UNITED STATES DISTRICT COURT FOR THE
NORTHERN DISTRICT OF OKLAHOMA

OKLAHOMA CHAPTER OF THE AMERICAN ACADEMY OF PEDIATRICS (OKAAP), *et al.*,	)	
Plaintiffs,	)	
v.	)	**Case No. 01-CV-0187-CVE-SAJ**
MICHAEL FOGARTY, Chief Executive Officer of the Oklahoma Health Care Authority (OHCA), *et al.*,	)	
Defendants.	)	

FINDINGS OF FACT AND CONCLUSIONS OF LAW

Introduction

Plaintiff Oklahoma Chapter of the American Academy of Pediatrics ("OKAAP") is a non-profit professional organization of pediatricians and pediatric specialists. Plaintiff Community Action Project of Tulsa County, Inc. ("CAPTC") is a non-profit organization located in Tulsa, Oklahoma. The individual named plaintiffs are thirteen children and their parents; they also serve as representatives of the class certified by the Court. Defendants are officials of the State of Oklahoma and Oklahoma Health Care Authority ("OHCA"), the designated agency responsible for implementing and administering Oklahoma's program to provide eligible children with the health and medical services at issue in this case.

Plaintiffs filed this action in March 2001, alleging essentially that defendants' policies and procedures denied or deprived eligible children of the health and medical care to which those children are entitled by federal law. Plaintiffs seek injunctive relief to ensure that eligible children receive that care. After the Court ruled on motions to dismiss, plaintiffs filed an amended complaint in May 2002. The Court defined and certified the plaintiff class of children on May 30, 2003. The

Court then held a non-jury trial for 19 days in April and May 2004. The parties made closing arguments and submitted proposed findings of fact and conclusions of law in July 2004.

On October 5, 2004, plaintiffs filed a motion for supplemental relief and request for preliminary injunction. The motion essentially requested that the Court enjoin defendants from denying coverage for the anti-immunoglobulin E ("IgE") drug Xolair (the trade name for omalizumab) to six class members suffering from elevated IgE-related symptoms and whose physicians determined Xolair to be medically necessary for them. The Court held a hearing on October 29 and November 1, 2004 to address this limited issue. The Court ordered additional medical evaluations and held an additional hearing on January 4, 2005. The parties submitted proposed findings of fact and conclusions of law regarding the Xolair issue on January 18, 2005.

I. FINDINGS OF FACT[1]

A. THE OKLAHOMA MEDICAID PROGRAM FOR CHILDREN

1. History

1. The Medicaid program was created in 1965 by Title XIX of the Social Security Act. Title XIX established a joint, cooperative federal-state program for furnishing and financing health care and services to individuals who qualify for cash or welfare assistance. Tr. Vol. IX, at 1126: 5-10. Title XIX's children's health care provisions were first made express in 1967. Each state decides whether to participate in the Title XIX's "Medical Assistance" program, and Oklahoma has chosen to participate. The Center for Medicare and Medicaid Services ("CMS"), formerly the Health Care Financing Agency ("HCFA"), in the United States Department of Health and Human

---

[1] Any conclusion of law more appropriately characterized as a finding of fact is incorporated herein.

Services, oversees the program for the Secretary. Defendant Oklahoma officials are responsible under Title XIX and by designation of State law, Okla. Stat. tit. 63, § 5005 et seq., for implementation of the program in accordance with the requirements imposed by Title XIX, its regulations, 42 C.F.R. § 440.40(b), 441-50 et seq., the terms of its waiver, and policy directions such as CMS's State Medicaid Manual. The State Medicaid Manual produced by CMS includes advisory and optional policies and procedures as well as mandatory policies and procedures. Tr. Vol. II, at 259:13-24; Pl. Ex. 2, at BB.0033. The State Medicaid Manual is neither a federal statute nor a federal regulation. Tr. Vol. II, at 344:11-18.

2. Participating states are reimbursed by CMS -- without any financial cap -- for the largest portion of their medical assistance expenditures, in exchange for compliance with the requirements of Title XIX. Under Title XIX, children's health care is mandatory upon each participating state and it includes "early and periodic screening, diagnostic, and treatment services" (sometimes referenced as "EPSDT") for individuals under the age of 21. 42 U.S.C. §1396d((a)(4)(B). Such services include comprehensive screening examinations, vision services, dental services, hearing services, and all other health care, diagnostic services, treatment, and other measures described by the statute as necessary to correct or ameliorate defects and physical and mental illnesses and conditions. See 42 U.S.C. § 1396d(r). Title XIX also requires "equal access," meaning that each participating state must "assure that payments . . . are sufficient to enlist enough providers so that care and services are available . . . at least to the extent that such care and services are available to the general population in the geographic area." 42 U.S.C. § 1396a(a)(30)(A).

3. Prior to 1995, Oklahoma operated on a "fee-for-service" basis for its Medicaid recipients. SoonerCare Application, 12/94, Pl. Ex. 669, Intro., at 10. "Fee-for-service" means that

when a provider sees a patient, and then files a claim with the state Medicaid agency for that service, the provider is paid a fee for that service. Tr. Vol. II, at 197:15-17; Tr. Vol. IX, at 1170:15-23. The agency responsible for administering Oklahoma's Medicaid program prior to 1995 was the Department of Human Services ("DHS"). SoonerCare Application, 12/94, Pl. Ex. 669, Ch. 2, at 18.

4. In 1989, Congress expanded the numbers of low income children who are entitled to health care, particularly those in working families whose jobs pay only low wages and for large families who have near-median family income. From 1988 to 1992, the number of Oklahomans enrolled in Oklahoma's Medicaid program increased from 245,000 to 360,000. OHCA Annual Report, Def. Ex. 35, at 19. Due to budgetary constraints, the State began exploring alternative ways in which to deliver Medicaid services. Id. Medicaid benefits and the population eligible for Medicaid were being reduced within the parameters allowed by federal law. Tr. Vol. XVII, at 2274:20 - 2275:15.

5. In 1993, OHCA was created by State statute, Okla. Stat. tit. 63, § 5004 et. seq., for the purpose of administering Oklahoma's Medicaid program. Tr. Vol. IX, at 1122:16-17. Under the statute, OHCA was given broad powers, including the power to purchase health care benefits for Medicaid recipients. Okla. Stat. tit. 63, § 5006. The Legislature also vested OHCA with the responsibility of converting the Oklahoma Medicaid program into a "managed care system." Id., § 5009. Managed care grew in response to health care costs increasing at a rate faster than inflation since the 1970s. Tr. Vol. II, at 232:24 - 233:5. On January 1, 1995, OHCA assumed total responsibility for administration of Oklahoma's Medicaid program. SoonerCare Application, 12/94, Pl. Ex. 669, Ch. 2 at 18.

6. On January 3, 1995, OHCA submitted an application to the federal government for development of a Medicaid managed care plan, SoonerCare. Pl. Ex. 669. The SoonerCare model required the grant of a waiver from certain Medicaid Act requirements. Id., Intro., at 8. If a waiver is granted, the State is not required to ensure the State Medicaid program is uniform statewide; the State can limit a beneficiary's freedom to choose a provider; the State does not have to ensure that the amount, duration, and scope of services under the program is the same for all individuals; and the State is not required to make Medicaid coverage retroactive to ninety days before eligibility. Tr. Vol. X, at 1357:19 - 1358:23. However, EPSDT services for children, including physician services, are mandatory and cannot be waived. Id. at 1358:14-17; see also Tr. Vol. XI, at 1541:10-12.

7. As part of its application, OHCA set forth eight specific objectives for the SoonerCare program. Pl. Ex. 669, Ch. I, at 14. The first objective for the SoonerCare program was to "improve access to preventive services, primary care, and early prenatal care for Oklahoma's Title XIX population." Id. In implementing SoonerCare, OHCA also sought a "greater degree of budget predictability" by moving from the fee-for-service model to a capitated model, "based on the concept of pre-payment." Id. Under the "capitated" model, the primary care physician ("PCP") receives a monthly payment for each patient regardless of whether the PCP sees each patient in the month for which payment is received. See Tr. Vol. III, at 456:5-15.[2]

8. During 1995, HCFA approved OHCA's waiver application, and SoonerCare was launched. As designed, SoonerCare included two major components, an urban model and a rural model. Pl. Ex. 669, Ch. I, at 15. Under the urban model, known as SoonerCare Plus, the State

---

[2] Foster children are exempt from the SoonerCare program and continue to receive services paid through the traditional fee-for-service. See 42 U.S.C. §1396u-2. These children do not have a medical home or care coordination.

contracted with health maintenance organizations ("HMOs") to enroll and serve recipients in exchange for monthly capitation payments. Id. SoonerCare Plus served beneficiaries residing in the Oklahoma City, Tulsa, and Lawton areas. OHCA Annual Report, Def. Ex. 35, at 26. Under SoonerCare Plus, beneficiaries selected a PCP. Id. The PCP was responsible for coordinating most of the beneficiary's health care, including referrals to specialists. Id. Under the rural model, known as SoonerCare Choice, OHCA contracted directly with PCPs to deliver a defined set of primary care services and care coordination in exchange for a monthly capitation payment. Pl. Ex. 669, Ch. I, at 15. Thus, SoonerCare Plus was fully-capitated, and SoonerCare Choice was partially-capitated.

9. In 1997, the Oklahoma Legislature passed a State law requiring Medicaid coverage of all children in families with a net income of 185% or less of the federal poverty level ("FPL"). Tr. Vol. IX, at 1134:22 - 1135:9. Also in 1997, Congress created the State Children's Health Insurance Program ("S-CHIP"), Title XXI, to cover additional uninsured children with family income up to 200% of the FPL. 42 U.S.C. §§ 1397aa; 1397jj(c)(4). In providing S-CHIP coverage, states were permitted to expand their Medicaid program, to create a new program, or to use a combination approach. Pl. Ex. 657, at 2.

10. On May 26, 1998, OHCA received approval to expand its Medicaid program to accommodate the S-CHIP population. Id. State dollars spent on S-CHIP are matched by the federal government at an "enhanced" rate, "which is higher than the Medicaid rate." Id. Oklahoma receives an 80% federal matching rate for State S-CHIP expenditures, versus a 70% match for the traditional Medicaid population. Tr. Vol. IX, at 1135:11-15. Oklahoma's S-CHIP program expanded Medicaid eligibility to include children, birth to seventeen years of age, from families with incomes at or under 185% of the FPL. Pl. Ex. 657, at 2. OHCA originally estimated that 40,995 newly-eligible children

would be enrolled under the S-CHIP Medicaid expansion. Id. at 2. As of July 12, 1999, OHCA had enrolled approximately 30,000 children through the S-CHIP Medicaid expansion. Id. at 3, 6.

11. Defendant Michael Fogarty has been CEO of OHCA since the year 2000, Tr. 3/14/03 at 202:5-9, and defendant Dr. Lynn Mitchell has been the Medicaid Director at OHCA since the year 2000, Tr. Vol. XIII, at 1690:18-23. As CEO, Fogarty has the duty to assure that Oklahoma's Medicaid program is implemented and administered consistent with the requirements of federal law, including Title XIX. Agreed Pretrial Order and Statement of the Case, Dkt. 196, at 5. As Medicaid Director, defendant Mitchell is responsible for implementing Oklahoma's Medicaid plan, contracting for services, monitoring the program, and ensuring compliance with federal law. Id.

12. In the fall of 2003, OHCA made a decision to dismantle the SoonerCare Plus Medicaid delivery system. Tr. Vol. X, at 1276:3-19. As of January 1, 2004, all of the SoonerCare Plus recipients were immediately transitioned to a fee-for-service program and were to be ultimately transitioned to the Choice delivery system by March 1, 2004. Id. at 1276:12-19. The SoonerCare Plus program was in existence for approximately eight years. Id. at 1272:11-16. As of June 30, 2003, there were 181,451 recipients enrolled in SoonerCare Plus. Def. Ex. 35 at 26. Of those 181,451 enrollees, 145,358 were children. Id. at 19, Fig. 16.

13. When OHCA transitioned from fully-capitated SoonerCare Plus to partially-capitated SoonerCare Choice, 96% of the SoonerCare Plus physicians in the southwest region contracted with SoonerCare Choice; 75% in the Tulsa area contracted; and 80% of the Oklahoma City providers contracted. Tr. Vol. X, at 1348:24 - 1349:12. Under the SoonerCare Plus system, the $200 capitation payment for each patient made twelve-month Medicaid eligibility more expensive than OHCA's budget could bear without additional legislative appropriation. OHCA estimates that,

under the fully-capitated system, it would have spent $2,000,000 a month on recipients who were no longer eligible for the program. By contrast, it expects the cost for recipients no longer eligible under the partially-capitated program to be about $200,000 per month. Tr. Vol. X, at 1265:21 - 1267:2.

2. Population Served

14. The Oklahoma Medicaid program covers children up to age 21 whose family income is 185% of the FPL or less. Tr. Vol. II, at 257:1-8. Approximately 355,000 of the 550,000 Oklahoma Medicaid recipients are children. Tr. Vol. IX, at 1127:5-8. Originally, the managed-care programs did not include Medicaid recipients who were beneficiaries of adoption subsidies, who were in State custody, or who were in an aged, blind, or disabled ("ABD") group with special needs. These individuals were in the fee-for-service program. Eventually, the ABD population was included in managed care. Tr. Vol. II, at 353:11-25.

15. The State of Oklahoma has increased Medicaid ranks by changing the maximum family income allowed from 100% or 133% of the FPL, depending on other characteristics of the recipient, to 185% of the FPL across the board. Tr. Vol. II, at 354:1-13. With 1114 PCPs in the SoonerCare program, the Oklahoma Medicaid system has the capacity to provide health care for 1,048,713 individuals. The SoonerCare population is about one-third that size, at approximately 348,000 recipients. Tr. Vol. XIX, at 2514:20 - 2515:3. Each individual physician's patient capacity is determined by the physician. Tr. Vol. XIX, at 2515:4-9.

16. Based on the number of children previously enrolled in the SoonerCare Plus HMO program, approximately 40% of children on Medicaid reside in urban areas surrounding Oklahoma City, Tulsa, and Lawton. Def. Ex. 35, at 19, 26. All Oklahomans are within forty-five miles of a

PCP contracted with OHCA. Tr. Vol. XIX, at 2517:1-12; Def. Ex. 17. On average, there is one OHCA-contracted pediatrician PCP within fourteen miles of each Oklahoma Medicaid recipient and five OHCA-contracted pediatrician PCPs within thirty-five and one-half miles. On average, there is one OHCA-contracted non-pediatrician PCP within four and one-tenth miles of each Oklahoma Medicaid recipient and five OHCA-contracted non-pediatrician PCPs within ten and nine-tenths miles. Tr. Vol. XIX, at 2518:21 - 2519:20; Def. Ex. 17.

17. The United States is one of twenty-five countries with established market economies--so-called developed nations. Of all nations, the United States, at $5,440 per capita, spends more on health care per person than any other country. The rest of the market-economy nations spend about $2,400 per capita for health care. The United States, however, is near the bottom of the market economies in the health of its population, as measured by life expectancy, infant mortality, age-adjusted death rates, and other health standards. Tr. Vol. VI, at 680:20 - 681:9.

18. Among the fifty states, Oklahoma ranks third highest in per capita cost of health insurance premiums. Tr. Vol. VI, at 681:12-16. Despite these health insurance premiums, Oklahoma is the only state whose health status has worsened since 1990, as measured by life expectancy and age-adjusted death rates. Tr. Vol. VI, at 683:7-16. In other words, poor health is a problem in Oklahoma for both Medicaid and non-Medicaid recipients. Tr. Vol. II, at 233:17-23. The health status of Oklahoma's poor children, in particular, has declined since 1990. Tr. Vol. VI, at 683:7 - 684:16. The number of children in Oklahoma without health insurance or Medicaid coverage is 40% higher than in the United States as a whole. In part, Oklahoma's worsening health status is the result of the uninsured and uncovered population. Tr. Vol. VI, at 684:9-23.

19. The poor health status of Oklahoma's children relative to other parts of the United States can also be attributed to Oklahoma's large number of unmarried teenagers who become pregnant, lower immunization rate, high rates of smoking and other tobacco use, high incidence of obesity, high rate of illegal sales of liquor to minors, high level of teen deaths in motor vehicle accidents, high teenage suicide rate, high numbers of child abuse and neglect cases, as well as the State population's general lack of exercise, television watching, low public-water-supply fluoridation, low use of automobile seat belts, and poor nutrition. Tr. Vol. VI, at 687:4 - 690:22; 702:11 - 703:17.

20. Children in financially-needy families and in State custody have greater health care needs than other children. Pl. Ex. 184, at BB.7361-62; Pl. Ex. 41, at BB.6721-23; see also Colleen A. Foley, Comment, The Doctor Will See You Now: Medicaid Managed Care and Indigent Children, 21 Seton Hall Legis. J. 93, 107-108 (1997). Stress associated with low wages, substandard housing, violence, and inadequate nutrition also contributes to higher rates of physical and mental illness for poorer children. Sidney D. Watson, Commercialization of Medicaid, 45 St. Louis U.L.J. 53, 56-57 (2001). Low-income children are more likely than other children to suffer from low birth weight, lead poisoning, rheumatic fever, and asthma, as well as vision, dental, speech, and behavioral problems. Foley, supra, at 108.

3. Funding

21. OHCA's state and federally-funded budget is set by the Oklahoma Legislature at approximately $2,500,000,000 annually. Tr. Vol. IX, at 1128:7-14. Federal funds currently

constitute about 70% of that amount and state funds constitute the remainder.[3] Id. at 1130:7-12. The agency allocates the legislative appropriation by type of service, such as physician services and hospital services. Id. at 1130:19 - 1131:6.

22. OHCA always receives a smaller legislative appropriation than it requests; however, deficit spending is not an option under Oklahoma law. Id. at 1131:14-22; 1132:15-18. OHCA has consistently requested funding from the Legislature to raise physician payment rates to 100% of the Medicare rate but the Legislature has consistently denied that request. Id. at 1181:23-25; Tr. Vol. X, at 1345:10 - 1346:3. OHCA may ask for a supplemental appropriation when the Oklahoma Legislature is in session and has done so often since its inception in 1995; however, the supplemental requests have not been fully funded by the Legislature. Tr. Vol. IX, at 1133:23 - 1134:13.

4. Rates

23. With the elimination of SoonerCare Plus, OHCA pays for a limited proportion of the medical services delivered to children served by Oklahoma's Medicaid system on the basis of fee-for-service. However, all children who are assigned to the SoonerCare Choice program, even infants, are initially in the fee-for-service delivery system.

24. Generally, when medical services are delivered on the basis of fee-for-service, physicians bill on the basis of procedures described in terms of "Current Procedure Terminology" or "CPT codes." See Tr. Vol. VI, at 663:25 - 664:4. CPT codes are published by the American Medical Association and mandated by federal law. There are two major categories of CPT codes:(1)

---

[3] The Court notes that, at this writing, the federal contribution will be decreased in October 2005 to about 68%. Barbara Hoberock, *Federal Medicaid Funds to Drop*, Tulsa World, January 30, 2005, at A15.

evaluation and management ("E and M") codes, and (2) procedure codes. E and M codes are best described as "office visit codes." Tr. Vol. I, at 38:23-25. Procedure codes are the codes used by physicians to bill for all non-E and M services. Tr. Vol. XVI, at 2175:10-17. All surgical and diagnostic procedures, for example, are billed as "procedure" services. Tr. Vol. V, at 579:22 - 580:12; Tr. Vol. XI, at 1512:6-14.

25. From 1995 through December 31, 2003, provider reimbursement under Oklahoma's Medicaid's fee-for-service schedule never exceeded 72% of Medicare. Agreed Pretrial Order and Statement of the Case, Dkt. 196, at 7; see Tr. Vol. X, at 1214:23 - 1215:23. Just months before the beginning of the trial of this matter, OHCA increased the fees for E & M codes to 90% of Medicare. Tr. Vol. XIX, at 2521:16-18; see Tr. Vol XV, at 1950:2-3.[4] According to Deborah Ogles, financial management director of OHCA, currently, physicians are reimbursed under Oklahoma's Medicaid fee-for-service fee schedule for "most codes," referring to the procedure codes, at "about 71 per cent of Medicare." Tr. Vol. XV, at 1949:24 - 1950:2.

26. OHCA sets its fee-for-service rates by determining its budget and setting a conversion factor on the basis of this sum. Id. at 1953:24 - 1954:8. "OHCA's stated performance measure for compliance with the equal access mandate is to raise provider reimbursement rates under Medicaid to 100% of the Medicare Fee Schedule." Agreed Pretrial Order and Statement of the Case, Dkt. 196, at 6. Yet, even 100% of Medicare is not considered an adequate rate to secure

---

[4] The E and M codes rate increase was funded through a temporary increase of the federal match. Tr. Vol. X, at 1219:1-23. The result is that this rate increase has not been built into the agency's budget. Id. at 1218:25 - 1219:7. At the time of trial, the increased rate was funded for 18 months only. Id. at 1219:17-23.

sub-specialists. See Tr. Vol. VI, at 665:2-5; Tr. Vol. VIII, at 1011:11-24 ("Medicare . . . is not a very good fee schedule to begin with.").

27. Under commercial plans, Oklahoma physicians are reimbursed at rates of 130% to 180% of Medicare. Tr. Vol. V, at 580:21-25; Tr. Vol. VII, at 942:21 - 943:4; Tr. Vol. VIII, at 1012:2-10. The average of the top five rates paid by private insurance companies to the university physicians is 140% of Medicare. Tr. Vol. XV, at 1971:13 - 1972:2. OHCA has received approval from CMS to raise rates to 140% of Medicare for the physicians who are employed by the State universities. This rate is sufficient to meet the current needs (but not any increased capacity) of medical practice at the University of Oklahoma ("OU") Children's Hospital. Tr. Vol. I, at 102:9-16. State university-employed physicians are located in Tulsa at the OU Medical School and the Oklahoma State University ("OSU") Osteopathic College of Medicine, in Oklahoma City at the OU Health Sciences Center, and at various residency programs around the State, such as at Enid, Lawton, Duncan, and Bartlesville. Tr. Vol. I, at 96:8 - 97:5; Tr. Vol. X, at 1235:18-23.

28. While most of the medical services provided by PCPs are included in a monthly capitated rate (discussed below), the medical services provided by non-pediatrician specialists and sub-specialists are paid for on a fee-for-service basis. Tr. Vol. X, at 1213:18-23. Accordingly, those specialists who primarily perform procedures such as surgery are paid approximately 72% of Medicare for most of their services. See Tr. Vol. XI, at 1512:2-14.

