PARENT MUST SIGN BELOW

Authorization to release information

I hereby authorize any insurance company, prepayment organization, employer, hospital or physician to release all information with respect to myself or any of my dependents which may have a bearing on the benefits payable under this or any other plan providing benefits or services. I hereby certify the information provided is correct and true to the best of my knowledge.

[redacted] _____ [redacted] _____

Patient or Parent (if minor) Date

Revised: 07/28/2014

[redacted]

Patient's Name (Last Name, First Name, Middle Initial)	Patient's Birth Date	Sex	Insured's ID number
[redacted]	[redacted]	M ☐ F ☑	[redacted]
Patient's Address (Number, Street)	Patient's Relationship to Insured (Insured=subscriber)		Insured's/Subscriber's Name (Last Name, First Name, MI)
[redacted]	Self ☐ Spouse ☐ Child ☑ Other ☐		[redacted]
City / State	Insurance Plan/ Program Name		Insured's Address (Number, Street, City, State, Zip Code)
[redacted]	[redacted]		[redacted]
Zip Code / Telephone w/Area Code	Insured's Policy Group or FECA Number		Ins… MM…
[redacted]	[redacted]		…urrent illness (first symptom) or pregnancy (LMP)
this claim.			MM / DD / YYYY / 2nd, 3rd digits for onset of 31= symptom, illness; 84=LMP / QUALIFIER
Signed: [redacted] Date			[redacted] / 4 ___

DIAGNOSIS OR NATURE OF ILLNESS OR INJURY (choose Maternal OR Infant codes, not both):

Maternal Diagnosis codes:

A-L	Code	Description
	Z39.1	Encounter for care and examination of lactating mother
	O91.03	Infection/abscess of nipple associated with lactation
	O91.13	Abscess/purulent mastitis of breast with lactation
	O91.23	Nonpurulent mastitis
	O92.03	Retracted nipple associated with lactation
	O92.13	Cracked nipple associated with lactation
	O92.20	Unspecified disorders of breast
	O92.29	Other specified disorders of breast (i.e., engorgement)
	O92.3	Agalactia (excludes O92.5)
	O92.4	Hypogalactia
	O92.5	Suppressed lactation (excludes O92.3)
	O92.70	Unspecified disorders of lactation (i.e., galactocele)
	O92.79	Other disorders of lactation (i.e., puerperal galactocele)
Other conditions:		

Infant Diagnosis codes:

A-L	Code	Description
Neonatal (onset 28 days or less):		
	P92.09	Other vomiting in newborn (excludes hiloum)
	P92.1	Regurgitation and rumination of newborn
	P92.2	Slow feeding of newborn
	P92.3	Underfeeding of newborn
	P92.4	Overfeeding of newborn
	P92.5	Neonatal difficulty in feeding at breast
	P92.6	Failure to thrive in newborn
	P92.8	Other feeding problems of newborn
	P92.9	Feeding problems of newborn, unspecified
Older infant/child (onset 28 days or more):		
	R62.51	Failure to thrive/poor weight
	R63.3	Feeding difficulties and mismanagement
	R63.4	Abnormal weight loss
	[redacted]	[redacted]
	K00.7	[redacted]
[redacted] conditions:		

PROCEDURES, SERVICES, OR SUPPLIES (CPT/HCPCS CODES):

Date of Service: [redacted] DD	Place of Service Code: ☐ 11 (Office) ☒ 12 (Home)	Name of Referring Provider (if applicable)	Referring Provider's NPI number (if applicable):
[redacted]			

☒	CPT	5th digit		Description	Charge
Office Visits (if linked to Preventive Med Counseling add MOD 25)					
	9920	1-5		New patient	
	9921	1-5		Established patient	
Preventive Medical Counseling (if linked to Office add MOD 25 to codes above)					
	9940	1-4		Individual: New or est. patient	
	9941	1-2		Group: New or est. patient	
Home Visits					
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	125
	9934	7-9		Established Pat…	
Telephone consult					
	9896	6-8		Brief-Intermediate-Lengthy	

☒	CPT	5th dig1	MOD	Description	Charge
Consultation: Physician Requested (Office or Other Outpatient)					
	9924	1-5		New patient or new referral	
	99350			Unstable, significant new problem	
Lactation Classes					
	S9443			Per session	
Education and Training for Patient Self Management					
	9856	1-3			
Health/Behavioral Assessment/Reassessment/Intervention					
	9815	0-4		Individual/Group/Family	
Other Procedures/Supplies					

Federal Tax ID Number	SSN / EIN	Patient's Account #	Mode of Payment	Total Charge	Amount Paid
[redacted]	☐ ☒	[redacted]	☐ Cash ☐ Charge ☑ Check (# ____)	$ 125.00	$ 125.00

Signature of Lactation Consultant, Including Degrees or Credentials	Service Facility Location Information	Billing Provider Name, Address / Ph. Number
[redacted] Signed / Date [redacted]	NPI Number for facility if different from NPI for billing	NPI for billing
		[redacted]

To the patient: Complete the patient information at the top of this form, sign and date. Payment is your obligation, regardless of insurance or other third party involvement.