29. One physician service that is not set as a percentage of Medicare is the case rate paid to emergency room ("ER") physicians. ER physicians receive $25 for seeing a child on Medicaid regardless of time expended or procedures performed. Tr. Vol. XVIII, at 2391:16-23. But, like the fee-for-service rates, the ER case rate was also set on the basis of the money available, and not on

the basis of how those services are valued in the private market. Id. When OHCA increased the rate for the E and M codes to 90%, it did not increase the ER case rate. Id. at 2393:18-23.

30. SoonerCare Plus has been eliminated and, currently, all recipients who were in that program have been assigned to SoonerCare Choice and a PCP. The SoonerCare Choice primary care case management ("PCCM") model is now the primary Medicaid delivery system statewide.

31. Currently, all SoonerCare Choice PCPs are paid a monthly capitated rate for a fixed set of services. Def. Ex. 35 at 27; see Pl. Ex. 224 at BB.7789. Most of the "office visit" E and M codes are absorbed into the Choice capitated rate. Tr. Vol. XX, at 2548:20-21. When OHCA increased E and M codes under the fee-for-service fee schedule to 90% of Medicare, there was no adjustment to the SoonerCare Choice capitation rates. Agreed Pretrial Order and Statement of the Case, Dkt. 196, at 9, ¶24.

32. Defendants believe that managed care is not necessarily a disincentive to providing EPSDT services. Tr. Vol. XVI, at 2111:14 - 2112:2. However, capitated programs such as Oklahoma's SoonerCare Choice can create "a financial incentive to underserve or deny beneficiaries access to needed care." Pl. Ex. 14, "Medicaid: Stronger Efforts Needed to Ensure Children's Access to Health Screening Services," U.S. GAO Report to Congressional Requesters, GAO-01-749 Medicaid EPSDT Services, July 2001, at 8. This is a problem that defendant Fogarty acknowledged. Tr. Vol. X, at 1285:5-17. Dr. Ramadan, a pediatrician in Ada, Oklahoma, testified that he refuses to participate in the PCP program because of its incentives to collect money without treating patients. Tr. Vol. IX, at 1104:6 - 1105:7.

5. Services

33. Title XIX mandates that EPSDT screening services are to be provided "at intervals which meet reasonable standards of medical and dental practice as determined by the State after consultation with recognized medical and dental organizations involved in child health care . . . ." 42 U.S.C. § 1396d(r)(1)(A)(i). Pursuant to this requirement, each Medicaid agency must establish a screening "periodicity schedule" to be followed by participating providers. State Medicaid Manual, Pl. Ex. 2, at § 5140. Defendants are also required to establish periodicity schedules for dental, vision, and hearing services. Id.; 42 U.S.C. § 1396d(r)(2), (3) and (4). In addition, immunizations are to be given in accordance with the schedule established by the Advisory Committee on Immunization Practices for pediatric vaccines. 42 U.S.C. § 1396d(r)(1)(A)(i); State Medicaid Manual, Pl. Ex. 2, at § 5122(A). EPSDT's medically necessary health care provision includes all medically necessary surgery, hospitalization, prescriptions, and behavioral health services. Tr. Vol. II, at 254:185 - 255:21.

34. "Services under EPSDT must be sufficient in amount, duration, or scope to reasonably achieve their purpose." State Medicaid Manual, Pl. Ex. 2, at § 5110. Defendants acknowledge this prohibits "arbitrary limits" on the provision of services under EPSDT. Tr. Vol. II, at 266:13-15. The federal government has also instructed defendants to "[b]roaden the EPSDT provider base" to include physicians in the public and private sectors. State Medicaid Manual, Pl. Ex. 2, at § 5220; Tr. Vol. II, at 270:21 - 271:5. OHCA pays the State Health Department to do EPSDT screenings at schools. Tr. Vol. X, at 1306:2-21.

35. Federal law also requires that defendants inform all eligible individuals under 21 and their families about EPSDT. 42 U.S.C. § 1396a(a)(43). In states like Oklahoma, where recipients are served by continuing care PCPs, those PCPs must furnish notification to recipients that they are

due to receive an EPSDT screening service. State Medicaid Manual, Pl. Ex. 2, at § 5310(D); Tr. Vol. XIII, at 1705:4-13. OHCA provides EPSDT education to providers and welfare agencies and EPSDT informational materials to county health departments, health care providers, DHS, the Women, Infants and Children program, SoonerStart and Children First programs in the State Health Department, Head Start, and school districts for dissemination to parents. Tr. Vol. II, at 294:21 - 295:8; 344:22 - 346:14; Tr. Vol. XIV, at 1794:23 - 1795:14.

36. In addition, OHCA provides parents with flyers and information booklets about EPSDT and sends them letters telling them when their children's EPSDT screenings are due. Tr. Vol. II, at 261:2-8; 345:19 - 346:14; Tr. Vol. XIV, at 1794:3-20. OHCA also sends parents a postcard describing EPSDT and reminding them of the need for a screening, as well as a postcard informing recipients of the SoonerCare help line, nurse advice line, and SoonerRide telephone numbers. This is recognized as a good way to increase EPSDT participation. Def. Ex. 9; Tr. Vol. II, at 349:2-16. In addition to separate educational pieces, the EPSDT information is also provided in the SoonerCare member handbook, which is printed in English, Spanish, and Vietnamese. Tr. Vol. XIV, at 1794:1-3.

37. OHCA's EPSDT guide sent to parents explains what EPSDT is, the age when screenings should be done, what an EPSDT screen includes, how to schedule EPSDT appointments, and the availability of SoonerRide transportation. Def. Ex. 1; Tr. Vol. II, at 346:15 - 348:20. When parents cannot understand the correspondence and other written materials sent them by OHCA, they contact the EPSDT division by telephone and ask for clarification, which is provided. Tr. Vol. II, at 368:20 - 369:17.

38. Outside of efforts by OHCA to educate and contact Medicaid recipients about EPSDT screening, health care providers also attempt to educate and contact such recipients, but the Medicaid recipients do not always appear for the screenings. Tr. Vol. I, at 113:16-21. OHCA notifies PCPs of children on their monthly roster of patients who have not received a recent EPSDT screening. See Tr. Vol. II, at 293:15-24; 338:2-7.

39. If parents do not access health care for their Medicaid recipient children through scheduled EPSDT screenings, OHCA contacts the parents to remind them of the need for examination. These communications occur more often than the annual contact recommended by CMS. See id. at 278:18-24.

40. OHCA works with the Oklahoma State Health Department, Department of Education, Department of Human Services, Office of Juvenile Affairs, and Department of Mental Health and Substance Abuse Services to provide services and outreach to Medicaid recipients. Tr. Vol. XIX, at 2529:9 - 2534:17. To increase historically low Medicaid participation, OHCA reduced the Medicaid application form from seventeen pages to one page, eliminated the financial assets test for individuals in the federal Temporary Aid to Needy Families ("TANF") program, and abolished the need for potential recipients to go to a DHS office to apply. These efforts caused a doubling in the Oklahoma Medicaid program. Tr. Vol. XVII, at 2276:14 - 2278:8.

41. OHCA uses radio and television public service announcements, newspaper advertisements, natural gas bill inserts, McDonald's restaurant tray liners, manned booths at state and community fairs, and flyers and posters in public office buildings, county welfare offices, doctors' offices, and libraries to make Oklahomans aware of the Medicaid program. The agency also provides forms to schools so children or parents can notify OHCA of their interest in the

Medicaid program. Tr. Vol. XX, at 2593:16 - 2594:16; 2598:1-13. OHCA's written materials are produced at a sixth-grade reading level, according to the Fleisch-Kincaid Scale. Id. at 2594:23 - 2595:6. OHCA also operates an Internet web site with program information. Id. at 2596:21-2597:3; see Tr. Vol. I, at 143:14-20.

42. Some Medicaid recipients do not have telephones. Tr. Vol. I, at 94:17-18; 112:16-19. Medicaid recipients also tend to be more mobile and this makes it difficult to send mailings to them. Tr. Vol. I, at 112:7-15. Health care providers have complained that Medicaid recipients miss appointments, smell bad, behave badly, bring destructive children to the providers' waiting rooms, and use emergency rooms unnecessarily. In response to that criticism, OHCA developed literature and had face-to-face meetings with Medicaid recipients explaining the importance of keeping appointments, personal hygiene, and appropriate use of emergency room, among other things. Tr. Vol. X, at 1335:18 - 1336:18.

43. OHCA provides Medicaid recipients a member handbook, which explains resources available, how to use the program, how to set an appointment, and what to do if the recipients have a medical question. It also lists health care providers available, EPSDT screening information, and telephone numbers for the nurse advice line and the SoonerCare help line. Tr. Vol. XX, at 2595:7-24. This information is provided in English, Spanish, and Vietnamese and on audiotape. Id. at 2595:25 - 2596:19. CMS has recognized OHCA's recipient manual as one of the "best practices" in the national Medicaid program. Tr. Vol. II, at 342:20 - 343:3.

44. Prior authorization is OHCA's approval of a health service or item before a Medicaid recipient is entitled to receive that service or item. Compared with private insurance, few Medicaid

services or items require prior authorization. Prior authorization is required for motorized wheelchairs and transplant services. Tr. Vol. XIX, at 2535:22 - 2536:13; 2536:23 - 2537:7.

B. OHCA'S ADMINISTRATION OF THE MEDICAID PROGRAM FOR CHILDREN

1. Provider Participation

a. Pediatricians

45. According to a 2003 survey conducted by the AAP, only 34% of Oklahoma's pediatricians participate fully in the Medicaid program by accepting all new Medicaid patients. Kletke Report, Pl. Ex. 203, at BB.10717.[5] At the same time, 69% of Oklahoma's pediatricians accept all new privately-insured patients. Id. In 2000, approximately 32% of Oklahoma's pediatricians participated fully in Medicaid. Id. at BB.10718; Tr. Vol. XII, at 1605:21-24. At 32% participation, Oklahoma had the second lowest percentage of Medicaid pediatrician participation in the nation. Kletke Report, Pl. Ex. 203, at BB.10734, Fig. 1.

46. The 2003 data show that only 18% of Oklahoma's office-based primary care pediatricians in private practice fully participate in Medicaid. Id. at BB.10746, Table B-1. For office-based non-primary care pediatricians in private practice, which includes sub-specialists, only 36.8% fully participate in the Medicaid program. Id. There is a much higher participation rate (80.8%) for non-office based pediatricians, which includes pediatricians employed by hospitals and

[5] Evidence of the degree of pediatrician participation is important because defendants have no system to identify specialists who have stopped accepting Medicaid patients or who have limited their Medicaid practice. Agreed Pretrial Order, Dkt. 196, at 9, ¶ 19. Further, defendants' list of contracted providers does not indicate whether any of those providers are actually accepting Medicaid patients. Id. at ¶ 21.

clinics, medical schools or universities, community health centers, and "other" patient care employment settings. Id. at BB.10715, n. 4.

47. Plaintiffs' statistics expert, Dr. Phillip Kletke, refers to these non-office based pediatricians as "safety net" providers, as they are pediatricians who "devote much of their practice to those patients who are not getting health care anywhere else." Tr. Vol. XII, at 1610:17-24. The data in Oklahoma demonstrate that the safety net pediatricians are already at "full [patient] capacity or beyond." Id. at 1614:1-4; see Tr. 3/14/03, at 152:11-19; Tr. Vol. I, at 29:19 - 30:10. On the other hand, the majority of Oklahoma pediatricians who limit their Medicaid participation have the practice capacity to accept additional patients. Kletke Report, Pl. Ex. 203 at BB.10717.

48. OHCA originally assigned all individuals in a family to the same PCP. When pediatricians complained that such assignment prevented them from receiving child patients whose parents were also on Medicaid, OHCA altered the assignment process and allowed children to be assigned to pediatrician panels. Tr. Vol. VII, at 919:13-22; Tr. Vol. X, at 1325:11 - 1326:12. Data reviewed by OFMQ "suggest that the practice of encouraging parents to choose [a] Pediatrician[] as their child's PCP may result in more beneficial immunization outcomes." Pl. Ex. 579 at 17. Indeed, some children have health needs that require the care of a pediatrician. See Tr. Vol. XIII, at 1741:16-23. However, many Medicaid children, including children who need the care and supervision of a pediatrician, do not have access to pediatricians.

49. The lack of pediatricians denies children needed diagnostic and treatment services. A pediatric cardiologist testified that he sees an "extraordinary number" of Medicaid children who find themselves in the hospital when their undiagnosed congenital heart disease becomes malignant. Tr. Vol. XI, at 1502:21 - 1503:20. Identifying congenital heart defects in children is difficult, but

easier for pediatricians than family practice doctors or general practitioners. In addition, doctors are more likely to identify congenital heart disease in privately-insured children than in Medicaid children. Id. at 1503:21 - 1504:12. If children do not regularly see a pediatrician for primary care, other serious conditions, such as cerebral palsy, may also go undetected, thus foreclosing early intervention treatments. See Crocker Trial Dep., Pl. Ex. A (attached to Pl. Proposed Findings and Conclusions, Dkt. 233), at 22:17 - 23:20.

50. Pediatricians needed for follow-up care are not readily available. Dr. Jackson testified that he has had great difficulty finding pediatricians who will provide care to his complex patients. Tr. Vol. XI, at 1505:4-9. Only 5%-10% of Dr. Jackson's current Medicaid patients are seen by pediatricians for follow up. Id. Dr. Banner has great difficulty finding pediatric PCPs to provide follow-up for his Medicaid patients in the Saint Francis PICU. Tr. Vol. IV, at 489:10 - 491:4. From a medical standpoint, Dr. Banner's patients in the PICU are often "very complicated," and a pediatrician is more apt to provide care to such complex patients. Id. at 490:24 - 491:4.

51. The lack of pediatricians participating in the SoonerCare Choice program has actually caused Dr. Banner, a pediatric intensivist, to serve in a primary care role for some complex Medicaid patients "because they just can't access it." Id. at 494:10 - 495:4. In one particular case, a child with spina bifida, a congenital spinal cord disorder, lost her pediatrician PCP. Id. After the child was re-assigned to a non-pediatrician PCP, she was readmitted to the PICU "multiple times." Id.

52. Dr. Siegler, a pediatric neurologist, testified that he treats class members with complicated medical problems who are assigned to nurse practitioners or physician's assistants as their PCPs. Tr. Vol. V, at 587:19 - 588:20. Dr. Siegler has some concern about sending a "really involved child," such as a child with epilepsy, back to a nurse practitioner for primary care. Id.

Children with such complex neurological conditions need a physician for follow up care, yet many children do not have access to a physician. Id.

53. Children living in rural Oklahoma counties often do not have access to pediatricians for primary care. In Ottawa County, for example, there is only one physician, a family practice doctor, who accepts Medicaid. Pl. Ex. 527 at 32. Currently, there are no pediatricians in Ottawa County, and the local hospital has not been able to successfully recruit a pediatrician for Ottawa County, in part because of the high percentage of Medicaid patients and low reimbursement rates. Tr. Vol. VII, at 932:1-22. A number of Medicaid patients in Ottawa County are assigned to the "Sunshine Clinic" as their PCP. Pl. Ex. 527 at 32; Tr. Vol. VII, at 924:19 - 925:1. Dr. Thomas Osborne testified that the Sunshine Clinic was created by the local hospital for the specific purpose of attempting to provide care for the children of Ottawa County, primarily Medicaid patients, who had "no other place to go . . . ." Id. at 931:2-8. The Sunshine Clinic is staffed by a nurse practitioner and a physician's assistant. Id. at 924:19 - 925:6. No physicians actually see patients at the Sunshine Clinic. Id. at 925:10-12.

54. The last pediatrician to practice in Ottawa County, Dr. Tom Tryon, now practices in Joplin, Missouri. Tr. Vol. VII, at 898:10 - 899:14. Dr. Tryon currently sees Medicaid patients from Ottawa County on occasion who appear at the hospital in Joplin. Id. at 915:23 - 916:8. One of these Medicaid patients, a child with severe asthma, was admitted to the hospital in respiratory distress. Id. at 916:9-20. If the child were on Dr. Tryon's panel, he would be one of Dr. Tryon's more complicated patients. Id. Upon discharge, this child's follow-up treatment was provided at the Sunshine Clinic. Id.

55. None of the pediatricians in Pontotoc County, Oklahoma is currently a SoonerCare PCP for children on Medicaid. Tr. Vol. I, at 152:14 - 153:24. The mother of two named plaintiffs testified that she would like for her children to have a pediatrician as their PCP, but they have been assigned to a general practitioner. Id.

b. Sub-Specialists

56. As noted above, HCFA conducted an audit in 1999 of Oklahoma's SoonerCare program. The findings of that audit were published in a report entitled Medicaid Program Review of Oklahoma's SoonerCare Program. In its audit, HCFA found deficiencies regarding access to specialty care in the SoonerCare Choice program.[6] Pl. Ex. 20 at BB.5272. Specifically, HCFA found the following problems with access to specialty care under SoonerCare Choice:

> PCPs are experiencing difficulty in locating speciality providers for their SoonerCare Choice patients. . . . [T]he proportion of Medicaid specialty providers that are willing to accept their patients has steadily dropped since the inception of the program . . . . [T]hey [PCPs] often spend considerable time and effort attempting to locate a specialist for their patients, frequently resorting to negotiation to secure the care their patients require. Patients in Konawa and Wewoka must often be referred to providers in Oklahoma City rather than closer providers in Ada and Shawnee. Many PCPs pointed to this issue as a major source of frustration and a significant factor in their decision to continue to participate in the SoonerCare Choice program.

---

[6] HCFA also identified deficiencies in access to specialty care for SoonerCare Plus members. Pl. Ex. 20 at BB.5287. Specifically, HCFA noted ". . . a shortage of pediatric sub-specialists which continues to be a problem and needs improvement." Id. HCFA found that "specialists primarily do not participate because of the lack of sufficient reimbursement for specialty care and an unwillingness to participate in SoonerCare or any other type of managed care model." Id. As a result, HCFA recommended that OHCA "[e]nsure that the [SoonerCare Plus HMOs] are trying to recruit and contract with more pediatric sub-specialists." Id. Nearly four years after issuance of HCFA's Medicaid Program Review, defendants admitted that OHCA had taken no specific action to recruit sub-specialists for the SoonerCare HMOs. Agreed Pretrial Order, Dkt. 196, at 8, ¶ 17.

Id. HCFA also found that "OHCA was cognizant of the [access to specialty care] problems but had not yet established a method of monitoring this in a systematic manner." Id.

57. OHCA responded to HCFA's concerns about access to specialty care in the Choice program by admitting that "*SoonerCare Choice* is aware of and had already identified the concerns outlined by HCFA regarding access to specialists for *SoonerCare Choice* members." Id. at BB.5273. OHCA represented to HCFA that it had addressed the access to specialty care problem by "reviewing access to specialty physician care on a case by case basis" and by creating "a Specialist Referral Directory for *SoonerCare Choice* providers." Id. at BB.5273, BB.5274. Despite this representation, OHCA currently does not provide a list of specialists to its PCPs. Agreed Pretrial Order and Statement of the Case, Dkt. 196, at 9, ¶ 20. Indeed, defendants have no system that enables them to identify the sub-specialists who are participating in Medicaid. Id. at 8, ¶ 16.

58. However, OHCA provider representatives have attempted to recruit specialists throughout Oklahoma. Tr. Vol. II, at 273:20 - 274:9. In addition, OHCA provides referral assistance to PCPs seeking the care of specialists. Tr. Vol III, at 414:3 - 415:2. OHCA has employed additional exceptional needs coordinators whose function is to help PCPs find needed specialists. Tr. Vol. X, at 1331:8-22. At the time of trial, OHCA had 21 or 22 nurses who served as exceptional needs coordinators. The agency was in the process of hiring more to bring the number to 30. Id. at 1318:8-14. OHCA exceptional needs coordinators are helpful to PCPs attempting to make referrals to specialists and dentists for Medicaid patients. Tr. Vol. VIII, at 963:11-17; 977:12-19.

59. OHCA also created a "medical referral" to allow an exceptional needs coordinator to approve an immediate referral to a specialist without going through the normal approval process

requiring communication from the patient's PCP. Tr. Vol. X, at 1329:17 - 1330:3. In response to provider complaints about the process for referring patients to specialists, OHCA created a "standing referral" that allows a PCP to make a referral once rather than every time a patient needs an appointment with the specialist. Tr. Vol. X, at 1329:3-16. OHCA also created provider representatives to assist PCPs' and specialists' offices with the Medicaid program. At the time of trial, the agency had eight provider representatives and two more were to be hired. Tr. Vol. X, at 1331:23 - 1332:16.

60. OHCA's increase in payment rates for E and M codes to 90% of Medicare has helped PCPs obtain referrals to specialists for Medicaid patients. Tr. Vol. VIII, at 963:17-20. The higher rate for university-based physicians will also help OU recruit additional speciality physicians to Oklahoma. Tr. Vol. XVII, at 2216:11 - 2217:13.

i. Pediatric Neurology

61. According to OHCA's Care Management Director, there are six pediatric neurologists who practice in Oklahoma: two in Oklahoma City; three in Tulsa; and one in Durant. Tr. Vol. XIV, at 1862:3-18; see Tr. Vol. V, at 569:18-19. Only four see any Medicaid patients: two in Oklahoma City; one in Tulsa; and one in Durant. Tr. Vol. XIV, at 1862:3-6. The pediatric neurologist who sees Medicaid patients in Durant comes in from north Texas and practices at a part-time satellite clinic. Id. at 1863:19-25. In addition, OHCA contracts with a pediatric neurologist in Wichita, Kansas. Id. at 1849:4-20. It is difficult for all patients, Medicaid and non-Medicaid, to access pediatric neurologists. Tr. Vol. I, at 101:18-25 - 102:8; Tr. Vol. III, at 418:14-24. There is a shortage of pediatric neurologists nationally, but Oklahoma's shortage in this field is more severe.

Oklahoma is a crisis area for pediatric neurology. Tr. Vol. I, at 140:25 - 141:1; Tr. Vol. V, at 592:24 - 593:2; Tr. Vol. XI, at 1449:23-25.

62. The one pediatric neurologist who sees some Medicaid patients in Tulsa, Dr. David Siegler, is not accepting any new Medicaid patients. Tr. Vol. XIV, at 1862:3-10; Tr. Vol. V, at 576:23-25. Until recently, Dr. Siegler practiced in a group with the two other pediatric neurologists in Tulsa. Tr. Vol. V, at 568:23 -569:7. The group limited its acceptance of Medicaid patients, as well as the time it set aside for Medicaid patient appointments. Id. at 569:25 - 573:6. Further, it implemented a "screening process" which required parents of Medicaid children to fill out an "involved" form describing the child's condition, treatment and medications, and, even if completed, did not guarantee an expeditious appointment. Id. at 572:1-573:1. Over time, the group further limited the Medicaid patients to only those with "epilepsy and spasticity." Id. at 573:9-22.

63. OHCA's Care Management Director testified that over the past year, Medicaid children with seizure disorders have had to wait upwards of six months for an appointment with a pediatric neurologist. Tr. Vol. XIV, at 1868:10-18. Dr. John Stuemky's Medicaid patients in Oklahoma City with seizure disorder must wait around a year to be seen by a pediatric neurologist. Tr. Vol. I, at 53:22 - 54:2. Some of these patients have poorly controlled seizures, and without the prompt care of a neurologist, the seizures will have a negative impact on school performance, development, behavior, and the "overall medical well-being" of these children. Id. at 54:7-16; Tr. Vol. IV, at 551:9-18. Other pediatricians testified as to the problems and difficulties they experience in securing timely appointments for their Medicaid patients, especially those with chronic and congenital conditions, who need the services of pediatric neurologists with offices relatively close

to their homes. <u>See</u> Tr. Vol. IV, at 548:24 - 549:12; 550:23 - 551:8; 551:23 - 552:24; Tr. Vol. III, at 396:6 - 398:8; Tr. Vol. II, at 214:5 - 218:13.

64. Several parents of class members testified as to serious problems their children have experienced in attempting to access pediatric neurological care. <u>See</u> Tr. Vol. VI, at 723:3 - 725:18; Tr. Vol. VI, at 773:11 - 778:20; Tr. Vol. IX, at 1095:22 - 1099:2. One parent, in particular, testified that she had to drive her daughter four hours to see a pediatric neurologist, and her daughter experienced a severe seizure en route. Tr. Vol. IX, at 1097:9- 1098:17.

65. Dr. Siegler testified that children on Medicaid do not have the same access to neurological services provided to children with private insurance because of low or nonexistent Medicaid reimbursement. Tr. Vol. V, at 597:2-25. The recent increase to 90% for E and M codes does not resolve the payment problems. <u>Id.</u> at 599:22 - 600:4. There is some work, <u>e.g.</u>, coordination of care, for which Medicaid will not pay. <u>Id.</u> at 597:10-25.

66. OHCA claims that its exceptional needs coordinators have always been able to obtain appointments for pediatric neurology of Oklahoma Medicaid patients requesting assistance themselves or through their physicians, Tr. Vol. XIV, at 1850:11-19, but this evidence did not address timeliness or distance issues.

ii. Otorhinolaryngology ("ORL") / Ear, Nose and Throat ("ENT")

67. There is an insufficient level of Medicaid participation on the part of ENT or ORL specialists. Office-based ENT specialists in Oklahoma will not see children on Medicaid. The wait for a Medicaid child to see an ENT specialist at the OU Medical Center is three months and an additional two to three months if surgery is needed. Tr. Vol. VI, at 665:23 - 666:4. The lack of Medicaid participation by private practice ENT specialists has created "almost a crisis situation" at

the OU Medical Center in Oklahoma City. Tr. Vol. I, at 52:16 - 53:1. Dr. Stuemky testified that children with private insurance have no problems accessing ENT services. Tr. 3/17/03 at 57:5-10 ("almost anytime, almost anywhere.").

68. Dr. Joseph Leonard, an ENT specialist in Oklahoma City, notified OHCA CEO Fogarty in a December 2000 letter that his group would no longer be accepting Medicaid patients. Pl. Ex. 208; Tr. Vol. VI, at 662:14 - 663:5. In the letter, Dr. Leonard raised several serious concerns regarding problems with the billing process and low reimbursement rates. Dr. Leonard also set out in the letter his concerns about access to ENT services for Medicaid children if changes were not made. OHCA has made no attempt to convince Dr. Leonard to stay in the Medicaid program. Id. at 663:19-24.

69. Dr. Block characterized children on Medicaid as having "very little access" to ENT specialists in Tulsa, while he has no problem finding ENTs willing to take his privately-insured patients. Tr. Vol. XVIII, at 2323:15-25; Tr. 3/14/03, at 167:11 - 168:22. The largest group of ENT physicians in Tulsa does not accept Medicaid patients. Tr. Vol. VII, at 950:3-5. This lack of ENT access is depleting the resources of some pediatric general surgeons in Tulsa, who, as of the time of trial, do not decline children on Medicaid. See Tr. Vol. VII, at 951:22 - 952:2.

70. Dr. Jane Thomason testified that she has had difficulty finding ENTs willing to take her Medicaid patients because the one ENT in Ponca City would not accept them, and only recently agreed to take "a select few." Tr. Vol. III, at 388:8-24; 412:5-8. She previously had to refer all of her Medicaid patients in need of ENT services to Oklahoma City or Tulsa. Id. at 391:20-24. Further, the children had to wait from two to four months to be seen by an ENT specialist, even

though the waiting period for a privately insured patient was around two weeks. Id. at 392:21 - 393:4.

71. Dr. Eve Switzer testified that the ENT specialists in Enid will not see Medicaid patients unless it is an emergency. She refers Medicaid patients who are not in emergency situations to ENTs in Stillwater or Oklahoma City, and the wait is generally from several weeks to a month. Tr. Vol. IV, at 549:19-25. The lack of ENT availability has led her to attempt to manage Medicaid children's uncontrolled ear infections with antibiotics, with the risk of creating "antibiotic resistant organisms." Tr. Vol. IV, at 550:3-22.

72. Chrystal McQuerry lives in Ponca City, Oklahoma. She testified that her PCP in Enid referred her son, Mason M., to an ENT in Stillwater, and Mason saw that ENT approximately one month after the referral. The Stillwater ENT subsequently referred Mason to an ENT in Oklahoma City, who saw Mason within two or three weeks. Tr. Vol. VI, at 720:13 - 722:7

73. Delays in treatment of chronic ear infections can result in developmental delays in children. Dr. Thomason testified that a two-month delay in seeing an ENT specialist for a child with problems such as chronic ear infections or fluid in the ears can lead to delay in the development of language skills. Tr. Vol. III, at 393:5-23. Dr. Leonard also testified as to the types of medical problems that a three- to six-month delay in receiving ENT specialty services can cause. Tr. Vol. VI, at 665:21 - 667:6. According to Dr. Leonard, around 50% of children who do not receive needed ENT services during the first year of life end up in special education classes due to hearing loss and learning disabilities. Tr. Vol. VI, at 666:7-18.

iii. Orthopedics

74. Oklahoma has only five or six pediatric orthopedists. Tr. Vol. VIII, at 1039:3-10. Pediatric orthopedists are in short supply nationwide. Tr. Vol. XI, at 1450:1-3. In Tulsa, Dr. Richard Ranne describes access to doctors who accept Medicaid as "extremely poor." Tr. Vol. VII, at 949:21 - 950:2. There are no orthopedists on staff at St. Francis Hospital who will accept children with Medicaid.[7] Id. Dr. Frederick Cohen, a Tulsa pediatrician, testified about a six-week ordeal his office encountered attempting, without success, to secure an orthopedic consult for a four-year-old girl with a fractured toe. Tr. Vol. XII, at 1579:3 - 1582:12. Calls to OHCA's case manager failed to identify any orthopedist in Tulsa available to provide services. Id. at 1581:10-18.

75. Dr. Mark Capehart, Tulsa's only fellowship-trained pediatric orthopedic sub-specialist, no longer accepts Medicaid. Tr. Vol. VIII, at 1031:10-16 and 1035:12-16. The lack of access to a pediatric orthopedist denies children with complex orthopedic problems needed care. General orthopedists do not typically "feel comfortable" treating complex scoliosis, dislocated hips, or spina bifida. Id. at 1034:25 - 1035:4. Failure to identify and treat an infant's dislocated hip can result in pain, "shortening of the leg[,] a severe limp[,] and ultimately arthritis of the hip, requiring a hip replacement." Id. at 1033:25 - 1034:10. Children born with club feet require weekly castings for their first three months or appropriate surgery. Id. at 1032:8-24. Thus, Medicaid children who live in Tulsa either do not receive orthopedic care or they must travel to Oklahoma City for treatment.

---

[7] However, children are treated if hospital staff rules and EMTALA require admission. Tr. Vol. IV, at 489:2-10. Children have been hospitalized to treat bone infections because of the inability to secure outpatient orthopedic services. Id. at 511:14-17; Tr. 3/17/03, at 64:6-18.

76. The lack of orthopedists accepting Medicaid is overwhelming Children's Hospital's orthopedic program. Tr. 3/17/03, at 64:6-17. More and more children from rural areas are being seen for care of injured extremities and fractures because orthopedists in their community no longer accept Medicaid. Id., Tr. Vol. I, at 52:7-25. Medicaid patients in Ponca City and Muskogee also experience difficulty in obtaining orthopedic services. Tr. Vol. II, at 212:23 - 213:3; Tr. Vol. III, at 393:24 - 394:17. In Ponca City, for non-surgical orthopedics or non-acute orthopedic surgery, the wait for Medicaid patients is a month or two. Tr. Vol. III, at 394:8-11. However, for the same services, a privately-insured child will be seen within a week or two. Id.

iv. Child Psychiatry / Mental Health

77. The mental health care system in Oklahoma generally is poor. Tr. Vol. VII, at 888:13-15. Indeed, one witness described access to psychiatric services for adults and children in Oklahoma as a whole as "horrendous." Tr. Vol. VI, at 694:2-8. Pediatric psychiatrists are in short supply nationwide. Tr. Vol. XI, at 1449:23 - 1450:5. Further, private insurance does not pay for psychiatric services in the same manner as other health care services. Tr. Vol. VI, at 694:25 - 695:9.

78. OHCA has contracted with 319 mental health agencies in all counties of the State. Tr. Vol. XV, at 1977:23 - 1978:5. OHCA Behavioral Health Division has always been able to locate mental health care for Medicaid recipients when asked to assist. Id. at 1979:13-24. OHCA also pays for medications used to treat depression in children. These medications can be prescribed by psychiatrists and PCPs. Tr. Vol. VII, at 880:24 - 881:21.

79. Despite OHCA's efforts, the network of child psychiatrists in Oklahoma who are willing to treat Medicaid children is inadequate. In Tulsa, there are ten to twelve total child psychiatrists, but only six or seven are available to Medicaid patients for inpatient services. Tr. Vol.

VII, at 849:12-23. There is only one child psychiatrist, Dr. Marcialee Ledbetter of the OU Pediatric Clinic, who accepts new Medicaid patients on an outpatient basis in Tulsa. Id. at 849:23-25. Dr. Ledbetter cannot meet the needs of all the children treated at the Clinic. Tr. Vol. XVIII, at 2328:23 - 2329:4.

80. Unless Dr. Block can refer his Medicaid patients to Dr. Ledbetter, "it's almost an impossible feat to get a child psychiatric services." Id., Tr. 3/14/03, at 174:25 - 175:9. With limited access to child psychiatrists, the pediatricians at the OU Clinic in Tulsa are asked to provide a level of psychiatric care that is "inappropriate." Tr. Vol. XVIII, at 2330:10-17. Specifically, due to the lack of access to pediatric psychiatry, general pediatricians are asked to refill psychotropic prescriptions, monitor the medications, and take care of the child's psychiatric needs, which they are not trained to do. Id.; Tr. 3/14/03, at 176:14-20. Although patients with private insurance wait to see a child psychiatrist, they will be seen within a few months. Tr. Vol. VII, at 852:22 - 853:6. On the other hand, there are very few child psychiatry services for the majority of Medicaid children whom Dr. Ledbetter sees, some of whom have violent behavioral issues. Id. at 842:6 - 878:12.

81. In Oklahoma City, there is a six-month waiting list for Medicaid patients in need of pediatric psychiatry. Tr. Vol. I, at 58:1-4. Even after that six-month waiting period, these Medicaid patients are seen once by a child psychiatrist for an assessment and are then "farmed out in the community" to social workers and medication follow-up by a PCP. Id. at 58:12-15; see Tr. 3/17/03, at 65:23 - 66:19.

82. Dr. William Featherston of Elk City, a pediatrician with over 40 years of professional experience in Oklahoma, has never been able to refer one of his Medicaid patients to a psychiatrist or psychologist. Tr. Vol. III, at 445:11-16. However, Dr. Featherston's privately insured patients

in need of mental health services are usually seen by a psychiatrist or psychologist within two or three weeks. Id. at lines 17-20. Some of these Medicaid patients were in serious need of psychiatric care, and going without such care caused "unbelievable" disruption to their families' lives. Id. at 445:21 - 446:15. Defendants point out that Elk City has only one psychiatrist, and pediatric psychiatry patients from Elk City are referred to the OU Health Sciences Center regardless of whether they are on Medicaid or private insurance. Tr. Vol. III, at 453:11-12; 453:24 - 454:5.

83. Dr. Ledbetter testified that delivery of needed psychiatric care to children on Medicaid is hampered by the lack of other needed services. Needed medication regimens are denied. Tr. Vol. VII, at 857:7 - 859:23. The amount of psychological testing is limited to four hours. Id. at 868:25 - 869:11. Needed evaluations, such as neuropsychological testing, are unnecessarily delayed. Id. at 870:16 - 872:24 (child waited a full year for neuropsychological testing). Plaintiff Jacob H. waited approximately two years to have a behavioral assessment. Tr. Vol. IX, at 1109:2-6.

84. Psychiatric "day treatment," which enables children to receive intensive treatment over a prolonged period without an inpatient stay, is not available to Medicaid children in Tulsa. Tr. Vol. VII, at 872:25 - 873:13. There are two facilities in Tulsa which offer psychiatric "day treatment" to privately-insured children. Id. at 873:14-19. There are also times when Medicaid children in need of immediate inpatient care cannot find a facility anywhere in Oklahoma willing to admit them. Id. at 874:5-875:12. In these situations, Dr. Ledbetter is sometimes forced to "reluctantly overmedicate[]" these children in order to keep them from harming themselves or anyone else. Id. at 875:5-12.

v. Urology

85. One of plaintiffs' witnesses, Dr. Wright, testified that there are two urologists in Stillwater, but both generally refuse to see Medicaid patients. Tr. Vol. VIII, at 964:18-24. One of Dr. Wright's Medicaid patients, a six-year-old girl with daytime enuresis, waited three to four months to be seen by a urologist in Oklahoma City. Id. at 965:1-9. Wright testified that, if this young girl had had private insurance, she likely would have been seen by one of the local urologists within a week. Id. at 965:9-11. One of the local urologists, Dr. Robert Lauvetz, testified that he will accept Medicaid patients if the Medicaid recipients' PCPs speak directly to him, and he does not refuse Medicaid referrals when the PCPs contact him. Tr. Vol. VIII, at 1007:18 - 1008:2; 1009:17-22.

vi. Electrophysiology

86. Electrophysiologists are specialists who treat children with congenital heart deformities. Tr. Vol. XI, at 1507:14 - 1508:3. Electrophysiology is the study of the way the human heart beats. Id. at 1507:14-15. Despite the need, the specialty of electrophysiology is unavailable to Medicaid children in Tulsa. Id. at 1508:2-4. Yet, there are approximately six electrophysiologists in Tulsa to whom privately insured patients have access. Id. at 1508:4-9.

vii. Nephrology

87. Dr. William Jackson knows of no nephrologist (kidney specialist) in Tulsa who accepts Medicaid patients. Id. at 1508:10-12. Dr. Jackson sends his Medicaid patients in need of nephrology to Oklahoma City. Id. at 1508:12-13. This presents a problem because parents of Medicaid children with "more than one congenital problem" are "unusually likely not to follow up" if the appointment is more than a few miles outside of the Tulsa area. Id. at 1508:15-24.

viii. Pediatric ER Physicians

88. The only hospital in the State with an emergency room staffed with pediatric ER doctors is Children's Hospital in Oklahoma City. Tr. Vol. I, at 42:4-8. The low reimbursement rates for ER doctors, together with the high percentage of children on Medicaid, has precluded Tulsa hospitals and Children's Hospital from recruiting pediatric ER physicians. Tr. Vol. IV, at 493:1 - 494:4; 498:9 - 499:9; Tr. Vol. I, at 42:9 - 43:19. Without pediatric ER physicians, children are admitted to the hospital solely for the reason they need to see a pediatrician. Tr. Vol. IV, at 495:5 - 496:20. Those children in ERs for trauma care are often "lost" in systems not staffed with doctors trained in pediatric trauma care. Tr. Vol. I, at 41:21 - 42:4.

ix. Pediatric Cardiology

89. Medicaid children in Northeastern Oklahoma have reasonable access to four pediatric cardiologists in Tulsa. Tr. Vol. XI, at 1490:3-7. In addition to this group, there are also five pediatric cardiologists in Oklahoma City. Id. at 1490:23 - 1491:2. At the time of trial, the policy of the Tulsa pediatric cardiologists was to take all patients, regardless of whether they had private insurance, Medicaid, or were without insurance, and to treat all patients the same. Approximately 50% of their practice involves Medicaid children. Id. at 1491:5-11. Given the size of their patient load, the pediatric cardiologists need six and a half to seven physicians in their group, but they have been unable to recruit additional doctors. Id. at 1491:17 - 1492:6. Unless there is a change in the rate paid for Medicaid, this situation cannot last:

> I think this summer we're going to have to make a change, and either we stop seeing Medicaid and allow some of the insured patients that we don't have -- that are booked too far out -- because we're too busy for the number of people we have -- moved back; either we stop seeing Medicaid entirely or we limit Medicaid as they do in Oklahoma City and other places; or, third choice is, simply leave the state.

Id. 1500:1-8.

x. Pediatric Surgery

90. Oklahoma has six pediatric surgeons, three each in Tulsa and Oklahoma City. Tr. Vol. VII, at 952:13-18. The pediatric surgeons in Tulsa accept Medicaid and non-Medicaid patients without distinction. Tr. Vol. VII, at 936:12 - 937:6. To provide such access, these doctors provide 24-hour coverage. Dr. Richard Ranne testified that he is on call 330 nights per year. Tr. Vol. VII, at 937:10 - 938:18. To handle the heavy work load, the doctors in his practice have attempted to recruit other pediatric surgeons, but have been unsuccessful, in part due to the number of Medicaid children they treat and the relatively low salary they receive. Id. at 940:4-20.

xi. General Surgery

91. The evidence regarding access to general surgeons is not as clear, but there is some evidence that Medicaid children suffer unreasonable delays due to the lack of general surgeons accepting Medicaid. For example, it took Dr. Jane Thomason of Ponca City four weeks to find a surgeon who would perform gall bladder surgery on a 17-year-old patient who was in severe pain. Tr. Vol. III, at 398:9-23. As a result, her patient missed school, work, and sports for a month. Id. at 398:24 - 399:2. Had this child been covered by private insurance, he could have had the surgery in Ponca City within a day or two. Id. at 398:21-22.

c. Claims Processing System

92. OHCA processes 2,000,000 health care payment claims each month. Tr. Vol. X, at 1336:24 - 1337:2. OHCA spent $30,000,000 from 2001 to 2003 developing a new computer system that allows electronic billing by health care providers. Id. at 1337:18-21. With the new electronic system, providers who file claims by the end of business on Tuesday will have funds deposited to

their bank accounts on Wednesday of the following week. This system has received full federal certification. Id. at 1338:3-8. Since OHCA's implementation of an electronic claims submission system, the claims process has improved for at least one health care provider. Tr. Vol. I, at 128:8-24; 130:24 - 131:5. Another provider admitted that electronic billing and payment is a more efficient system than paper billing and payment. Tr. Vol. IX, at 1056:9-11.

93. Oklahoma's Medicaid fee schedule is on OHCA web site. See Tr. Vol. XI, at 1473:17-19. Private insurers require health care providers to bill according to procedure codes. Tr. Vol. III, at 406:11-18. Some private insurers require PCPs to show a patient cannot be successfully treated with an inexpensive drug before paying for a more expensive drug, such as Strattera, a treatment for attention deficit hyperactivity disorder ("ADHD"). Id. at 407:6 - 408:10. It is reasonable for OHCA to seek to pay for the least expensive drug that may treat a health care problem. Id. at 408:11-20.

94. OHCA created a so-called "administrative referral" which allows payment through the claims system for specialty services already rendered without a PCP referral. Tr. Vol. X, at 1330:15-25.

95. Despite OHCA's upgrade to its system, a high percentage of Oklahoma's pediatricians cite hassles in the claims processing structure as a very important reason for limiting participation in Medicaid. Kletke Report, Pl. Ex. 203, at BB.10731 (Table 7). For instance, 72% of pediatricians complain about "unpredictable payments," while 65% report "payment delays" as a very important factor in their decision to limit Medicaid participation. Id. Likewise, 59% of pediatricians responded that "excessive paperwork" is very important in determining the degree of their Medicaid participation. Id.

96. In the experience of OHCA's Care Management Director, when a specialist decides to limit his participation in Medicaid, "it's usually due to a claims or billing issue." Tr. Vol. XIV, at 1869:14-19. At the time of trial, the Care Management Director was aware of current providers who had closed their Medicaid practices due to claims or billing issues. Id. at 1870:4-8.

97. One billing issue is OHCA's practice of refusing to pay for pre-surgery consultation when a provider bills for the consultation and surgery for the same patient on the same day. Tr. Vol. VI, at 661:1-20. Dr. Leonard, an ENT specialist, stopped accepting Medicaid patients in part because OHCA's claim processing system would not reimburse him for these same-day consultations. Id. at 662:4 - 663:24. Dr. Leonard explicitly complained about the claims processing problem, but OHCA was unresponsive. Id.