[redacted]

Patient's Name (Last Name, First Name, Middle Initial)	Patient's Birth Date	Sex	Insured's ID number
[redacted]	[redacted]	[redacted]	
[redacted]	Patient's Relationship to Insured (Insured=subscriber) Self ☐ Spouse ☐ Child ☑ Other		Insured's/Subscriber's Name (Last Name, First Name, MI)
[redacted]	[redacted]		[redacted]
[redacted] phone w/Area	Insured's Policy Group [redacted] FECA Number	Insured's Birth Da[redacted]	Sex
[redacted] this claim.		[redacted] or pregnancy (LMP) MM / DD / YYYY	2nd, 3rd digits for onset of 31= symptom, illness; 84=LMP / QUALIFIER 4 ___

DIAGNOSIS OR NATURE OF ILLNESS OR INJURY (choose Maternal OR Infant codes, not both):

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	O92.03	Retracted nipple associated with lactation
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	O92.5	Suppressed lactation (excludes O92.3)
	O92.70	Unspecified disorders of lactation (i.e., galactocele)
	O92.79	Other disorders of lactation (i.e., puerperal galactocele)
Other conditions:		
		[redacted]

Infant Diagnosis codes:

A-L	Code	Description
Neonatal (onset 28 days or less):		
	P92.09	Other vomiting in newborn (excludes bilious)
	P92.1	Regurgitation and rumination of newborn
	P92.2	Slow feeding of newborn
	P92.3	Underfeeding of newborn
	P92.4	Overfeeding of newborn
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	P92.6	Failure to thrive in newborn
	P92.8	Other feeding problems of newborn
	P92.9	Feeding problems of newborn, unspecified
Older infant/child (onset 28 days or more):		
	R62.51	Failure to thrive/gain weight
	R63.3	Feeding difficulties and mismanagement
	R63.4	Abnormal weight loss
		weight gain
Other conditions:		

PROCEDURES, SERVICES, OR SUPPLIES (CPT/HCPCS CODES):

Service [redacted]	Place of Service Code: ☐ 11 (Office) ☑ 12 (Home)	Name of Referring Provider (if applicable)	Referring Provider's NPI number (if applicable):

☒	CPT	5th digit	MOD	Description	Charge
Office Visits (if linked to Preventive Med Counseling add MOD 25)					
	9920	1-5		New patient	
X	[redacted]	1-5		[redacted]	50.00
Preventive Medical Counseling (if linked to Office add MOD 25 to codes above)					
	9940	1-4		[redacted] New or est. patient	
	9941	1-2		[redacted] New or est. patient	
Home Visits					
	9934	1-5		[redacted]	
[redacted]					50.00
Telephone consult					
	9896	6-8		Brief-Intermediate-Lengthy	

☒	CPT	5th digit	MOD	Description	Charge
Consultation: Physician Requested (Office or Other Outpatient)					
	9924	1-5		New patient or new referral	
	99350			Unstable, significant new problem	
Lactation Classes					
	S9443			Per session	
Education and Training for Patient Self Management					
	9896	1-3			
Health/Behavioral [redacted]					
	9815	0-4		Individual/Group/Family	
Other Procedures/Supplies					

Federal Tax ID Number	SSN	EIN	Patient's Account #	Mode of Payment	Total Charge	Amount Paid
[redacted]	☐	☒		☐ Cash ☐ Charge ☑ Check (# ____)	$ 50.00	$ 50.00

Signature of Lactati[redacted] Consultant, including Degrees or [redacted]	Service Facility Location Information	Billing Provider Name, Address Ph[redacted]
[redacted] Signed Date	NPI Number for facility if different from NPI for billing	NPI for billing [redacted]

UMR MEMBER CLAIM REIMBURSEMENT FORM

LARIMER COUNTY
COMMITTED TO EXCELLENCE

Larimer County Employee Benefit Plan
200 West Oak Street, Suite 3200
Ft. Collins, Colorado 80521

To be considered a valid claim, submit your receipt or itemized statement along with this completed claim form containing the required information listed below.

Submit claims to: UMR - Attn: Larimer County Team
20021 - 120th Ave, 2nd Fl, Ste 200
Bothell WA 98011 / Fax: 866-859-1113
Email: LCReimbursementClaim@umr.com

EMPLOYEE INFORMATION

EMPLOYER **LARIMER COUNTY / DEPT:**	GROUP NUMBER [redacted]
EMPLOYEE - LAST, FIRST, MI [redacted]	MEDICAL ID NUMBER WITH UMR
[redacted]	CITY [redacted] STATE [redacted]
[redacted] DATE OF BIRTH	PHONE NUMBER [redacted]
[redacted]	EMAIL [redacted]

PATIENT INFORMATION (if other than employee)

LAST NAME, FIRST, MI [redacted]	RELATIONSHIP TO EMPLOYEE: [redacted]

PROVIDER INFORMATION

PROVIDER NAME: [redacted]	PROVIDER TAX ID (9 digits): [redacted]
PROVIDER PHONE NUMBER: [redacted]	(USA only: required field-please contact provider if statement or receipt is missing information.)