98. In the past, OHCA repeatedly denied claims submitted by the Children's Hospital ER, requiring the office staff to continually re-submit claims. Tr. Vol. I, at 128:8-20. Dr. Featherston had a claim erroneously denied for a supposed lapse in eligibility. Tr. Vol. III, at 442:6 - 443:1. While the claim was eventually paid, it took several phone calls and letters to resolve the issue. Id. One of the reasons that Dr. Featherston dropped out of the Medicaid program was the impact that billing hassles had on increasing his office's overhead expenses. Id.

d. Appeals Process

99. Medicaid recipients can administratively appeal OHCA's health payment and related decisions. See Tr. Vol. II, at 233:24 - 234:2. No named class-action plaintiff or witness in this case filed an appeal of any kind with OHCA. Add'l Stip., Dkt. 214, ¶ 6. However, OHCA's administrative appeals process has contributed to providers' unwillingness to participate in the Medicaid program. Tr. Vol. I, at 86:13 - 87:2. Currently, the appeals process is poorly understood

by Medicaid providers and is "viewed as terribly difficult to access." Id. at 86:15. It is Dr. Stuemky's understanding that a provider cannot appeal a decision of OHCA to an administrative law judge without first hiring a lawyer. Id. at 86:15-22. The "lack of an effective, affordable easy-access appeals process has been a source of never-ending complaints and frustration of health care providers and consultants." Id. at 86:22-25.

2. Reimbursement Rates

a. Defendants' Funding Requests

100. In its Fiscal Year 2001 Budget Request submitted to the Legislature in October 1999, OHCA represented that an increase in provider reimbursement was needed in order to "comply with federal regulations which require that [provider] payments be consistent with efficiency, economy and quality of care, and [] adequate to enlist enough providers so that services are available to Medicaid recipients to the same extent they are available to the general population." FY-2001 Budget Request, Ex. 422, Operations Funding Changes, at 26, BR-40B. At that time, OHCA requested that provider rates be increased to "75% of Medicare's current allowable." Id.

101. OHCA's present stated performance measure for compliance with the Medicaid Act's equal access mandate is to raise provider reimbursement rates under Medicaid to 100% of the Medicare Fee Schedule. Agreed Pretrial Order and Statement of the Case, Dkt. 196. at 6, ¶1. Despite these performance measures, from 1995 through December 31, 2003, provider reimbursement rates under Oklahoma's Medicaid Fee Schedule never exceeded 72% of Medicare. Id. at 7, ¶ 2. At the time of trial, physicians were reimbursed under Oklahoma's Medicaid fee-for-

service fee schedule for "most codes," including procedure codes, at "about 71 per cent of Medicare." Tr. Vol. XV, at 1949:24 - 1950:2. For services billed as E and M codes, physicians (not capitated) are reimbursed under the Medicaid fee schedule at 90% of Medicare. Id. at 1950:2-4.

102. In its Fiscal Year 2003 Budget Request, OHCA sought from the Legislature an increase in physician reimbursement to "100% of the Medicare Fee Schedule" in order to comply with the federal equal access mandate. See FY-2003 Budget Request, Pl. Ex. 424, at BR-40B, pp. 41, 43. OHCA further recognized that, if the reimbursement increase was not realized, it could "possibly jeopardize access to care." Id. at BR-40B, p. 41. OHCA provided certain "Client Information" to the Legislature, identifying OHCA's clients who would be affected by the proposed increase in reimbursement rates as all beneficiaries with "acute medical care needs." Id. at BR-40B, p. 42. OHCA further estimated that a total of 545,000 potential and 533,000 actual beneficiaries would be affected by the rate increase. Id. At the class certification hearing, defendant Fogarty confirmed that the Fiscal Year 2003 Budget Request essentially requested an increase in rates in order to comply with the law and alleviate the access problems experienced by Oklahoma's Medicaid children. Tr. 3/14/03, at 236:20-24; see id. at 234:6-13. However, the annual cost of increasing Medicaid payment rates to 100% of the Medicare rate would be $38,000,000. Tr. Vol. XVII, at 2270:8 - 2271:24.[8]

103. In its Fiscal Year 2004 and Fiscal Year 2005 Budget Requests, OHCA again requested an increase in physician reimbursement to 100% of Medicare and again represented that this increase was needed in order to comply with the equal access mandate. FY-2004 Budget

---

[8] If eligibility were reduced in order to increase rates to 100% of Medicare rates, approximately 28,000 children would be removed from the Medicaid rolls. Tr. Vol. XVIII, at 2395:1-8.

Request, Pl. Ex. 460 at BR-40B, pp. 35-36; FY-2005 Budget Request, Ex. 461 at BR-40B, pp. 31-32.[9] Low provider reimbursement rates make it difficult to attract physicians to participate in Oklahoma's Medicaid program. As defendant Fogarty testified, and defendant Mitchell agreed, Medicaid physician reimbursement rates "are low, were low, and that this is a factor that makes it difficult to recruit physicians." Tr. 3/14/03, at 215:25 - 216:1; Agreed Pretrial Order and Statement of the Case. Dkt. 196, at 7, ¶ 4; 8, ¶ 14.

b. Providers' Unwillingness to Treat Medicaid Patients

104. Dr. David Skaggs has studied the difference in access to physicians for Medicaid children and those with private insurance. In one nationwide study, he found that physicians are far less willing to treat Medicaid children than children with private insurance; further, the study indicated that the amount a state pays makes a difference in access. Pl. Ex. 367-C. Seeking surgeons for similar children, one with private insurance and the other covered by Medicaid, the study found that only 48% of the surgeons were willing to schedule an appointment for the child with Medicaid, while all of them saw the child with private insurance. Tr. Vol. X, at 1192:11-24. Of the three Oklahoma surgeons that participated in the study, none would see the child with Medicaid. Id. at 1193:2-4. All three would see the child with private insurance. Id. The study found a significant correlation between what a state paid doctors to provide medical services to patients with Medicaid and the access to those services. Id. at 1192:21-24.

---

9 While OHCA maintains that the reason it has failed to increase reimbursement rates stems from budgetary constraints, studies have shown that increased physician reimbursement can actually lead to overall budgetary savings in a state's Medicaid program. Berman Trial Dep., 5/26/04, Pl. Ex. B (attached to Plaintiffs' Proposed Findings of Fact and Conclusions of Law, Dkt. 233), at 26:16 - 28:22.

105. Approximately ninety-three percent (93.2%) of Oklahoma's pediatricians report that low reimbursement is a very important reason why they would limit their participation in the Medicaid program. Kletke Report, Pl. Ex. 203 at BB.10731, Table 7. Low reimbursement is by far the primary reason that pediatricians limit participation in the Medicaid program. Id. Sixty-nine and a half percent (69.5%) of Oklahoma's pediatricians report that Medicaid reimbursement does not cover their overhead expenses. Id. at BB.10732, Table 8. In addition, 50% of Oklahoma's pediatricians, including sub-specialists, responded that they will either see few Medicaid patients or stop seeing Medicaid patients altogether if Medicaid payments remain the same. Id.

106. In HCFA's Medicaid Program Review, the agency made clear its finding of a link between low reimbursement rates and inadequate provider participation in Oklahoma's Medicaid program. Medicaid Program Review of Oklahoma's SoonerCare Program, Pl. Ex. 20, BB.5272, BB.5287. Specifically, HCFA found that "[l]ow fee-for-service payments" was one of the factors contributing to a shortage of specialists participating in the SoonerCare Choice program. Id. at 3. In response, OHCA admitted that ". . . low reimbursement rates," among other factors make it "difficult to attract additional specialists to participate in the Medicaid program." Id. at BB.5273. Similarly, HCFA found that "specialists primarily do not participate [in the SoonerCare Plus program] because of the lack of sufficient reimbursement for specialty care and an unwillingness to participate in SoonerCare or any other type of managed care model." Id. at BB.5287.

107. On January 19, 2001, the HCFA Director released a memorandum regarding access to care for Medicaid children. Pl. Ex. 30. In it, HCFA acknowledged the relationship between inadequate reimbursement rates and inadequate access to care and stated that:

> One way to assess whether State payments are sufficient to enlist enough providers so that there is adequate access to services is to compare State Medicaid

> reimbursement rates (including fee-for-service rates and rates paid to providers by managed care organizations under contract with the State Medicaid agency) to the rates of commercial payers for comparable services in comparable geographic area.

Id. at BB.0028. Current Medicaid reimbursement in Oklahoma is significantly less than rates paid to physicians by private insurance plans. See, e.g., Tr. Vol. V, at 580:21-25; Tr. Vol. VII, at 942:16 - 943:4; Tr. Vol. VIII, at 1011:11 - 1012:10; Tr. Vol. XI, at 1499:1-9.

108. However, one doctor testified that he is prohibited by contract from disclosing reimbursement rates paid by private insurers. Tr. Vol. XII, at 1590:16 - 1591:16. Another doctor testified that private insurers do not pay the full charges billed by physicians. They pay a lesser amount, which may be higher or lower than the Medicare rate. Tr. Vol. III, at 457:9 - 458:5.

109. Several physician specialists who treat children testified that they either do not participate in the Medicaid Program or limit their participation primarily due to low reimbursement rates, among other complaints. These include David Siegler, the pediatric neurologist from Tulsa, Tr. Vol. V, at 576:23-25; Joseph Leonard, an ENT specialist, Tr. Vol. VI, at 665:9-13; Edward Barns, another ENT specialist, Tr. Vol. IX, at 1052:24 - 1053:14; Mark Capehart, a pediatric orthopedist, Tr. Vol. VIII, at 1035:12-18; Robert Lauvetz, a urologist in Stillwater, Tr. Vol. VIII, at 1007:18 - 1009:15; 1010:17 - 1011:10. Others physician specialists who accept all Medicaid patients testified that the low reimbursement rates have caused them financial difficulty and an inability to recruit pediatric specialists. These include Richard Ranne, a pediatric surgeon, Tr. Vol. VII, at 942:7-15, and William Jackson, a pediatric cardiologist, Tr. Vol. XI, Id. at 1499:10-19; 1500:1-8. However, many of these physicians were unaware of the cost, or unable to state the cost, to provide their services. Leonard Test., Tr. Vol. VI, at 671:4-12. Barns Test., Tr. Vol. IX, at

1058:3 - 1059:21; Capehart Test., Tr. Vol. VIII, at 1041:9-18; Lauvetz Test., Tr. Vol. VIII, at 1021:17 - 1024:4; Jackson Test., Tr. Vol. XI, at 1521:20 - 1523:4.

110. Other physician witnesses were also questioned as to reimbursement rates. Dr. Michael Stratton, a private practice pediatrician, testified that approximately 60% of the patients at his clinic are Medicaid recipients. OHCA pays the clinic at least $750,000 per year. This amount is sufficient to make a living. Tr. Vol. II, at 224:16 - 225:13. Dr. William Banner, a pediatric intensivist, would not speculate as to the reimbursement rates that would meet the needs of physicians. Tr. Vol. IV, at 532:13 - 533:5.

111. Defendants presented evidence indicating that the cost of psychiatric services in Oklahoma, including the physician's salary, is $100 - $150 per hour. Tr. Vol. VI, at 708:21-25. The time spent by a psychiatrist on a patient's visit for drug management is about ten minutes, resulting in a cost of sixteen dollars and sixty-seven cents to twenty-five dollars. Id. at 709:19 - 710:3. The drug management CPT code is 90862. OHCA's payment for that code is $47.69. Def. Ex. 18, code 90862. Physicians performing psychiatric diagnostic interview examinations are paid $140.48. Id., code 90801. Physicians performing interactive psychiatric diagnostic interviews are paid $149.28. Id., code 90802. Individual psychotherapy sessions are paid by OHCA at a rate that ranges from $60.34 to $145.78. Id., codes 90804 to 90829.

c. Capitation-Specific Issues

112. OHCA has increased the capitation payment for SoonerCare Choice 51% since 1996. Tr. Vol. X, at 1217:2-10. In the previous fully-capitated SoonerCare Plus program, OHCA paid an HMO about $200 per month per Medicaid recipient enrolled with the HMO. In turn, the HMO provided all Medicaid benefits for that individual. In the partially-capitated SoonerCare Choice

program, OHCA pays a PCP about $20 per month to provide a limited range of services. Outside that range, services are paid for by OHCA on a fee-for-service basis. Tr. Vol. X, at 1343:13 - 1344:14.

113. Yet, the majority of pediatricians report that Medicaid rates, including capitation rates, are insufficient to cover overhead expenses. As a result, pediatricians limit or refuse to treat Medicaid children. See Kletke report, Pl. Ex. 203, at BB.10731-32 (Tables 7 and 8); Tr. Vol. XII, at 1616:22 - 1617:2; see also Tr. Vol. VII, at 905:23 - 908:1; Tr. Vol. III, at 443:10 - 444:3. Twenty-four of the 133 E and M codes are included in the services covered by the SoonerCare capitation payment. The remaining 109 E and M codes are paid to contracted PCPs at 90% of the Medicare payment rate for such codes. All E and M codes have been paid at the 90% rate to specialists and other physicians who are not contracted as SoonerCare PCPs since January 1, 2004. Trans. Vol. XIX, at 2521:16-21. However, the January 1, 2004 rate increase did not affect the SoonerCare Choice PCP capitation rate. Agreed Pretrial Order and Statement of the Case, Dkt. 196, at 9, ¶24. 114. Many federally-mandated services for Medicaid children are included in the capitation rate. EPSDT screening, immunizations and lab tests are capitated services. Pl. Ex. 224 at BB.7789-92; Tr. Vol. XVII, at 2289:5-7. The federal government has recently required states to pay actuarially sound capitation rates. Oklahoma was to implement these actuarially sound rates with the contract renewal period in January 2005, using Mercer, a well-reputed firm, as the actuary. Tr. Vol. X, at 1340:18 - 1342:12; Tr. Vol. XI, at 1441:12-18. Nonetheless, the financial incentives in a capitated program, particularly with a low capitation rate, reward those providers who do not provide preventative care, including EPSDT services. See Tr. Vol. X, at 1285:5-20; 1312:14-1317:2; Tr. Vol. XI, at 1425:16-24; Tr. Vol. VII, at 905:23 - 908:1. OHCA's Bonus Program has

not overcome the financial disincentive of the capitation rate to assure that children receive mandated services. Tr. Vol. X, at 1289:8 - 1291:4. EPSDT Bonus Payment Report, SFY 2001, Pl. Ex. 497.

d. State-Employed Physicians

115. On December 30, 2003, CMS approved OHCA's request to pay State-employed physicians (employed by OU and OSU) an enhanced reimbursement rate equal to "140% of the Medicare allowable." Def. Ex. 21, at 3a. While OHCA's plan had been approved by CMS, as of the time of trial, a contract between OU and OHCA implementing the rate increase had not been executed. Tr. Vol. XVII, at 2225:1-16. The rate increase poses a risk of alienating private practice physicians, a risk recognized by defendant Fogarty. Tr. Vol. X, at 1228:8-25; 1226:21-25. Nonetheless, he did not consult any private practice physicians before launching OHCA's plan to pay university physicians at a rate of 140% of Medicare. Id. at 1225:12-19.

116. Dr. Dewayne Andrews, Dean of the OU College of Medicine, was concerned that if the rate increase were implemented, physicians in private practice will cease participating in Medicaid and send all their Medicare patients to the medical school. Tr. Vol. XVII, at 2244:13-15. Even if the increase were implemented, Dr. Andrews could not commit that the funding would result in an increased access to specialty care, such as pediatric neurology, at the College of Medicine. Id. at 2216:11 - 2217:24. He testified that it is not OU's "mission at the College of Medicine to provide services for the Medicaid population." Id. at 2246:23-25. The College of Medicine intended to use the increased Medicaid reimbursement revenue "to cover some of the enormous debts that we incurred in the Heartland health plan." Id. at 2218:18-21.

117. The proposed rate increase could have a negative impact on access to care. Dr. Lauvetz testified that he might actually cease all participation in Medicaid if the proposed rate increase is implemented. Tr. Vol. VIII, at 1013:16 - 1015:7. Dr. Barns, who is an unpaid volunteer faculty member at OU, and who has not participated in Medicaid since 1997, testified that paying university physicians double the rate paid to those in private practice is "certainly the wrong way to entice" physicians to participate in the program. Tr. Vol. IX, at 1054:3-12. As Dr. Ranne sees it, if the proposed rate increase for State-employed physicians goes through, 140% of Medicare will be the "new benchmark" for what it will take to get private practice physicians to participate in Medicaid. Tr. Vol. VII, at 944:3-15.

118. OHCA claims that it implemented the increase, in part, in an attempt to recruit more specialists to the State. Tr. Vol. IX, at 1142:21-1143:1. OHCA is able to make the increase because the universities will pay the State's 30% share of the difference between the current rate and the higher rate. Tr. Vol. IX, at 1143:5 - 1144:16; Tr. Vol. X, at 1342:18 - 1343:12. In addition to paying health care claims generated by the university-employed physicians, OHCA also makes graduate medical education supplemental payments to the medical schools in the sum of $120,000,000. It also pays sixteen hospitals with residency training programs the sum of $60,000,000. It pays Tulsa's Hillcrest Hospital, the OU Health Sciences Center, and the OU Medical Center in Oklahoma City for additional residency training the sum of $11,000,000. These payments began after the creation of OHCA. Tr. Vol. IX, at 1144:18 - 1146:23.

e. Increases

119. OHCA increased all physician fee-for-service rates 18% in August 2000 and increased E and M codes payment rates to 90% of Medicare in January 2004. Tr. Vol. X, at 1214:23

- 1216:13. The increase of E and M codes rates was funded by a one-time, 3% increase in federal matching funds. Tr. Vol. X, at1217:17 - 1218:5. With the increase in these rates, Oklahoma now ranks third in the nation in the rates paid for the codes most often used by pediatricians. Tr. Vol. IX, at 1091:13-22.

120. Other efforts by OHCA to increase rates include the August 2000 increase in rates for dental care by 60%. That increase placed Oklahoma fifth in the nation for such rates. Tr. Vol. XV, at 1934:15-22. OHCA has also created the first program in the nation to pay physicians' Medicaid reimbursements into tax-deferred accounts. These payments create the equivalent of a 20% - 40% increase in rates. Tr. Vol. XVII, at 2280:6 - 2281:20.

3. Quality Assurance Program and Quality of Care Issues

121. Defendant's expert Yvonne Powell testified that, in order to be effective, State Medicaid quality assurance ("QA") or quality monitoring programs must be sound in both design and function. Tr. Vol. XVI, at 2133:18 – 2134:7. In Powell's view, it is not enough to merely conduct quality monitoring and to make findings. Id. According to Powell, if a problem is found during the quality monitoring process, the Medicaid agency must take some sort of corrective action in response, such as formulating a "correction report" or a "compliance plan." Id. at 2134:24 - 2135:13. Quality problems identified in the QA process must be "circl[ed] back" by the agency and "addressed" in some meaningful way. Id. at 2135:10-13.

122. The annual HCFA-416 report is "the only way" in which defendants "monitor the rate of EPSDT performance." Agreed Pretrial Order and Statement of the Case, Dkt. 196, at 10, ¶ 32. The fact that the HCFA-416 for FY-2002 was not produced until the late stages of trial in 2004 suggests that defendants did not monitor the rate of EPSDT compliance for over a year, as that

report was originally due to be submitted to CMS on April 1, 2003. Defendants do not review any "monthly or interim EPSDT compliance reports or data" and have "no mechanism to monitor EPSDT performance on a day-to-day basis." Id.

a. Delayed Appointments

123. Due to an insufficient number of providers willing to see Medicaid patients, recipients in Oklahoma often experience long delays in obtaining appointments for provision of medically necessary care. See, e.g., Tr. Vol. XIV, at 1868:10-18, 1854:17-21 (6-9 months for a child with seizures to see a pediatric neurologist). OHCA does not track the length of time to appointment. Id. at 1876:18-20. OHCA has no knowledge as to whether the problem with specialty appointment delays is improving or deteriorating. Id. at 1876:21-24. OHCA has no timeliness standards for specialty care. Tr. Vol. XI, at 1547:13-23; Tr. Vol. II, at 280:11-23.

124. OHCA does use recipient surveys to assess, among other things, the issues of delays in care. Tr. Vol. XIII, at 1680:22 - 1681:1. From 1999 to 2000, the percentage of children with special needs whose parents reported that they never or only sometimes receive care went up from 23% to 26%. Pl. Ex. 584 at 10. Similarly, in an April 2001 consumer survey of the parents of SoonerCare Choice children, over 20% reported that their children never or sometimes get care without long waits. Pl. Ex. 574, Figure 5; Tr. Vol. XIII, at 1683:5 - 1684:17. Dr. Mitchell concedes that as indicators of delays in recipients receiving care, these surveys may suggest a shortage of resources (i.e., providers). Tr. Vol. XIII, at 1685:13-23.

125. SoonerCare's status as a waiver program places additional federal requirements on defendants, known as "special terms and conditions." Tr. Vol. XVI, at 2141:2 - 2143:4. One of those "special terms and conditions" is a requirement that "[a]ppointments to specialists, except for

specialists providing mental health and substance abuse services . . . shall not exceed 30 days for routine care or 48 hours for urgent care." SoonerCare Terms and Conditions, Pl. Ex. 20, at BB.5317. While the evidence indicates that the days to appointment for several specialties exceeds the 30-day requirement, defendants have not attempted to track days to appointment as a part of their quality

monitoring function.

b. After-Hours Access

126. PCP coverage for 24 hours a day, 7 days a week is not a federal requirement under Medicaid. Tr. Vol. XI, at 1487:17-20. However, defendants have made it a State requirement. Under the SoonerCare Choice contract, PCPs are required to "[e]nsure the availability of twenty-four (24) hours per day, seven (7) days per week, telephone coverage which will immediately page an on-call professional." Pl. Ex. 224 at BB.7769, ¶ 2.3(A). OHCA provides a nurse advice line to assist Medicaid recipients with after-hours health care issues and triage. Tr. Vol. II, at 343:14-344:7; Tr. Vol. X, at 1350:5-24. However, the contract makes it clear that the nurse advice line is not a substitute for the 24-hour access required by ¶ 2.3(A). Pl. Ex. 224, at BB.7782, ¶ 6.2.

127. Dr. Johnston, President of the AAP, explained that 24-hour access is an essential element of the medical home. Tr. Vol. IX, at 1065:15-21. When PCPs fail to provide for round-the-clock access to an on-call professional, diagnosis and treatment of conditions can be delayed and become more severe. Tr. Vol. III, at 440:6 - 441:5. In some cases, a PCP's failure to provide 24-hour access can be life threatening. Tr. Vol. XI, at 1510:11 - 1511:25. In Dr. Jackson's experience, PCPs will no longer refer a Medicaid child with a heart condition to him if the child experiences a

problem after 4:00 p.m. Id. at 1511:3-21. Instead, these children have to go an emergency room, where the physicians are not trained in how to deal with pediatric heart conditions. Id.

128. OHCA feels that, realistically, it cannot strictly enforce the 24-hour accessibility provision of the contract for capitation. Tr. Vol. X, at 1301:16 - 1304:8. Defendants do not take any corrective remedial action against PCPs who violate the 24-hour accessibility provision, nor do the defendants give any bonus or other incentive to PCPs who comply with the 24-hour accessibility provision. Id. at 1304:6-8.

c. Hospital Admission Access

129. In monitoring whether its SoonerCare Choice PCPs are complying with the contract's 24-hour availability requirements, OHCA also monitors whether PCPs have an "ER/Hospital Arrangement." See, e.g., Pl. Ex. 614, Provider Site Visit, at 1. As Dr. Stratton explains, it is very important to a child's health that his PCP have admitting privileges with the local hospital. Tr. Vol. II, at 212:7-22. In Muskogee, two out-of-town PCPs do not have admitting privileges to the local hospital. Id. at 209:5 - 212:22. By not having admitting privileges, these PCPs compromise the well-being of their Medicaid patients. Id. at 212:14-19. Defendants' site visit reviewers also found that many SoonerCare Choice PCPs do not have an "ER/Hospital Arrangement." Pl. Exs. 614, 615, 619, 621, 625, 626, 627, 630 and 633, Provider Site Visits, at 1. Yet, in none of these cases was the lack of an ER/Hospital Arrangement reported as a contractual or quality deficiency. Id.

130. In the current SoonerCare program, inpatient hospital admissions are covered on a fee-for-service basis. Tr. Vol. I, at 99:3-18. In response to criticism of the early SoonerCare Choice contract's provision that penalized PCPs monetarily when their Medicaid patients went to hospital emergency rooms for non-emergent issues, OHCA dropped the penalty. Tr. Vol. X, at 1334:10-25.

d. Non-Physician Providers

131. Health care treatment, screening, and diagnosis of children are within the scope of practice of nurse practitioners, physician assistants, family practice doctors, and general practice doctors. Tr. Vol. II, at 227:21 - 228:2; see Tr. Vol. IX, at 1119:17-20; 1081:24 - 1084:5. In Oklahoma, licensed physician assistants are able to, among other things, see patients in the office, do nursing home rounds, assess medical conditions, take medical histories, perform physical examinations, write prescriptions, refer patients to specialists, review laboratory test results, review X-rays, and perform minor surgical procedures. Tr. Vol. V, at 640:4-24. Licensed nurse practitioners in Oklahoma are able to provide "cradle to grave" health care, including to: diagnose and treat patients; perform minor surgery; suture wounds; provide care for chronic conditions such as diabetes and hypertension; treat infectious diseases; and take care of ordinary injuries. Tr. Vol. VI, at 736:14 - 737:1.

132. Hence, the lack of participation of primary care physicians has led OHCA into promoting and participating in the establishment of what plaintiffs refer to pejoratively as "Medicaid mills," or health-care facilities set up for the sole purpose of providing primary care services to Medicaid recipients. OHCA provider representative, Susan Mohler, testified about her work in establishing several such clinics. For example, she helped open the Sunshine Clinic (discussed above) in Miami, Oklahoma. Tr. Vol. XV, at 2024:18-23. She was also involved in the establishment of the Sweeten Clinic in Bartlesville, Oklahoma. Id. at 2034:25 - 2035:2. In addition to these two clinics, she also worked to establish clinics staffed with nurse practitioners in both Catoosa and Pryor, Oklahoma. Id. at 2035:14-20.

133. A physician assistant and a nurse practitioner testified that their work at the Sweeten Clinic was severely limited by the lack of medical supplies and adequate staff, as well as support from the supervising physician and the OHCA. Tr. Vol. V, at at 626:18 - 627:25; 630:22 - 631:3; 632:3-4; Tr. Vol. VI, at 747:19 - 748:10; 752:11 - 755:6. Michelene Jackson, the physician assistant initially hired to staff the clinic, notified Mohler of the lack of supplies at the Sweeten Clinic on two different occasions, to no avail. Id. at 628:1-5; 629:4 - 630:12. After Jackson left the Clinic, she wrote a letter to Mohler which summarized Jackson's problems at the Sweeten Clinic. Pl. Ex. 196.

134. Jackson was succeeded by Helen McHale, a nurse practitioner. Tr. Vol. VI, at 735:12-16; 738:24 - 739:22. McHale testified that, under the SoonerCare contract, she was only to see patients ages 14 and up, but OHCA continued to assign young children and infants to McHale as their PCP. Id. at 740:11 - 741:5; 744:2 - 745:25; 747:1-4. When McHale complained, Mohler offered no assistance. Id. at 746:1-25; 748:15 - 749:24; 751:8 - 752:10. McHale also contacted OHCA regarding the lack of supplies, but Mohler offered no assistance. Id. at 751:8-23; 752:4-10. After contacting OHCA "at least ten times" regarding the problems at the Sweeten Clinic and receiving no support, McHale decided to leave the Sweeten Clinic, as the situation there had forced her to "contribut[e]" to the provision of "bad care." Id. at 756:15 - 758:9; Pl. Ex. 214.

4. EPSDT

135. EPSDT screening is an important preventive health care measure to assure that Medicaid children reach "optimal mental, physical and social health." Tr. Vol. IX, at 1070:3-4. If children do not receive EPSDT screenings, they can "suffer negative health consequences." Agreed

Pretrial Order and Statement of the Case, Dkt. 196, at 7. The State Medicaid Manual[10] provides that states are required to "[a]ssure that health problems found are diagnosed and treated early, before they become more complex and their treatment more costly." State Medicaid Manual, Pl. Ex. 2, at § 5010(B). Defendants are required to provide Medicaid children with necessary health care "as soon as possible." Tr. Vol. II, at 264:6-8.

a. Screening Services

136. The State Medicaid Manual sets out state participation goals for EPSDT screening services, and directs states to report their progress in achieving these goals. Pl. Ex. 2 at § 5360. For the purposes of reporting to HCFA/CMS, an EPSDT screening must consist of all of the following five components:(1) a comprehensive health and developmental history; (2) a comprehensive unclothed physical examination; (3) appropriate immunizations according to age and health history; (4) laboratory tests (including age-appropriate blood lead level assessment); and (5) health education. Id. at § 5360(D).

137. In reporting its level of compliance, each state must compute an annual "participant ratio." Id. at § 5360(B). The participant ratio is calculated by dividing the number of Medicaid-eligible children who received at least one initial or periodic screening service during the fiscal year, by the number of Medicaid-eligible children who should have received at least one periodic screening service in that year. Id. Each state's participant ratio is reported annually on a form known as the HCFA Form 416. Id.; Tr. Vol, II, at 300:1 - 301:9. HCFA/CMS set a goal for each

---

[10] HCFA/CMS establishes EPSDT guidelines in its State Medicaid Manual, which sets forth in detail the basic services that should be provided by states under the EPSDT program. Pl. Ex. 2, Pt. 5. The State Medicaid Manual is essentially a Medicaid agency's "instruction book" on how to meet its federally-mandated obligations. Tr. Vol. II, at 259:25 - 260:3.

state to achieve an 80% participant ratio by 1995. Pl. Ex. 2 at § 5360. That goal is not a Medicaid requirement. Tr. Vol. XI, at 1487:12-14.

138. In 1995, Oklahoma's participant ratio was 27%. Pl. Ex. 475. In 1996, it was again 27%. Pl. Ex. 474. In 1997, the participant ratio improved to 35%. Pl. Ex. 473. For fiscal year 1998, Oklahoma reached a 40% participant ratio. Pl. Ex. 472. The ratio fell seven percentage points in 1999 to 33%. Pl. Ex. 471. In 2000, the participant ratio fell again to 29%. Pl. Ex. 470. Oklahoma's ratio for 2001 was 36%. Pl. Ex. 469.

139. According to data obtained from HCFA/CMS, Oklahoma's participant ratio in 1999 ranked nationally as the fifth worst (of 44 states for whom CMS listed information). Wegner Report, Pl. Ex. 683, at Ex. W.5. Similarly, in 2000, Oklahoma's participant ratio ranked as the third worst nationally (of 26 states for whom CMS listed information). Id. at Ex. W.6.

140. Defendants point out that the HCFA Form 416 does not count EPSDT services paid through the managed care capitation payment. The U.S. General Accounting Office has criticized the HCFA Form 416 for under-reporting EPSDT screenings in managed care systems. Tr. Vol. II, at 339:5-18; 340:19 - 342:16; Tr. Vol. XI, at 1447:11-24; Pl. Ex. 14, at 3-4. Because EPSDT screenings, including immunizations, are included in the capitation payment and do not generate a separate claim for payment, accurate information about EPSDT rates is difficult to obtain. Numbers are under-reported because there is no financial incentive to provide encounter data. Tr. Vol. X, at 1308:23 - 1309:16.

141. The Oklahoma Foundation for Medical Quality ("OFMQ") is an independent agency with which OHCA contracts to conduct external quality assurance reviews of Oklahoma's Medicaid program. Tr. Vol. II, at 307:7-16. The quality assurance reports generated by OFMQ are called

Quality Improvement System for Managed Care ("QISMC") reports. Pl. Ex. 580, 582 and 686. QISMC is a HFCA/CMS initiative "to protect and improve the health and satisfaction of beneficiaries." Pl. Ex. 580 at 1. In July 1999, OHCA adopted QISMC as its structural performance measure for the SoonerCare program. Id.

142. In compiling data for the QISMC reports, OFMQ reviews medical records. Tr. Vol. II, at 308:5-8. Only after reviewing sample recipient medical records does OFMQ report whether an EPSDT screen has been performed. Id. at 308:10-14. The QISMC reports have two EPSDT performance indicators:(1) the unadjusted EPSDT rate; and (2) the adjusted EPSDT rate. Pl. Ex. 580 at 2. The unadjusted rate simply measures the proportion of SoonerCare Choice children in the sample who received age-appropriate EPSDT examinations according to the EPSDT periodicity schedule. Id. The adjusted rate measures the proportion of SoonerCare Choice children who fall into the adjusted rate category plus all children who did not receive an EPSDT examination where: (1) the parent or guardian refused an EPSDT exam for the child; (2) the SoonerCare Choice program or provider made at least two attempts to contact the parent or guardian to schedule the EPSDT exam; or (3) the current PCP made at least two attempts to obtain medical records from the previous PCP. Id. at 4.

143. In counting EPSDT examinations, OFMQ does not measure whether a complete EPSDT screening had been performed. See Tr. Vol. II, at 317:3-8. Instead, OFMQ gives credit for an "EPSDT examination" when it finds documentation of a physical, which included a comprehensive health and developmental history. Pl. Ex. 580 at 3. In the April 2002 QISMC EPSDT report, OFMQ reported that, during year II (data collected from 1/1/99-12/31/99) of the study, SoonerCare Choice had achieved an unadjusted rate of 43.8%; and an adjusted rate of 44.8%.

Pl. Ex. 580 at 6.[11] This was a slight improvement from year I, when the unadjusted rate was 40.9% and the adjusted rate was 41.6%. Id. However, during year III (data collected from 9/02-3/03 for services rendered in 2001) of the QISMC project, the unadjusted and adjusted EPSDT rates dropped to 37.9%. Pl. Ex. 686 at 6.

144. Aside from the low EPSDT rates, OFMQ also found that, even when a physical examination and history had been performed, otherwise essential elements of an EPSDT screening had not been performed. For instance, during year II, in cases where OFMQ had counted an EPSDT examination, it found that the child's height, an important developmental measure, had only been recorded 66% of the time. Pl. Ex. 580 at 11. OHCA's EPSDT manager admitted at trial that recording a child's height is an essential element of a complete EPSDT screen. Tr. Vol. II, at 318:5-18.

145. OFMQ also found that for a significant number of children receiving an examination during year II, other required components of an EPSDT screening had not been performed, including health education, behavioral assessment, and immunizations. Pl. Ex. 580 at 11. OFMQ's findings in this regard were very similar to its findings during year I and year III. Pl. Ex. 582 at 11; Pl. Ex. 686 at 10. During the third year of the study, the percentage of children who had been examined, but who had not had their height measured, dropped from 66% to 61%. Pl. Ex. 686 at 10. Also,

---

[11] The HCFA-416 data does not capture data for EPSDT screens performed on Native American children through Indian Health Services ("IHS"), but OFMQ asked IHS to identify all encounters during year I, and not just those for EPSDT examinations. Pl. Ex. 582 at 12. OFMQ found that "although the procedure for reviewing additional IHS records did produce a high rate of medical records reviewed for the Native American sample (70.1 percent), it did not increase the EPSDT rate." Id. During year II, OFMQ found that "no EPSDT examinations had been performed at IHS facilities." Pl. Ex. 580 at 12. Native American children have had the lowest EPSDT rates of the four racial groups studied over the three years of the QISMC study. Pl. Ex. 582 at 9; Pl. Ex. 580 at 9; and Pl. Ex. 686 at 8.

during year III, OFMQ found documentation of health education, a required component of an EPSDT screening, in only 40% of the 37.9% of cases where some examination had been performed. Id.

146. Appropriate blood lead screening is a required component of an EPSDT screening service. 42 U.S.C. § 1396d(r)(iv). All children are considered at risk and must be screened for lead poisoning. State Medicaid Manual, Pl. Ex. 2, at § 5123.2(D)(1). HCFA/CMS requires that all children receive their blood lead toxicity screening "at 12 months and 24 months of age." Id. (emphasis in original). Nonetheless, only 1,821 of 63,801, or fewer than 3%, of eligible one- and two-year-olds received blood lead screens in 2001. Pl. Ex. 469, lines 1 and 14. Similarly, in fiscal year 2000, OHCA reported that 908 of 58,249, or 1.5%, of eligible one- to two-year-olds received a blood lead screening. Pl. Ex. 470, lines 1 and 14.

147. OFMQ reported that if PCPs had taken advantage of "missed opportunities" to screen children, the EPSDT rate would have risen dramatically. Pl. Ex. 580 at 12-13; Pl. Ex. 686 at 12. Specifically, OFMQ found a significant number of cases where a child had an encounter with his PCP, but the PCP had failed to perform an EPSDT examination. Id. During year III of the QISMC study, if PCPs had taken advantage of these missed opportunities to perform an EPSDT examination, the SoonerCare Choice EPSDT rate would have increased by 30%. Pl. Ex. 686 at 12; Tr. Vol. XX, at 2557:19-24. Based upon this "missed opportunities" data, defendants' expert Yvonne Powell opined that, "there needs to be [a] focus on educating both physicians and families as to EPSDT." Tr. Vol. XVI, at 2189:6-12.

148. The original SoonerCare contracts provided a sanction when PCPs did not meet EPSDT goals. In response to criticism of that sanction, OHCA eliminated the penalty and created

a bonus payment for PCPs who reach a target rate for EPSDT screenings. Tr. Vol. X, at 1286:14-20; 1335:1-10. Nonetheless, OHCA records for the 2001 State Fiscal Year ("SFY") reveal that many providers in this program reported doing fewer than 10% of the EPSDT examinations required by their patients. Pl. Ex. 497, EPSDT Bonus Payment Report, SFY 2001.

b. Immunizations

149. The Oklahoma Medicaid program pays for childhood vaccinations, and the State's county health departments offer the vaccinations for free. Tr. Vol. VIII, at 998:14-23. At the time of trial, at least twelve of the named class plaintiffs were current on their immunizations. Tr. Vol. I, at 178:5-7 (Jacob H.); Tr. Vol. I, at 172:5-24 (Everett H.); Tr. Vol. VI, at 731:1-9 (Chrystal M.'s two children); Tr. Vol. VI, at 781:9-18 (Christine M.'s three children); Tr. Vol. VI, at 817:21 - 818:5 (Traci R.'s child); Tr. Vol. VII, at 836:20 - 837:1 (Patsy K.'s child); Tr. Vol. IX, at 1099:16-19 (Sherry Lou E.'s three children). The evidence shows that a significant number of other Medicaid children are not current.

150. Health Employer Data Information Set ("HEDIS") is a quality assurance tool used by entities which provide managed care to monitor whether they are "meeting some standards with regard to access and delivery of specific services." Tr. Vol. VIII, at 992:10-16. According to 2001 HEDIS data, all four SoonerCare HMOs were below the 2000 Medicaid mean in administering the Hib (*Haemophilus influenzae* type b conjugate) vaccinations. Pl. Ex. 359 at OHCA.0608. Two of the four HMOs were below the Medicaid mean in the Combination 1[12] and DTP (Diphtheria, Tetanus and Pertussis) vaccinations. Id. Only 33.45% of children in Prime Advantage HMO,

---

[12] Combination 1 includes the DTaP/DT (Diptheria and Tetanus Toxoids and Acellular Pertussis/Diptheria and Tetanus Toxoids), IPV (Trivalent Inactivated Polio Virus), MMR (Measles, Mumps, Rubella), Hep B (hepatitis B), and Hib vaccinations.

54.40% of children in Unicare HMO, and 2.30% of children enrolled in CommunityCare HMO received the Combination 1 vaccinations. Id. Just over half of the children enrolled in Prime Advantage and 5.51% of CommunityCare children received a DTP. Id.

151. In 2003, Unicare HMO reported that less than half of its enrolled children had received the DTP vaccination, and only 35% had received the Combination 1 vaccinations. Pl. Ex. 505 at OHCA.0890. During that same year, Prime Advantage HMO reported that fewer than 50% of its child members had received the DTP vaccination and only 32% had received the Combination 1 vaccinations. Pl. Ex. 507 at OHCA.1105.

152. After reviewing HEDIS data for 2000 and 2001, plaintiffs' immunization expert, Dr. Louis Cooper, concluded that "children in the Oklahoma Medicaid program . . . are at unnecessary risk of illness, disability and death from vaccine-preventable diseases." Pl. Ex. 359 at BB.10757 (emphasis in original). Dr. Cooper noted that, for the reporting period, only one HMO had reached national Medicaid mean values for all vaccines and that five of eight HEDIS reports included immunization levels at or below the lowest 10th percentile. Id. Overall, at 65%, Oklahoma ranks in the lowest three of all fifty states for vaccination coverage. Id. However, Dr. Cooper's data does not distinguish between the immunization rate for non-Medicaid eligible Oklahoma children from the rate for Medicaid eligible Oklahoma children. Tr. Vol. VIII, at 1001:17-21.

153. In its year III (data for services rendered in 2001) QISMC EPSDT report, OFMQ reported the percentage of children in its sample who had received required immunizations out of those who had received some form of physical examination. Pl. Ex. 686 at 4, 10. Specifically, OFMQ reported the 22.9% of SoonerCare Choice children had received a Hepatitis B vaccination, 30.8% had received the polio vaccination, and 42.9% had received the DTP vaccine. Id. In a 1998

focused study of the SoonerCare Choice program, OFMQ found that Choice was below the 80% benchmark in all but one of the required immunizations. Pl. Ex. 500 at 6. OFMQ specifically reported that only 37.6% of Choice members had been vaccinated for varicella, commonly known as chicken pox. Id.

154. OFMQ has also found a connection between better immunization numbers and pediatric primary care. In a 2001 Childhood Immunization QISMC report, OFMQ found that "[t]he data suggest that the practice of encouraging parents to choose [a] Pediatrician[] as their child's PCP may result in more beneficial immunization outcomes." Pl. Ex. 579 at 17. Quality health care for children "requires completion of basic immunizations to prevent illness, disease and medical problems." Pl. Ex. 41 at BB.6755. Defendant Fogarty agrees that the immunization rate is "one of the measures" which should be used to measure the "quality of a particular delivery system for children." Tr. Vol. X, at 1312:3-6.

c. Periodicity Schedule

155. As set forth above, EPSDT screening services are to be provided "at intervals which meet reasonable standards of medical and dental practice as determined by the State after consultation with recognized medical and dental organizations involved in child health care . . . ." 42 U.S.C. § 1396d(r)(1)(A)(i). Each Medicaid agency must establish an EPSDT screening "periodicity schedule" to be followed by participating providers. State Medicaid Manual, Pl. Ex. 2, at § 5140. OHCA has not consulted with child health care organizations in establishing its periodicity schedule. Tr. Vol. X, at 1210:16-22.

156. The first periodicity schedule was established by the American Academy of Pediatrics ("AAP") in the early to mid-1980s. Tr. Vol. IX, at 1071:21-25. It is not mandated by

law. Id. at 1084:23-25. The AAP periodicity schedule was drafted by experts in the field for the purpose of creating a uniform set of guidelines for the optimal intervals of time in a child's life when children should be examined by their physician. Id. at 1072:5-11. The AAP periodicity schedule is updated "every three or four years." Id. at 1072:12-13.

157. Comparing Oklahoma's periodicity schedule (Pl. Ex. 224, at BB.7850) with the AAP's periodicity schedule (Pl. Ex. 3), current AAP President Carden Johnston came to the conclusion that there are "[s]ignificant qualitative and quantitative differences" between the two. Tr. Vol. IX, at 1072:25 - 1073:6. For instance, the AAP schedule requires a newborn examination, and the SoonerCare Choice schedule does not. Id. at 1073:8-17. In addition, the AAP periodicity schedule includes annual checkups during the adolescent years, while the SoonerCare Choice schedule provides for screenings only on a bi-annual basis after the age of six. Compare Pl. Ex. 3 with Pl. Ex. 224 at BB.7850. There is also a specific provision in the AAP periodicity schedule for infant "sleep positioning counseling," and the SoonerCare Choice schedule makes no mention of such counseling. Compare Pl. Ex. 3 with Pl. Ex. 224 at BB.7850. In Dr. Johnston's opinion, the SoonerCare Choice periodicity schedule does not reflect "in quality and quantity" the care recommended by the AAP. Tr. Vol. IX, at 1074:20-21.

158. In contrast to Dr. Johnston's testimony, Dr. Steven Wegner testified that Oklahoma's EPSDT periodicity schedule is sufficient. Tr. Vol. XI, at 1476:6-25. Dr. Wegner compared the Oklahoma schedule with that of North Carolina, for whom he consults. Id. Defendants also point out that the latest AAP periodicity schedule is under review by the AAP. Tr. Vol. XI, at 1443:6 - 1444:1; 1446:6-24.

d. Outreach and Follow-Up

159. There is a federal requirement for PCCM programs like SoonerCare Choice that PCPs must engage in EPSDT outreach and notify recipients when they are due for an EPSDT screening. Tr. Vol. XIII, at 1705:2-13; State Medicaid Manual, Pl. Ex. 2, at BB.0067 (§ 5310(D)). Aside from the federal obligation, Dr. Mitchell believes that a call from the doctor's office is a powerful outreach tool in terms of encouraging Medicaid recipients to utilize EPSDT services. Id. at 1707:10-20. The SoonerCare Choice provider contract also requires PCPs to conduct and document EPSDT outreach and to "conduct and document follow ups with all members under the age of 21 who have missed appointments." Pl. Ex. 224 at BB.7770, ¶ 2.5(A)(2).