TYPE OF SERVICE (check all that apply)

	VISION EXAM	DO YOU HAVE VSP COVERAGE? IF SO, ATTACH VSP EXPLANATION OF BENEFITS					
	MEDICAL		OFFICE VISIT		FLU SHOT		ACUPUNCTURE
			LAB / X-RAY		IMMUNIZATION		MASSAGE
		✓	OTHER: briefly describe services received	[redacted]			

RECEIPT MUST SHOW: Date of Service, Provider's Name, Patient Name, Diagnosis, Charge for Each Service
NOTE: Your claim may require routing to verify provider network status
VISION/MASSAGE/ACUPUNCTURE CLAIMS: Diagnosis may not apply (will not route networks)
WRITE MEMBER ID ON EVERY PAGE SUBMITTED. KEEP A COPY OF RECEIPT(S) FOR YOUR RECORDS.

SEND PAYMENT TO:

	✓	MEMBER	PROVIDER

EMPLOYEE RELEASE

Authorization to pay benefits to Employee

I hereby authorize payment of benefits directly to me for services, but not to exceed the reasonable and customary charge for said services. I understand I am financially responsible for any charges not covered by this authorization.

[redacted] [redacted]
Covered Person Date

PATIENT OR PARENT MUST SIGN BELOW

Authorization to release information

I hereby authorize any insurance company, prepayment organization, employer, hospital or physician to release all information with respect to myself or any of my dependents which may have a bearing on the benefits payable under this or any other plan providing benefits or services. I hereby certify the information provided is correct and true to the best of my knowledge.

[redacted] [redacted]
Patient or Parent (if minor) Date

Revised: 07/28/2014

PO Box 30541
Salt Lake City UT 84130-0541

[redacted]

QUESTIONS / CONCERNS Contact 1-800-834-3482.

INTERNET: Online services are available 24 hours a day at www.umr.com.

APPEAL:
You may file an appeal of the claim decision by sending a written request and pertinent information within 180 days from the date of this Notice to **"Claims Appeal Unit, P.O. Box 30546, Salt Lake City, UT 84130-0546".** Refer to your current benefit booklet for information on the appeal process. A printable appeal form may also be accessed at www.umr.com to attach to your request for appeal. You may supply additional information with your appeal. You may request copies (free of charge) of information relevant to your claim by contacting us at the above address.

OTHER RESOURCES TO HELP YOU:
For questions about your appeal rights, this notice, or for assistance if your plan is governed by ERISA, you can contact the Employee Benefits Security Administration at 866-444-EBSA (3272). If your plan is not governed by ERISA, you can contact the Department of Health and Human Services Health Insurance Assistance Team at 1-888-393-2789.

EXTERNAL REVIEW OPTION:
If we continue to deny the payment, coverage or service requested, or if you do not receive a timely decision, you may be able to request an external review of your claim by an independent third party, who will review the denial and issue a final decision. Your written request must be received by UMR within four (4) months of the date you receive this notice.

HELP STOP FRAUD! If you know or suspect any illegal activity concerning claims, contact our anti-fraud unit by calling 1-800-356-5803. You do not need to identify yourself.

Refer to your benefit booklet for more details on claim determination.

Please call the number located above if you need diagnosis and/or treatment code information for this claim.

PO Box 30541 Salt Lake City UT 84130-0541
1-800-834-3482
www.umr.com

Employee	[redacted]
Member ID	[redacted]
Patient	[redacted]
Notice Date	[redacted]
Employer Name	[redacted]
Employer Number	[redacted]

EXPLANATION OF BENEFITS NOTICE - THIS IS NOT A BILL

Provider: [redacted] **Patient Account:** **Claim Control Number:** [redacted]

Service Description	Dates of Service From:	To:	Amount Billed	Amount Not Payable	See Note Section	Less Deductible	Allowable Amount	%	Plan Benefit Amount	Amount Paid	Provider May Bill You
Home Service	[redacted]		$125.00	$125.00	947					$.00	$125.00
Home Service			$50.00	$50.00	947					$.00	$50.00
		Totals	$175.00	[redacted]		$0.00	$0.00	[redacted]	$0.00	$0.00	$175.00

Note Section

947 Charge(s) denied. This service is excluded by your health plan. Refer to General Exclusions in your benefit booklet.

Benefit Period	Benefit Level	Applied To Date
[redacted]	$130 Ind Annual Maximum	
	$500 In Net Ind Cal Yr Deductible	
	$1,000 In Net Fam Cal Yr Deductible	[redacted]
	$1,000 Out Net Ind Cal Yr Deductible	
	$2,000 Out Net Fam Cal Yr Deductible	[redacted]
	$7,000 Out Net Ind Out-of-Pckt	
	$14,000 Out Net Fam Out-of-Pckt	[redacted]
	$3,500 In Net Ind Out-of-Pckt W/Integration	

Benefit Period	Benefit Level	Applied To Date
[redacted]	$7,000 In Net Fam Out-of-Pckt W/Integration	[redacted]