160. Dr. Mitchell testified that she was not aware of OFMQ's finding that SoonerCare Choice PCPs were failing to meet this obligation. Tr. Vol. XIII, at 1709:11-16. In consecutive years, OFMQ advised that EPSDT rates could be improved if PCPs would contact parents or guardians to schedule appointments; yet, at the same time, it found that Choice PCP's were "not making efforts to contact parents or guardians or previous PCP/CMs or that they are not documenting their efforts." Pl. Exs. 582 at 12; 580 at 12. After reviewing OFMQ's findings, Dr. Mitchell stated that it "appear[ed]" OFMQ had found a failure by providers to conduct EPSDT outreach as required. Tr. Vol. XIII, at 1711:2-5.

161. In terms of EPSDT quality assurance, Powell points to OHCA's "site visit reports," or on-site reviews, as providing the agency with "a detailed assessment of providers' EPSDT screening efforts." Powell Report 3/8/03, Def. Ex. 16, at III-3. OHCA's site visits or on-site reviews are essentially an audit, which allows OHCA to monitor the operations of its providers. Id. at III-2. OHCA's Surveillance, Utilization and Review System ("SURS"), an auditing unit, reviews EPSDT billings, among other things, and seeks recoupment of improperly paid funds from PCPs.

Tr. Vol. II, at 356:20 - 357:22. OHCA has terminated PCPs and demanded repayment of capitation payments made. Tr. Vol. X, at 1368:14-18.

162. The site visit reports indicate that some SoonerCare Choice PCPs have failed to engage in EPSDT outreach and/or follow-up, in violation of their contractual obligations. Pl. Exs. 614, 615, 619, 621, 623, 624, 625, 626, 627, 630 and 633. Yet, such failures were never reported as deficiencies. Id.[13] When one physician, who had merely performed eight of 866 needed screens, was randomly selected for an on-site audit, the auditors found no follow-up when EPSDT screens were missed, and no outreach. Tr. Vol. X, at 1289:9-15; 1295:3 - 1296:8; Pl. Ex. 492, at 22; Pl. Ex. 633, at 2-3. Dr. Mitchell, overseer of quality assurance at OHCA, acknowledged at trial that SoonerCare Choice PCPs were not complying with the contractual and federal EPSDT outreach requirements. Tr. Vol. XIII, at 1715:12-24; 1716:9-24.

163. OHCA does send EPSDT reminder letters to recipients through OHCA's fiscal intermediary, but Dr. Mitchell could not quote the illiteracy rate of the Medicaid population in Oklahoma. Id. at 1719:7-13. CMS requires that state Medicaid agencies "utilize accepted methods for informing persons [about EPSDT] who are illiterate, blind, deaf, or cannot understand the English language." State Medicaid Manual, Pl. Ex. 2, at BB.0041 (§ 5121(C)). At trial, Dr. Mitchell pointed to other outreach measures that OHCA has taken independent of PCP outreach, but defendants have not conducted their own analysis as to whether those measures have been effective

---

[13] For instance, as part of the October 2003 site visit for a Choice PCP, the reviewer noted that the doctor did not have any follow-up procedures for patients who missed EPSDT appointments and did not engage in EPSDT outreach or education. Pl. Ex. 627, Provider Site Visit, at 2-3. However, after finding these obvious deficiencies in the operation of this PCP's office, the reviewer reported that the "site visit went well with no deficiencies being found." Pl. Ex. 627, Memo from Alexis Howard to Nancy Austin, 10/20/03.

in increasing EPSDT rates. Tr. Vol. XIII, at 1721:4-17. However, of the named class plaintiffs, the EPSDT screenings for at least five were current at the time of trial. Tr. Vol. I, at 178:5-8 (Jacob H.); Tr. Vol. I, at 172:5-24 (Everett H.); Tr. Vol. VI, at 731:1-9 (Chrystal M.'s two children.); Tr. Vol. VI, at 817:21 - 818:5 (Traci R.'s child).

e. Diagnosis

164. The evidence shows that some class members have been unable to obtain essential diagnostic services. For instance, Dr. Tawfik Ramadan suspects that named plaintiff Jacob H. has sleep apnea. Tr. Vol. IX, at 1106:15 - 1107:23; Tr. Vol. I, at 164:24 - 165:24. Sleep apnea is a serious condition in children, where the child actually stops breathing for periods of time during the night. Tr. Vol. IX, at 1107:1-7. While Dr. Ramadan has attempted for approximately three years to find a sleeping disorder facility to perform a necessary diagnostic sleep study on Jacob, he has been unable to find a facility willing to accept SoonerCare. Id. at 1107:8-16. Similarly, at the time of the class certification hearing, named plaintiff Katelyn W. had been unable to secure a medically necessary prosthetic shoe insert to replace her amputated foot. Tr. 3/14/03, at 23:1 - 24:25; 26:1 - 27:10.

165. In the area of pediatric cardiology, Medicaid patients in the Tulsa area have no access to a diagnostic tool called cardiovascular magnetic resonance angiography ("MRA"). Tr. Vol. XI, at 1494:24 - 1495:19. At the same time, privately-insured patients have no problem accessing MRA services. Id. at 1495:20-21. MRA is a non-invasive procedure, which can be used to safely diagnose approximately 350 deformities that make up congenital heart disease. Id. at 1495:25 - 1496:7. MRA is important because it allows many children to forego heart catheterization, which is painful and poses risks to the patient. Id. at 1496:8-17.

f. Dental Services

166. Of 413,302 children eligible to receive EPSDT dental services in fiscal year 2001, only 69,360 children (17%) received any dental services. Pl. Ex. 469, ln. 12a. Of that number, 56,760 received preventive dental services, and 36,913 eligible children received dental treatment services. Ex. 469, lines 12b, 12c. For the fiscal years 1998, 1999 and 2000, defendants reported that 10% (29,210 of 280,645), 13% (41,637 of 327,768) and 13% (47,992 of 376,173), respectively, of the eligible children received any dental services. Pl. Exs. 472, lines 1 and 14; 471, lines 1 and 12a; and 470, lines 12 and 12a. Thus, on average, only 13.2% per year of EPSDT-eligible children received any dental services during the three-year period of 1998 through 2001. Yet, approximately 68% of Oklahoma children have untreated dental caries. Tr. Vol. VI, at 714:14 - 715:5.

167. These numbers are of particular concern given the characteristics of this population. Plaintiffs' expert David Johnsen testified that dental caries are more prevalent in low income children and patterns of decay appear at an earlier age and are more severe. Tr. Vol. V, at 607:13-16. Severe dental caries are found in 10-15% of low income children, and for Native Americans, this number can be as high as 50%. Id. at 607:20-24. While dental caries are curable, they are infectious and, if left untreated, can cause "pain and infection, loss of function [and] become unsightly." Id. at 614:12-14.

168. Dr. Johnsen made no claims about lack of access to dental care for Medicaid recipients in Oklahoma. Tr. Vol. V, at 615:2-8. The number of dentists contracted with OHCA has increased from fewer than three hundred to more than five hundred fifty over the last two years. Tr. Vol. X, at 1352:19-21. To the knowledge of OHCA's dental manager, no dentist has refused to provide dental care to a Medicaid recipient child since the payment rate was increased 60% in

August 2000. Tr. Vol. XV, at 1936:4-8. Several named class members have access to dentists and dental care. See Tr. Vol. I, at 169:2-4; 179:11-25; Tr. Vol. VI, at 728:21 - 729:4. Tr. Vol. VI, at 781:2-8.

169. Several physicians testified that access to dental care remains a problem, and serious health consequences to children can result from lack of dental care. Tr. Vol. VI, at 714:14 - 715:5; see Tr Vol. XI, at 1508:25 - 1510:10 (endocarditis is higher in one doctor's Medicaid patients); Tr. Vol. III, at 401:13 - 402:20 (lack of access to dental care in Ponca City has caused health problems for some Medicaid children)[14] ; Tr. Vol. IV, at 552:25 - 553:14 (no access to dental care for Medicaid children under three years old from dentists in Enid); Tr. Vol. XVIII, at 2331:22 - 2332:3 (only one pediadontist in Tulsa has been willing to accept Medicaid patients from the OU Tulsa Pediatric Clinic[15] on a regular basis);" Tr. Vol. I, at 56:19 - 57:6 (some Medicaid patients in Oklahoma City wait for a dental appointment one to two years.)

g. Transportation

170. Defendants are required to provide transportation to health care appointments, when requested and necessary. State Medicaid Manual, Pl. Ex. 2, at BB.0056 (§ 5150). OHCA provides transportation to Medicaid recipients through the SoonerRide program. Tr. Vol. II, at 275:17-19. As an example of the program's usage, SoonerRide provided approximately 36,000 trips for

---

[14] Chrystal McQuerry, mother of two class members testified that she could take her children to a dentist in Ponca City who accepts Medicaid, but she chooses instead to travel to Oklahoma City for dental appointments twice a year per child. Tr. Vol. VI, at 726:7-10; 728:21 - 729:4.

[15] The OU-Tulsa Pediatric Clinic serves approximately 12,000 children on Medicaid. Tr. 3/14/03, at 150:12-14. The OU Clinic is a safety net provider that accepts any Medicaid patient. Id. at 157:1-12. The numbers of children treated by the clinic has grown beyond its designed capacity because of a lack of pediatric providers in the community. Id.

Medicaid recipients needing transportation to health care appointments in the month of January 2004. Tr. Vol. X, at 1346:23 - 1347:5. OHCA also pays for a Medicaid recipient and a companion to travel to and stay at an in-state or out-of-state hotel related to a health care appointment. Tr. Vol. X, at 1347:6-19. When families are required to travel long distances for health care appointments, the exceptional needs coordinators make the Medicaid recipients aware of transportation and lodging assistance. Tr. Vol. XIV, at 1858:2 - 1859:3. OHCA's printed materials state: "SoonerRide provides transportation if you do not have a ride to your PCP or CM specialist, pharmacy, or hospital." Tr. Vol. VI, at 783:5 - 784:3; Def. Ex. 34, at 18. Defendants point out that some recipients are aware of the program but choose not to use it. See Tr. Vol. VI, at 727:19 - 728:7; Tr. Vol. I, at 180:1-8.

171. Dr. Thomason has attempted to schedule transportation services for her Medicaid patients, but has found SoonerRide to be unavailable at times. Tr. Vol. III, at 415:3-13. As Dr. Thomason explains, it is already "very tricky to coordinate" specialty appointments for her Medicaid patients. Id. at 415:6-8. The unpredictability of SoonerRide means that recipients run the risk of losing their scheduled appointment and having to wait to schedule a new appointment. Id. at 415:10-11.

172. Similarly, Dr. Siegler testified that transportation problems are "probably the most common cause" of Medicaid recipients failing to show up for appointments. Tr. Vol. V, at 585:12-17. While Dr. Siegler is aware that SoonerRide exists, he has found that many of his Medicaid patients are not aware of the availability of transportation services: "there's kind of a communication issue." Id. at 601:9-15. Dr. Stuemky, a pediatrician and health care administrator with 28 years of experience, describes SoonerRide as a program that he has heard exists, but that

he has not seen as an “active part” of his Medicaid patients’ lives. Tr. Vol. I, at 141:23 – 142:17. Like Dr. Siegler, Dr. Stuemky describes a breakdown in communication with regard to transportation services, as providers and recipients alike do not know how to access SoonerRide. Id.

173. Oklahoma’s Medicaid State Plan provides that OHCA will not only provide transportation if needed, but for patients who have their own car, OHCA will also provide payment on a mileage basis. State Medicaid Plan, Pl. Ex. 38, at BB.6246. The State Plan additionally provides that OHCA will reimburse recipient families for room and board expenses if required to meet the patient’s needs. Id. However, in the information provided to recipients, the 2004 SoonerCare Choice Member Handbook, there is no mention of room and board assistance, nor any mention that transportation assistance is available to those who have their own private transportation. Def. Ex. 34 at 18; Tr. Vol. X, at 1238:6 - 1241:1. SoonerRide is not mentioned in the Handbook until page 18. Id.

174. The mother of one class member testified that she was unaware that OHCA would provide gas money and room and board payments as part of SoonerRide. Tr. Vol. VI, at 784:1-13. Consequently, she paid for a hotel room in a city four and a half hours from her home when she took her daughter there for 9:00 a.m. appointment with a pediatric neurologist. Id. at 774:10 - 776:9. Due to the expense of the trip, the child did not make it to a follow-up appointment with the neurologist. Id. at 776:19 - 777:5. Although the mother did not look at all OHCA materials about Medicaid, after reviewing the Member Handbook, she did not believe that SoonerRide would have been any help to someone like her, who had private transportation but needed money for room and board. Id. at 779:19 - 780:6; 784:1 - 785:9.

h. Xolair[16]

175. As stated above, after the non-jury trial, plaintiffs requested that the Court enjoin defendants from denying coverage for provide the anti-immunoglobulin E ("IgE") drug Xolair (the trade name for omalizumab) to six class members suffering from elevated IgE-related symptoms and whose physicians determined Xolair to be medically necessary for them. Six class members suffer significantly from asthma, as well as related allergies, atopic dermatitis, and other health problems associated with traditional treatment for children suffering from elevated IgE levels.

176. Xolair is a relatively new, very expensive drug that has proven to be extremely effective in diminishing or eliminating the symptoms that these children suffer. The cost of Xolair treatment for one year is about $10,000. A single shot costs about $500. Tr. 10/29/04, at 17:20-24; 44:2-6. For individuals with IgE levels above 700 ml. per International Unit, Xolair treatment requires more than five shots of the drug monthly. Id. at 29:13-19. The cost of the inhaled steroid Advair, a more common method of treatment for asthma, ranges from $90 - $140 for one month of treatment. Id. at 18:7-13.

177. Genentech created Xolair and Novartis co-promotes the drug with Genentech. Id. at 135:14-20. However, these companies do not promote or recommend Xolair for children less than twelve years of age because the drug is not approved by the United States Food and Drug

---

16 At the final hearing on the Xolair issue, plaintiffs moved to have the evidence presented at the Xolair hearings included in the record as a whole. Defendants objected, and the Court took the issue under advisement. After reviewing the record, the Court finds that the evidence should be included in the record as a whole, given testimony in plaintiffs' case-in-chief by Dr. Marcialee Ledbetter that OCHA had denied prior authorization for medication, and by Dr. Robert Block that he had experienced difficulty in obtaining authorization for medications needed by his Medicaid patients. See Tr. Vol. VII, at 857:5 - 860:3; Tr. 3/14/03, at 178:6 - 179:14.

Administration ("FDA") for children under the age of twelve. Id. at 136:5- 5; 138:6-20. On June 20, 2003, the FDA approved Xolair "for adults and adolescents (12 years of age and above) with moderate to severe persistent asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids." Pl. Ex. 32; Def. Ex. 44. The drug's manufacturer, Genentech, did not seek approval of Xolair for use in children under the age of 12 even though the company had conducted a study of the drug's safety in that age group. Def. Ex. 43, at 8, 52, 58-59.[17] Genentech and the FDA have expressed a desire for additional safety studies before Xolair can be approved for that age group. Id. at 154 - 59.

178. Some literature suggests an increased risk of cancer associated with the use of Xolair. Tr. 10/29/04, at 99:17 - 100:10; Tr. 11/01/04, at 298:11-25; Def. Ex. 43, at 67-70; Def. Ex. 45, at 10-11; Def. Ex. 56, at Bates 603. This literature indicated that study participants on Xolair had a two-and-one-half times greater rate of malignancy than study participants on placebos. Tr. 10/29/04, at 41:21-25. However, two doctors testified at trial that this risk has not proven true. Id. at 13:12-22; 14:17-18; 187:19 - 188:8. Several peer-reviewed medical journal articles detail the findings from studies concerning the use of Xolair in children, ages six to twelve. See Pl. Exs. 7-10. Two of these studies found that Xolair is safe and effective in reducing asthma exacerbations and in reducing the need for inhaled steroids. Pl. Ex. 7 (William Berger, et al., Evaluation of Long-Term Safety of Anti-IgE Antibody, Omalizumab, in Children with Allergic Asthma, 91 ANN. ALLERGY ASTHMA

---

[17] Plaintiffs objected to this exhibit at trial, and the Court took the objection under advisement. Having reviewed the document, the Court finds that it does not indicate a lack of trustworthiness and shall be admitted under Fed. R. Evid. 803(8).

IMMUNOL., 182-88 (2003)); Pl. Ex. 8 (Henry Milgrom et al., Treatment of Childhood Asthma with Anti-Immunoglobulin E. Antibody (Omalizumab), 108 PEDIATRICS 36 (2001)).

179. One of the doctors who testified a trial is James T. Love, M.D. He is board certified in pediatrics, allergy, asthma and immunology. Tr. 10/29/04, at 6:12-13. Based upon the published pediatric studies and his own professional experience, he does not believe that the age limitation of 12 years is medically appropriate. Id. at 27:12-17; see id. 56:13-23. Another doctor who testified was a pediatric pulmonologist, Santiago Reyes, M.D. Dr. Reyes testified that, at least within the pediatric pulmonology community, it is generally accepted to consider Xolair for use in children under twelve with moderate to severe asthma which has been poorly controlled by maximum doses of conventional therapies. Id. at 198:11-20; see Pl. Ex. 11 (Letter from Louey K. Nassri, M.D. to Nancy Nesser, D.Ph., J.D. (Feb. 24, 2004)). He is currently conducting a clinical Xolair study for children, ages six to twelve, with moderate to severe asthma, who have failed to respond to traditional medications. Id. at 181:23-182:4. However, children who have been treated with Xolair in the past are not candidates for inclusion in the study. Id. at 182:15-19.

180. Defendants point out that there is no evidence that any peer-reviewed articles concerning the study of Xolair use in children less than twelve years of age have been listed in the compendia identified in 42 U.S.C. §1396r-8(b)(g)(1)(B)(i). The compendia are reference books containing FDA indications for uses of drugs and indications for non-approved uses that have become the standard of care. Tr. 11/01/04, at 253:7-15.

181. In addition, the National Asthma Education and Prevention Project (NAEPP) publishes accepted health-care practice standards and guidelines for asthma, and these guidelines do not include the use of Xolair. See NAEPP, Guidelines for the Diagnosis and Management of

Asthma, Expert Panel Report 2, NIH Pub. No. 97-4051 (July 1997), at http://www.nhlbi.nih.gov/guidelines/asthma/asthgdln.htm; NAEEP, Expert Panel Report: Guidelines for the Diagnosis and Management of Asthma, Update on Selected Topics 2002, NIH Pub. No. 02-5074 (June 2003), at http://www.nhlbi.nih.gov/guidelines/ asthma/asthupdt.htm; see Tr. 10/29/04, at 53:7 - 54:14; 63:15 - 20; Tr. 11/01/04, at 256:3-9.

182. Studies of Xolair continue to be conducted as to the safety and efficacy of the drug. See Tr.10/29/04, at 50:24 - 51:8; see also id. at 191:14-20. There is not yet a substantial body of literature on the use of Xolair in children less than the age of twelve years. Id. at 55:3-6. As set forth above, Dr. Reyes is currently conducting a study of the use of Xolair in children from six to twelve years of age to determine the drug's safety and efficacy in that population. Id. at 181:21-24; 190:1 - 191:4. There are also currently studies being conducted on the safety and effectiveness of inhaled steroids which have been on the market for decades. Id. at 58:25 - 59:5.

183. Xolair dosage has not been studied in children under six years of age. Id. at 38:1-12. Although a doctor can predict with a certain degree of accuracy the biological half-life of Xolair in a child, it is not possible to use adult studies to predict how all body systems of children in this young of an age group will be affected by Xolair. Id. at 38:13-24. Children metabolize drugs differently than adults. Id. 72:5-9. Their nervous systems change as they grow. Id. at 34:15-24. Two pivotal trials of Xolair involved adults who weighed thirty kilograms or more. Tr. 11/01/04, at 297:17-23. Genentech has not urged the use of Xolair in individuals weighing less than thirty kilograms. Tr. 10/29/04, at 198:21 - 199:3. The safety of Xolair use in children cannot be accurately predicted because the drug has not been used even in adults long enough to make such predictions. Id. at 38:22 - 39:2.

184. Third-party payors require prior approval for all use of Xolair. Id. at 43:23-25. Physicians have difficulty obtaining such approval, and some third-party private insurance companies "flatly deny" payment for use of the drug. Id. at 43:8-14; see id. at 16:1-6. At least three third-party providers in Oklahoma will not pay for Xolair use in children less than twelve years of age because such use is still investigational and not approved as safe and effective by the FDA. Id. at 98:20 - 99:16; 103:14 - 105:13; Tr. 11/01/04, at 283:25 - 284:13.

185. There are many drugs which are not tested for safety and efficacy in children of various ages. As such, these drugs are not FDA-approved for use in children. Physicians at trial testified that the drug manufacturers do not conduct studies on children because the pediatric market is not very profitable for them. Tr. 10/29/04, at 22:10-15. For this reason, physicians who care for children often prescribe drugs "off-label." Id.; see Tr. 11/01/04, at 330:11-13. The asthma inhaler Seravent is one example. Physicians often prescribe it for children as young as six months of age. Tr. 10/29/04, at 22:4-6. According to the American Academy of Pediatrics, "[t]he off-label use of a drug should be based upon sound scientific evidence, expert medical judgment or published literature." Pl. Ex. 12, American Academy of Pediatrics Committee on Drugs, Uses of Drugs Not Described in the Package Insert (Off-Label Uses), 110 PEDIATRICS 181 (2002).

186. OHCA pays for many drugs for use by children which are not FDA-approved for use by children. Tr. 10/29/04, at 224:25 - 225:3. According to OHCA's pharmacy director, OHCA has covered Xopenex, Proventil and Albuterol, asthma medications which are not FDA-approved for use in children. Tr. 11/01/04, at 247:6-21. Xopenex, like Xolair, is a new drug. The process by which the OHCA Drug Utilization Review ("DUR") Board approved Xopenex was conducted in the summer of 2004. Id.

187. Five of the six class members who sought supplemental relief in this Court began taking Xolair in the fall of 2003. One child, D.R., has lung damage which "seems to be irreversible." Tr. 10/29/04, at 25:24-25. D.R. and his sibling, L.R., suffer from frequent and sometimes life-threatening asthma attacks, even with use of daily breathing treatments or inhalers. Pl. Mot. for Supp. Relief, Dkt. # 241, Ex. B., at ¶¶ 1-4. D.R. and L.R. have three siblings who suffer from less severe allergic asthma and other IgE-related symptoms. Id. (All five of these children are hereinafter referenced as the Rhone children.) D.R. has a constant wheeze when he breathes. D.R. and L.R. are on several traditional medications, including inhaled corticosteroids and oral steroids, at and above the recommended dosages. Yet, these medications have not adequately controlled the severe, persistent asthma these children suffer. Tr. 10/29/04, at 63:5 - 64:4; Pl. Sub. of Court-Ordered Eval., Dkt. # 256, Ex. B. The long-term use of inhaled steroids at high dosages can cause height diminution, cataracts, and the weakening of bones. Tr. 10/29/04, at 11:2-8.

188. All of the Rhone children have also been diagnosed with atopic dermatitis, or eczema. Tr. 10/29/04, at 64:12-16. L.R.'s atopic dermatitis manifests in scales and cracks in ths skin that lead to bleeding and infections so severe that she often cannot wear shoes or sleep. Pl. Mot. for Supp. Relief, Dkt. # 241, Ex. B at ¶ 2. The Rhone children have all missed a significant amount of school due to their illnesses, and they cannot fully participate in extracurricular activities. Id., Ex. B. at ¶ 5.

189. Timothy Shann, M.D., a pediatrician, began treating the Rhone children with Xolair on October 21, 2003. Tr. 10/29/04, at 65:22-24; 67:25 - 68:2. D.R. was seven years of age at the time and L.R. was two years of age. Id. at 61:12 - 14. Dr. Shann arrived at an appropriate dose of Xolair for each of the Rhone children only after consulting with a representative from the drug

manufacturer who was specifically trained in dosage calculation. Id. at 67:13-24. D.R. weighs 34 kilograms; L.R. weighs less than twelve kilograms. Def. Ex. 63, Bates 221, 223. Their IgE levels are well above the 700 IU/ml. level. In September 2003, D. R. had an IgE level of 2,310 and L.R. had an IgE level of 1,888. Pl. Ex. 2, at BB.11081; Pl. Ex. 5 at BB.11523. When Dr. Shann prescribed Xolair for these children, he was unaware of any articles or studies indicating the efficacy of the drug in children. He wanted to publish his own article, using these children as his study subjects. Tr. 10/29/04, at 72:10-22.

190. Dr. Shann submitted a "Statement of Medical Necessity for Xolair" to a pharmacy on behalf of each of the Rhone children. Def. Ex. 63. OHCA initially approved and paid for their use of the drug, and the Rhone children experienced remarkable improvement in their health and quality of life. Within a matter of months, their asthma attacks ceased, their skin cleared, and they began eating a full and balanced diet. Pl. Mot. for Supp. Relief, Dkt. # 241, Ex. B, at ¶ 7. They no longer missed school due to illness, they were able to play sports and with other children, and they were able to sleep soundly through the night. Id. at ¶ 8. Dr. Shann was able to take them off all of their traditional medications. Id. at ¶ 7; see Tr. 10/29/04, at 68:8-11.

191. Like D.R. and L.R., L.H. suffers from severe, persistent asthma. She has been hospitalized due to asthma attacks eight or nine times since shortly after her birth more than eleven years ago, and she has taken multiple asthma medications over the years. Pl. Mot. for Supp. Relief, Dkt. # 241, Ex. C., at ¶ 2. In general, L.H. must puff on an anti-asthma inhaler twice every three hours, and she wheezes when exposed to smoke, perfume or any strong odor. Id. Ex. C., at ¶ 4. Her asthma and allergies make it impossible for her to participate in sports. Id. Ex. C, at ¶ 5.

192. Dr. Shawna Duncan of Muskogee, L.H.'s primary care physician, referred L.H. to Dr. Louay Nassri, a pediatric pulmonologist in Fort Smith, Arkansas, in early summer 2003. Id. at ¶ 6. Dr. Nassri diagnosed L.H. as having severe, persistent asthma. Pl. Ex. 6 at BB.11577. Dr. Nassri tried several different medications, without effecting an improvement in her condition. Pl. Mot. for Supp. Relief, Dkt. # 241, Ex. C., at ¶ 6. On August 20, 2003, Dr. Nassri sought and obtained preauthorization to prescribe Xolair for L.H., who was nine years old at the time. Def. Ex. 62. As with the Rhone children, L.H's condition improved remarkably with Xolair. Pl. Mot. for Supp. Relief, Dkt. # 241, Ex. C., at ¶ 7. For the first time in her life, she began breathing clearly. Id.

193. On October 14, 2003, OHCA's Drug Utilization Review Board, or DUR voted to require prior authorization of Xolair. The issue had been placed previously on the agenda for discussion on September 9, 2003. Pl. Ex. 14. The Board approved the following prior authorization criteria:

1. Client must be between 12-75 years of age.
2. Client must have a diagnosis of severe persistent asthma (as per NAEPP guidelines).
3. Client must have a positive skin test to at least one perennial aeroallergen. Positive perennial aeroallergens must be listed on the petition.
4. Client must have a pretreatment serum IgE level between 30-700 IU/ml.
5. Client weight must be between 30-150 kg.
6. Client must have been on high dose ICS [inhaled corticosteroids] (as per NAEPP guidelines) for at minimum the past three months.
7. Medication must be prescribed by either a pulmonary or an allergy/asthma specialist.
8. Client must have been in the ER or hospitalized, due to an asthma exacerbation, twice in the past six months. Date of visits must be listed on the petition.

Pl. Ex. 13 at BB.11633.

194. The DUR Board did not consider the peer-reviewed literature relied upon by the plaintiffs regarding the safety and efficacy of Xolair for use in children. See Tr. 10/29/04, at 206:21 - 207:8. A representative of the OU College of Pharmacy was responsible for presenting the relevant literature and making a recommendation to the Board, and drafting the criteria for the Board's consideration. Tr. 11/01/04, at 290:15-25; 294:6-13. The representative read all the materials, spoke with a Genentech representative, and chose not to present any pediatric Xolair study to the DUR because she considered the data incomplete. Id. at 291:1 - 294:3; 295:21 - 296:3; 305:13-21. She was particularly concerned about side effects and the underrepresentation of African-Americans in the studies. Id. The representative testified that the medical literature did not establish that Xolair is generally recognized as safe and effective for children less than twelve years old. Id. at 299:12 - 20.

195. Neither the Rhone children nor L.H. were eligible for Xolair under the prior authorization period, and OCHA ceased authorizing the drug for them in early 2004. The symptoms reoccurred as before Xolair treatment in the six children on whose behalf plaintiffs requested the preliminary injunction. The children were placed back on maximal traditional therapy, but the symptoms returned to where they were prior to Xolair treatment – some in even greater severity. Tr. 10/29/04, at 70:1-14; Pl. Mot. for Supp. Relief, Dkt. # 241, Ex. B at ¶ 15, Ex. C, at ¶ 9.

196. OCHA did not notify Dr. Shann, D.R. and L.R.'s parents, or L.H.'s mother of its decision or the reasons for it. Pl. Mot. for Supp. Relief, Dkt. # 241, Ex. B, at ¶ 9, Ex. C. at ¶ 8; Tr. 10/29/04, at 69:12-21. The Rhone children's mother, LeCinda Rhone, filed administrative grievances. Pl. Mot. for Supp. Relief, Dkt. # 241, Ex. B, at ¶10; Pl. Ex. 18 at BB.11863-74. OCHA sent her "Program Panel Grievance Review" reports upholding the denial for Xolair based upon the

DUR Board prior authorization criteria. Ex. B-1, attached to Pl. Mot. for Supp. Relief, Dkt. #241, Ex. B. LeCinda Rhone filed an appeal which was heard before an Administrative Law Judge. Pl. Ex. 18 at BB.11857. OHCA's pharmacy director testified at the hearing that there had been no published studies regarding use of Xolair in children under twelve. Pl. Ex. 19 (Hrg. Trans. at 14:7-10.) Yet, she admitted at trial that there was such a study at the time of the administrative hearing. Tr. 10/29/04, at 207:22 - 208:2. She also testified that she had conducted no independent study of the peer-reviewed literature and had not reviewed a Xolair Formulary Dossier provided to her before the administrative hearing. Id. at 208:19-25. The ALJ denied the appeal in part based upon the pharmacy director's testimony.

197. L.H.'s mother, Linda Hargrove, filed an administrative appeal of the discontinuation of Xolair on behalf of L.H., but the appeal was denied as untimely. Tr. 11/01/04, at 278:13-17. The Court suggested during trial that defendant Fogarty consider waiving the untimeliness. Id. at 280:7 - 281:12. He did so and granted the appeal on November 24, 2004. Def. Ex. 71,[18] at 4. That determination retroactively granted the original prior authorization request by Dr. Nassri. In particular, Fogarty waived the age criterion, given that L.H. was eleven years old at the time of the determination. He also waived the criterion that a recipient visit the emergency room or be hospitalized twice in the past six months. The Court appreciates and commends OHCA Director Fogarty for his effort in this regard.

198. At the Court's direction, the Rhone children were re-evaluated. The Court directed plaintiffs to obtain a second opinion from another tertiary specialist with regard to both medical

---

[18] Defendants submitted two different exhibits numbered 71. The one attached to the Motion to Admit Supplemental Evidence, Dkt. # 259, is the one referenced here.

necessity for Xolair and lack of efficacy of traditional medications/therapies, and the result of a request for prior authorization of Xolair either to the Drug Utilization Review (DUR) Board or defendant Fogarty.[19] Tr. 11/01/04, at 386:17-21. Dr. James Love determined that Xolair was medically necessary for only two of the five Rhone children that this time: D.R. and L.R. See Pl. Sub. of Court-Ordered Eval., Dt. # 256, Ex. B.

199. OHCA's prior authorization criteria for Xolair is perhaps too stringent and its approval process flawed in some respects. The Court is encouraged by testimony at trial that the OHCA DUR Board reconsiders its decision to require prior authorization for a drug and payment by the Oklahoma Medicaid program at least annually. Tr. 11/01/04, at 250:24 - 251:5. It could be that, with additional studies, Xolair becomes generally recognized as safe and effective for children under the age of 12.

5. Eligibility/Enrollment

200. OHCA employs presumptive eligibility for children and pregnant women, whereby these individuals are assumed eligible for Medicaid when they apply and begin to receive medical assistance services prior to final determination. Tr. Vol. XVI, at 2108:4-13. Newborn children of Medicaid-covered mothers are automatically covered by the Medicaid system upon birth, and their bills are paid under a fee-for-service arrangement until the parent chooses a PCP for the child or OHCA assigns a PCP upon the parent's failure to choose timely. Tr. Vol. X, at 1261:16 - 1264:11. OHCA and DHS provide a Form NB1 to hospitals so that, if a new mother is not a Medicaid

---

[19] The Court also directed Fogarty and the OHCA pharmacy director to continue discussions with the manufacturer of Xolair regarding the possibility of the manufacturer providing the drug as part of an individualized study of five or six children. The parties have not made the Court aware of any progress in that regard.

recipient but the newborn child is eligible for Medicaid, the hospital can inform DHS, OHCA's eligibility agent. Tr. Vol. XVII, at 2297:14 - 2299:12.

201. As a result of a recommendation by the SoonerCare Task Force to increase the Medicaid eligibility period from three months to a full year, OHCA asked the Oklahoma Legislature to appropriate funding for that increase; however, that funding was not appropriated. Tr. Vol. VII, at 918:25 - 919:7. Nonetheless, OHCA extended eligibility to six months. OHCA also worked with the DHS to change the eligibility system so that, at the end of the period, recipients could renew eligibility for an additional six months rather than lose eligibility automatically. Id. at 913:5-25. After Medicaid recipients have gone through four and one-half months of their six-month eligibility, DHS, acting as OHCA's eligibility agent, sends the recipients notice that their Medicaid eligibility will soon expire and asks them to renew their eligibility. If the renewal is not made, a ten-day notice goes to the recipients. Failing a response, the Medicaid eligibility ceases. Tr. Vol. X, at 1256:2-21. If a Medicaid recipient acts after the ten-day notice but not in time to prevent a lapse in Medicaid eligibility, that person is placed in the fee-for-service system until the first day of the following month, when the recipient is put back into the panel of the Medicaid-paid PCP he had last in the previous six months. Id. at 1256:23 - 1258:1. OHCA CEO Fogarty expects to switch to twelve-month Medicaid eligibility by July 2005. Id. at 1267:3-6.

202. In response to complaints that health care providers could not determine whether individuals presenting themselves at their offices with a Medicaid card were indeed eligible for the program, OHCA created the recipient eligibility verification system ("REVS") which allowed providers to telephone to confirm eligibility. Id. at 1327:14-22. The eligibility verification system was updated to include a permanent identification card that can be electronically "swiped" to

determine eligibility. The system was further updated with an Internet web site. Id. at 1328:11 - 1329:1.

7. Auto-Assignment/Continuity of Care

a. Continuity of Care

203. There is an important connection between establishment of a "medical home" for a child and preventive health care for that child. Tr. Vol. IX, at 1065:22 - 1066:9. The AAP sees the pediatrician's office as a "medical home" for each child. Id. at 1064:20-23. The "medical home" is a place where a child can go over a long period of time to receive comprehensive, compassionate, and continuous care. Id. at 1064:23 - 1065:21. Continuity of care is "one of the most important aspects" of the physician-patient relationship. Tr. Vol. II, at 204:24-25. Continuity of care means that the patient will see a particular doctor over a prolonged period of time, and that doctor will become familiar with that patient's health care problems and needs, thereby optimizing the care that patient can receive. Id. at 205:1-13. When a patient's continuity of care is disrupted by assigning a child to a new physician, it can place the child at risk. Id. at 205:14-23.

b. OHCA's Default Enrollment / Auto-Assignment System

204. Under Oklahoma's auto-assignment system, Medicaid recipients have the opportunity to select the PCP they want at the time of enrollment or renewal. Tr. Vol. I, at 92:16 - 93:15; Tr. Vol. II, at 229:12-21. OHCA allows Medicaid recipients to change their PCPs as often as they want. Tr. Vol. I, at 132:19-24. OHCA contracts with an outbound telephone service to contact new recipients to urge recipients to choose a PCP and to inform them of services available. Tr. Vol. XIII, at 1757:17 - 1758:9.

205. The auto-assignment system is based, in part, upon the premise that further attempts to have Medicaid recipients choose a PCP would extend the time that recipients have no "medical home," creating access-to-care problems. Tr. Vol. I, at 95:13-23. When Medicaid recipients do not choose a PCP, OHCA chooses a provider for them so that they will have a medical home. Id. at 93:22-25. When Medicaid recipients lose Medicaid eligibility, they can remain in their medical home with the PCP they have been seeing through the Medicaid program. Id. at 92:9-15; 118:4-19. OHCA's current automatic assignment system places a Medicaid recipient who has lost and regained eligibility in less than 180 days back with the PCP the recipient had in the past. Tr. Vol. XIV, at 1788:11 - 1789:10; 1792:19 - 1793:22. However, if a doctor has a patient limitation, OHCA may not be able to reassign a former Medicaid patient to that doctor's panel when the panel is full. Tr. Vol. I, at 123:19 - 124:18. If for some reason a Medicaid recipient is mistakenly switched to another PCP and the recipient does not learn of the change until the patient appears at the original PCP's office for an appointment, the recipient and the recipient's original PCP can contact OHCA by telephone and arrange to have the appointment paid for by Medicaid. Tr. Vol. X, at 1260:9-20.

206. As OHCA transferred more than 200,000 SoonerCare Plus recipients to SoonerCare Choice, 83% of the recipients in the southwest portion of the State chose a PCP, meaning OHCA had to assign only 17% to a primary care provider; 83% in the northeast region also chose a PCP; and 82% in the central region chose a PCP. Tr. Vol. X, at 1326:20 - 1327:11. Ninety-six percent (96%) of the SoonerCare Plus physicians in the southwest region contracted with SoonerCare Choice; 75% in the Tulsa area contracted; and 80% of the Oklahoma City providers contracted. Tr. Vol. X, at 1348:24 - 1349:12.

207. According to OHCA's SoonerCare Director, as designed, auto-assignment of a recipient to a new PCP should occur only when: (1) there is no record of a PCP choice in OHCA's system; (2) the recipient had not been previously assigned to a SoonerCare PCP making reassignment impossible; or (3) there is no existing family relationship enabling the recipient to be assigned to a family member's PCP. Tr. Vol. XIV, at 1787:2-8. In the year 2003, 23% of Medicaid recipients in Oklahoma were auto-assigned to a new PCP. Id. at 1784:9-10. In early 2004, approximately 34,000 SoonerCare Plus recipients were auto-assigned to a new PCP. Id. at 1811:3-14.

208. Defendants' expert acknowledges that, as a matter of federal law, any default enrollment or auto-assignment system must "seek to preserve existing provider-patient relationships." Tr. Vol. XVI, at 2159:1-17. According to Powell, the default enrollment provisions of the Medicaid Act "put[] the burden on the State to try to set up a process that…recognizes that existing [provider-patient] relationship." Id. at 2161:15-17. However, under the current SoonerCare Choice "auto-assignment" system, there is no mechanism to assign a recipient to his previous PCP, selected by a recipient while in fee-for-service, if that recipient has been out of the Medicaid system for 180 days and fails to choose a PCP at the time of an eligibility re-determination. Agreed Pretrial Order and Statement of the Case, Dkt. 196, at 9-10, ¶ 26. OHCA's computer system retains data for upwards of six years for recipients who lose eligibility. Tr. Vol. XIV, at 1819:3-8. Defendants could retrieve the last-assigned PCP of a recipient who had lost eligibility for one year. Id. at 1819:14-18.

209. It may not always be the failure of the recipient to make a provider choice that leads to an auto-assignment. OHCA has found errors made by "help line" personnel when parents call

to choose a PCP for their children. Tr. Vol. XIV, at 1823:21 - 1825:3. OHCA has not conducted a study to determine the help line's rate of error in recording recipient PCP choice. Id. at 1825:11-14. OHCA also acknowledges the possibility that DHS could fail to enter PCP choice information into OHCA computer system. Id. at 1822:4-9.

c. Auto-Assignment of Newborns

210. As discussed above, Medicaid-eligible newborns are classified as "fee-for-service" until a choice of PCP is on file or, if no choice of PCP is filed within a certain time period, the newborn is auto-assigned. Tr. Vol. X, at 1261:16 - 1264:11. On average, if no choice of PCP is on file with OHCA after 45 days, the infant will be auto-assigned. Tr. Vol. XV, at 2082:8-17. OHCA encourages hospitals in Oklahoma to ensure that every Medicaid baby has a PCP before leaving the nursery. Tr. Vol. XVII, at 2298:9-14. However, babies are not recognized as Medicaid eligible until a form is filled out by the parent, and then obtained and entered into OHCA computer by a DHS case worker. Id. at 2298:4 - 2299:4. Even in cases where an infant has seen a particular PCP for the first month and a half of life, that infant could be assigned to a different one if no written choice of PCP has been filed with OHCA.

211. In Oklahoma City, Dr. Stuemky frequently sees Medicaid infants leave the Children's Hospital nursery without being assigned a PCP. Tr. Vol. I, at 48:5-7. The problem stems from the fact that the OU pediatric clinic has reached its patient capacity and that many PCPs in the community are also refusing to accept new Medicaid patients. Id. at 48:1-7. From a medical standpoint, the lack of a PCP is problematic, as all newborns should be seen by a PCP in the first one or two weeks after birth. Id. at 48:13-22. Newborns who leave the hospital without a PCP likely will not have a PCP or medical home for at least one month after birth.

212. After Dr. Eve Switzer complained about her infant patients being auto-assigned away, OHCA set up a special process that allows Dr. Switzer to fax a parent's PCP choice form to OHCA for her newborn patients who have not been assigned to her or who have been assigned to another PCP. Tr. Vol. XIV, at 1910:13-22. OHCA has not considered making this special process a statewide initiative. Id. at 1914:10 - 1915:8. Although Dr. Switzer has made use of the special process of faxing PCP choice forms to OHCA, often it takes a couple of months for OHCA to assign Dr. Switzer as a newborn's PCP. Tr. Vol. IV, at 562:4-11. Dr. Switzer has never been able to have one of her newborn patients assigned to her on the same day that she faxes the choice form to OHCA. Id. at 562:12-13.

d. Notice

213. In 1998, the Oklahoma Legislature created the Advisory Task Force on SoonerCare. Pl. Ex. 252. The objective of the Task Force was to first review and evaluate the SoonerCare program, and then to make recommendations to the Legislature as to how to improve the program. Tr. Vol. I, at 69:12-17. The Task Force was chaired by Dr. John Stuemky. Id. at 69:6-10. OHCA's current SoonerCare Director, Rebecca Pasternik-Ikard, was the agency's representative. Id. at 69:18-24. Dr. Mike Stratton, a pediatrician at the Children's Clinic in Muskogee, was also a Task Force member. Tr. Vol. II, at 203:15-16. Auto-assignment was a "great deal of the concern" of the Task Force. Tr. Vol. I, at 77:4-5.

214. The Task Force's Education Work Group made several findings and recommendations concerning OHCA's auto-assignment system. Pl. Ex. 255. Specifically, with regard to SoonerCare Choice, the Task Force found that:

> patients who lose eligibility often end up assigned to a different provider than they had during the previous eligibility period. Therefore, auto-assignment of SoonerCare

> members often leads to member and provider confusion, disruption of the continuity of care, payment difficulties, and unnecessary use of the emergency department.

Id. at BB.2115. Despite this finding, problems with the SoonerCare Choice auto-assignment system are ongoing and occur on a regular basis. Tr. Vol. II, at 200:24 - 201:11; Tr. Vol. VIII, at 966:10-20; Tr. Vol. III, at 383:2-22; Tr. Vol. IV, at 553:25 - 554:20.

215. Similarly, the Task Force made findings concerning problems with auto-assignment in the SoonerCare Plus program:

> Auto-assignment by its very nature is an arbitrary decision and results in dissatisfaction and additional work for everyone involved. There will be less switching of providers, less confusion for recipients, less work on the part of all participants (providers, MCOs, and OHCA) and cost savings to OHCA, DHS, and MCOs if the patient ends up assigned to an acceptable provider from the start.

Pl. Ex. 255 at BB.2114. Yet, Dr. Stuemky observed no improvement in the auto-assignment system during the time the SoonerCare Plus program existed. Tr. Vol. I, at 78:18 - 79:4. Pursuant to its findings that the auto-assignment system was disruptive of continuity of care, the Task Force made several recommendations, including a recommendation that the eligibility period be increased to twelve months, and that before auto-assigning any recipient, the enrollment agent should contact that recipient three times, using at least two different methods of communication. Pl. Ex. 255 at BB.2114, ¶ 4.1; BB.2115, ¶ 7. These recommendations were not implemented by OHCA due to lack of funding, as discussed above, but OHCA was able to increase the enrollment period to six months.

216. During the weeks of March 8 and March 22, 1999, HCFA conducted an audit of Oklahoma's SoonerCare program. The audit findings were published in a report entitled Medicaid Program Review of Oklahoma's SoonerCare Program. Pl. Ex. 20. During the course of the audit, HCFA found and put the defendants on notice of the problems with the auto-assignment system. Pl. Ex. 20 at 8. Specifically, HCFA found that the practice of placing recipients with an established

PCP into the auto-assignment "pool" was "contrary to the continuity of care/medical home principle . . . ." Id. OHCA responded that it was working with DHS and its own provider representatives to remedy the problem. Id. at 8-9.

e. Consequences of Auto-Assignment

217. Defendant officials were also put on notice when Dr. Banner, Director of the Saint Francis PICU, notified OHCA officials of the death of one of his Medicaid patients in 2002. Tr. Vol. IV, at 506:13 - 507:24. In Dr. Banner's opinion, the child's death was due, at least in part, to auto-assignment. Specifically, the child was scheduled to have laser surgery of her airway but, when she went to the hospital to have the surgery, she was informed that there was no authorization for the surgery due to a change in her PCP. The mother was not aware of the change. While the child awaited an appointment with a new PCP to obtain proper authorization, she had an "airway event and arrest[]" and died after life-sustaining attempts failed. Id. at 507:6-21.

218. Less serious failures in the auto-assignment system have also had a negative impact on the continuity of patient care and the lives of Medicaid patients. Several pediatricians testified at trial as to serious problems they and their patients experience due to auto-assignment. These problems include, among other things, assignment of siblings to different PCPs, and assignments to PCPs who practice farther away from the PCP to whom the patient was initially assigned. See Tr, Vol. IV, at 489:11 - 490:23; Tr. Vol. VIII, at 966:10 - 975:10; Pl. Ex. 81, 101-103; Tr. Vol. VI, at 782:12 - 805:15; Tr. Vol. II, at 206:22 - 207:14; Tr. Vol. III, at 385:24 - 388:4; Tr. Vol. XVIII, at 2340:13 - 2341:11; Tr. Vol. IV, at 554:6-20.

f. North Carolina Approach

219. Testimony at trial established that, with effective outreach and enrollment systems, children can have medical homes without auto-assignment. Like Oklahoma's SoonerCare Choice program, North Carolina also delivers Medicaid services through a PCCM system under a federal waiver. Tr. Vol. XI, at 1407:1-7; 1410:6-11. However, unlike Oklahoma, North Carolina does not have an auto-assignment system. Id. at 1413:9-10. North Carolina has successfully been able to sign up 90% of its new recipients with a PCP at the time of eligibility determination. Id. at 1412:21 - 1413:4. Rather than auto-assign the other 10% who do not choose a PCP at the time of eligibility determination, enrollment caseworkers in North Carolina follow up with each recipient who has not chosen, until a choice is made. Id. at 1413:4-15. Within a month after eligibility determination, virtually every recipient chooses a PCP. Id. Once a recipient has been assigned to a chosen PCP, that choice is not interrupted unless the recipient requests a change. Id. There is no possibility of a procedure not being performed due to an unauthorized referral, because any PCP with a "number" is authorized to make a referral regardless of who is the assigned PCP. Id. at 1414:3-15.

II. CONCLUSIONS OF LAW[20]

A. FEDERAL MEDICAID PROGRAM GENERALLY

1. In 1965, Congress enacted Title XIX of the Social Security Act, 42 U.S.C. § 1396 et seq. ("Medicaid Act"), establishing a cooperative federal-state program designed to provide medical assistance to the poor. See Atkins v. Rivera, 477 U.S. 154, 156 (1986); see also Frew ex

---

[20] Any finding of fact which is more appropriately characterized as a conclusion of law is incorporated herein.

rel. Frew v. Hawkins, 540 U.S. 431, 433 (2004). As a general rule, Medicaid is the payor of last resort. See, e.g., Sullivan v.County of Suffolk, 174 F.3d 282, 285 (2nd Cir. 1999). The costs of the Medicaid program are shared between the federal government and participating states. See Atkins, 477 U.S. at 156-57.

2. "The State [Medicaid] plan is a comprehensive written statement submitted by the agency describing the nature and scope of its Medicaid program and giving assurance that it will be administered in conformity with the specific requirements of [the Medicaid laws]. The State plan contains all information necessary for CMS [Centers for Medicare and Medicaid Services] to determine whether the plan can be approved to serve as a basis for Federal financial participation (FFP) in the State program." 42 C.F.R. § 430.10. The U.S. Secretary of Health and Human Services, acting through CMS, may waive the State plan requirements. 42 U.S.C. § 1396n(b). "Waivers are intended to provide the flexibility needed to enable States to try new or different approaches to the efficient and cost-effective delivery of health care services, or to adapt their programs to the special needs of particular areas or groups of recipients. . . ." 42 C.F.R. § 430.25(b).

3. While a state's participation in the Medicaid program is optional, once a state chooses to participate, it must comply with the Medicaid Act and its implementing regulations. See Harris v. McRae, 448 U.S. 297, 301 (1980); AMISUB v. State of Colorado Dept. of Social Services, 879 F.2d 789, 794 (10th Cir. 1989); see also Frew, 540 U.S. at 433. However,

> the failure of a State authority to comply with State regulations cannot alone give rise to a § 1983 cause of action. To state a federal cause of action, a plaintiff must allege a 'specific conflict between a state plan or practice on the one hand and a federal mandate on the other.' The fact that federal law conditions State participation in the Medicaid program on the State's adoption of a Medicaid plan does not thereby transform provisions of a State's plan into federal law.

Concourse Rehabilitation & Nursing Ctr. Inc. v. DeBuono, 179 F.3d 38, 43 (2nd Cir. 1999) (internal citations omitted).

4. The Medicaid Act requires "that a participating State agree to provide 'financial assistance to the 'categorically needy' with respect to five general areas of treatment . . . [including] periodic screening and diagnosis of children . . . . '" Harris, 448 U.S. at 301-02. "While [Colorado Health Care Ass'n v. Colorado Dep't. of Social Servs., 842 F.2d 1158, 1168 (10th Cir. 1988),] does declare that a State Medicaid Agency may consider budgetary constraints, budgetary constraints cannot excuse noncompliance with federal Medicaid law." AMISUB, 879 F.2d at 800 (citations omitted).

5. The Medicaid Act does not require exhaustion of state administrative remedies before bringing a § 1983 claim. Alacare, Inc.-North v. Baggiano, 785 F.2d 963, 967-69 (11th Cir. 1986); Greenwald v. Axelrod, 48 B.R. 263, 270-71 (S.D.N.Y. 1984); see Talbot v. Lucy Corr Nursing Home, 118 F.3d 215, 219-220 (4th Cir. 1997) (applying reasoning of Alacare to hold that exhaustion of state administrative remedies is not required prior to filing a § 1983 for enforcement of Medicare Act). In determining whether the actions of responsible Medicaid agency officials are to be afforded judicial deference, the Court's first inquiry is whether the officials' actions have met the specific requirements of federal and state law. See AMISUB, 879 F.2d at 795 (citing Colorado Health Care Assoc., 842 F.2d at 1165).

B. PAYMENTS TO PROVIDERS

1. "Equal Access"

6. The "equal access" provision, 42 U.S.C. § 1396a(30)(A), has been a part of the Medicaid Act since 1989. As codified, it requires that a State plan for medical assistance

> provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan (including but not limited to utilization review plans as provided for in section 1396b(i)(4) of this title) as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area; . . .

42 U.S.C. § 1396a(a)(30)(A) (emphasis added).

7. On May 21, 2002, this Court held that § 1396a(30)(A), among other Medicaid Act provisions, creates federal rights that are enforceable by providers and recipients alike under § 1983. OKAAP v. Fogarty, 205 F. Supp. 2d 1265, 1272 (N.D. Okla. 2002). At that time, there was a split of authority on this issue. Compare Westside Mothers v. Haveman, 289 F.3d 852, 864 (6th Cir. 2002) (enforceable by recipients, and providers have standing); Visiting Nurse Ass'n v. Bullen, 93 F.3d 997, 1004 (1st Cir. 1996) (enforceable by providers and recipients); Methodist Hospitals, Inc. v. Sullivan, 91 F.3d 1026, 1029 (7th Cir. 1996) (enforceable by providers); Arkansas Medical Society v. Reynolds, 6 F.3d 519, 523-29 (8th Cir. 1993) (enforceable by providers and recipients); with Pennsylvania Pharmacists Assn. v. Houstoun, 283 F.3d 531, 541-42 (3rd Cir. 2002) (not enforceable by providers; enforceable by recipients); Walgreen Co. v. Hood, 275 F.3d 475, 477 (5th Cir. 2001) (same); Evergreen Presbyterian Ministries, Inc v. Wood, 235 F.3d 908, 929 (5th Cir. 2000) (same).

8. Since the Court's opinion, the Supreme Court has ruled that a plaintiff may bring suit under §1983 as an intended beneficiary of a statute only if the statute itself unambiguously demonstrates congressional intent to confer an individual or personal right on that plaintiff. Gonzaga University v. Doe, 536 U.S. 273, 283 (2002). The Medicaid statute was not at issue in Gonzaga, but several courts have applied Gonzaga to find that providers do not have enforceable

rights under § 1396a(a)(30)(A). E.g., Long Term Care Pharmacy Alliance v. Ferguson, 362 F.3d 50, 58-59 (1st Cir. 2004); In re NYAHSA Litig., 318 F. Supp. 2d 30, 39-40 (N.D. N.Y. 2004); Clayworth v. Bonta, 295 F. Supp. 2d 1110, 1122-24 (E.D. Cal. 2003); Burlington United Methodist Family Servs. Inc. v. Atkins, 227 F. Supp. 2d 593, 595-97 (S.D. W.V.2002). Others, however, continue to hold that providers do have such rights. Pediatric Specialty Care, Inc. v. Arkansas Dept. of Human Services, 364 F.3d 925, 930 (8th Cir. 2004); Association of Residential Resources in Minnestoa (AARM) v. Minnesota Comm'r of Human Servs., No. 03-2438, 2003 WL 22037719, at *7 (D. Minn. Aug.29, 2003). The Court is aware of only one post-Gonzaga court holding that § 1396a(a)(30)(A) does not afford recipients enforceable rights under § 1983. Sanchez v. Johnson, 301 F. Supp. 2d 1060, 1062-64 (N.D. Cal. 2004).

9. The Court finds that those authorities holding that providers do not have enforceable rights under § 1396a(a)(30)(A) are more thoroughly researched and better-reasoned that those that find to the contrary. Indeed, the Pediatric Specialty Care and AARM opinions do not mention Gonzaga and the conclusions therein are primarily based on an analysis of whether the providers and recipients had a constitutionally-recognized property interest under §1396a(a)(30). Pediatric Specialty Care, 364 F.3d at 930; AARM, 2003 WL 22937719, at *7. Accordingly, the Court concludes that OKAAP, as it represents Medicaid providers, does not have enforceable rights under § 1396a(a)(30)(A), and should be dismissed from this lawsuit. The Court's May 21, 2002 ruling on this issue is hereby vacated to that extent. However, the Court concludes that the individual class members continue to have standing to enforce § 1396a(a)(30) as Medicaid recipients. See Clark v. Richman, 339 F. Supp. 2d 631, 640 (M.D. Pa. 2004); Clayworth v. Bonta, 295 F. Supp. 2d 1110,

1122-24 (E.D. Cal. 2003). Plaintiff Community Action Project of Tulsa County, Inc. ("CAPTC") also remains a plaintiff as it represents the interests of certain recipient class members.

10. The equal access regulation, 42 C.F.R. § 447.204, has been part of the Medicaid structure for over 35 years. See DeGregorio v. O'Bannon, 500 F. Supp. 541, 548-49 n.13 (E.D. Pa. 1980). It has been in its current form since 1978. The regulatory provision is identical to the statutory provision, without the phrase "in the geographic area." See 42 C.F.R. § 477.204. In the legislative history, Congress explained its reasons for expanding Medicaid eligibility and codifying the equal access regulation. H.R. Rep. No. 101-247, at 390 (1989), reprinted in 1989 U.S.C.C.A.N., 1906, 2116. According to the report, Medicaid eligibility for pregnant women, infants and poor children would "not have [its] intended effect if physicians are not willing to treat Medicaid patients." Id. Congress further recognized that, "without sufficient payment levels, it is simply unrealistic to expect physicians to participate in the [Medicaid] program . . . ." Id.

11. The key question for determining whether a state is violating the substance of the equal access provision depends upon the meaning of the language, "available to recipients at least to the extent that those services are available to the general population." Clark v. Kizer, 758 F. Supp. 572, 575 (E.D. Cal. 1990), aff'd in relevant part sub nom, Clark v. Coye, 967 F.2d 585 (9th Cir. 1992). The Clark v. Kizer court turned to the legislative history quoted above to find that "the test for evaluating access is to compare the access of beneficiaries to the access of other individuals in the same geographic areas with public or private insurance coverage." Id. (citing H.R. Rep. No. 101-247, at 390-91, reprinted in 1989 U.S.C.C.A.N. 1906, 2116.) Access by the uninsured is not to be part of the comparison. See Arkansas Medical Soc'y, Inc. v. Reynolds, 6 F.3d 519, 527 (8th Cir. 1993)

12. Defendants argue that the equal access provision is unenforceable because the term "geographic area" is too vague, citing Methodist Hospital v. Indiana Family & Social Servs. Admin., 860 F. Supp. 1309, 1332-33 (N.D. Ind. 1994). However, the appellate court reviewing Methodist Hospital expressly rejected the notion that the phrase "geographic area" was too vague to confer an enforceable right. Methodist Hospital v. Sullivan, 91 F.3d 1026, 1029 (7th Cir. 1996); see Evergreen Presbyterian Ministries Inc. v. Hood, 2365 F.3d 908, 931 (5th Cir. 2000). As the Methodist Hospital appellate court stated, the meaning of "geographic area" depends on "what function the boundary serves." 91 F.3d at 1029. The court further explained: "How large a geographic area is appropriate may depend on the kind of medical service: emergency care must be swift, and hence close, but longer travel times are tolerable when obtaining outpatient care for chronic conditions." Id.

13. The legislative history, referenced by Clark v. Kizer, speaks to this issue in greater detail:

> The Committee bill clarifies that the equal access test is to be applied in relation to the supply of providers in a geographic area. Thus, if a particular geographic area within a State has a smaller number of physicians per thousand insured population than other parts of the State, or than the State as a whole, the Medicaid payments would have to be at a level that ensures that Medicaid beneficiaries in that area have at least the same access to physicians as the rest of the insured population in that area. The Committee bill would not require that Medicaid payment levels be high enough to induce physicians to relocate into this area.
> The Committee expects that the Secretary, in determining whether services are available to Medicaid beneficiaries at least to the extent that services are available to the general population, will compare the access of beneficiaries to the access of other individuals in the same geographic area with private or public insurance coverage (whether in the form of indemnity, service, or prepaid benefits). It is obvious that Medicaid beneficiaries are likely to have better access to care than individuals without insurance coverage and without the ability to pay for services directly. The question which the Secretary must ask is whether Medicaid beneficiaries have access to provider services that is at least as great as that of others in the area who have third party coverage.

H.R. Rep. No. 101-247, at 390-91, reprinted in 1989 U.S.C.C.A.N. 1906, 2116-17.

14. In this case, plaintiffs have shown that in cases where the overall resources are scarce throughout the State, such as pediatric neurology, Medicaid recipients do not have equal access to care. As such, with regard to pediatric neurology, the appropriate geographic area is the entire State. On the other hand, plaintiffs have shown that, in cases where the overall resources are available in local communities, such as ENT services in Ponca City, Medicaid recipients do not have access to the same extent as their privately insured counterparts. In regions where care is available to one segment of the population but not the other, the appropriate "geographic area" is the local community.

15. Defendants also contend that the equal access provision requires only a substantive result, but does not require any particular method or process for getting to that result. See Rite Aid, Inc. v. Houstoun, 171 F.3d 842, 851-52 (3rd Cir. 1999); see also Methodist Hosps., Inc. v. Sullivan, 91 F.3d at 1030. The Court agrees, but the State must have some method or process for considering "the relevant factors of equal access, efficiency, economy, and quality of care as designated in the statute when setting reimbursement rates." Arkansas Med. Soc'y, Inc. v. Reynolds, 6 F.3d 519, 530 (8th Cir. 1993). It should, for example, "rely on responsible cost studies, its own or others', that provide reliable data as a basis for its rate setting." Orthopedic Hosp. v. Belshe, 103 F.3d 1491, 1496 (9th Cir. 1997). The State should at least identify specialties where there is an access problem and conduct studies of the private insurance rates being paid to those specialties. Defendants should also examine access to care for non-Medicaid population compared to the Medicaid population to determine the degree of compliance. Defendants cannot set rates solely on the basis of the available budget. See Reynolds, 9 F.3d at 531.

16. In finding a violation of the equal access provision, the court in Clark v. Kizer. 758 F. Supp. 572 (E.D. Cal. 1990), aff'd in relevant part sub nom, Clark v. Coye, 967 F.2d 585 (9th Cir. 1992), utilized a multi-factor approach, including several outlined in an amicus brief filed by the Secretary of Health and Human Services. Id. at 576-78. The two major factors considered by the Clark court were "the level of physician participation in the Medicaid program" and "the level of reimbursement to participating physicians." Id. at 576-77. In addition, the court also considered: whether "providers [are] widely opting out of the Medicaid program or restricting their Medicaid caseloads"; "whether there is a steady stream of reports that recipients are having difficulty obtaining care"; and admissions by state agency personnel "that reimbursement rates are inadequate and that the equal access provision is being violated." Id. at 577-78. In addition, the Clark court looked to the "utilization rate" as a factor that "may be considered," but noted that this factor was "not dispositive." Id. at 578. These factors have been cited approvingly by subsequent courts. See Clark v. Richman, 339 F. Supp. 2d 631, 644 (M.D. Pa. 2004); Memisovski ex rel. Memisovski v. Maram, No. 92 C 1982, 2004 WL 1878332 at *42 (N.D. Ill. Aug. 23, 2004); Arkansas Medical Soc'y, Inc. v. Reynolds, 834 F. Supp. 1097, 1100 (E.D. Ark. 1992).

17. The record in this case demonstrates that OHCA has frequently set rates below the levels which OHCA admits are adequate to assure there are enough providers to serve Medicaid enrolled children. The mandates of the federal Medicaid law preclude such rate setting. In violation of 42 U.S.C. § 1396a(a)(30)(A), defendants have failed to set physician reimbursement rates at a sufficient level to attract enough providers such that health care services are "available to [children on Medicaid] at least to the extent that those services are available" to the insured population.

a. Physician Participation

18. In its analysis of the "level of participation" factor, the Clark court noted that the "longstanding criterion" utilized by the Department of Health and Human Services for implementation of the equal access requirement is a two-thirds participation ratio. Id. at 576. Also, in determining the percentage of provider participation in the program, the Clark court specifically looked to providers who were in "full participation." Id. "Full participation" means "accepting all Medicaid patients who present themselves for treatment." Id. As found in the Findings of Fact, pediatrician participation in Oklahoma's Medicaid program, full or otherwise, is significantly lower than the two-thirds benchmark. It is equally clear that "the majority of participating providers are not full participants" in Oklahoma's Medicaid program. Id.

b. Reimbursement

19. The second "major factor" which the Clark court considered in assessing compliance with the equal access mandate was the level of reimbursement. Clark, 758 F. Supp. at 577-78. In deciding that California's dental rates were inadequate, the Clark court considered the fact that the rates there fell well short of the defendant's stated goal of "90% of the average allowance of private insurers." Id. at 577 n.3. Defendants contend that "[n]either §1396a(a)(3)) nor its implementing regulations require a state or its Medicaid agency to explicitly consider and make findings on efficiency, economy and quality of care before setting or implementing reimbursement rates." Def. Second Amended Findings of Fact and Conclusions of Law, Dkt. # 234, at 34, ¶ 10 (citing California Ass'n of Bioanalyists v. Rank, 577 F. Supp. 1342, 1359 (C.D. Cal. 1983)). This assertion is in direct conflict with Arkansas Med. Soc'y, Inc. v. Reynolds, 6 F.3d 519, 529-31 (8th Cir. 1993). Further, the effect of defendants' rate-setting and implementation speaks for itself.

20. Defendants point out that the "State is required by 42 U.S.C. §1396a(a)(30) to safeguard against unnecessary utilization of medical care and services and to assure that medical payments are not in excess of reasonable charges consistent with quality of care." Def. Second Amended Findings of Fact and Conclusions of Law, Dkt. # 234, at 35, ¶ 18) (citing Medical Soc'y of New York v. Toia, 560 F.2d 535, 537 (2nd Cir. 1977)). But that is not the issue here. The issue here is sufficient reimbursement to assure equal access.

21. While there is no established percentage for sufficient Medicaid reimbursement rates under federal law, rates which consistently fall well below what is allowed under Medicare, let alone under private insurance, have been shown to be inadequate to attract enough providers so that health care services are available to Medicaid recipients to the same extent as those services are available to the general population. OHCA admits that, to comply with federal equal access mandate, physician reimbursement rates need to be at least 100% of the Medicare fee schedule. The evidence also shows that they may need to be higher to attract and retain sufficient specialists and sub-specialists. This is for defendants to decide. This Court holds only that the current level of Medicaid physician reimbursement in Oklahoma is insufficient as a matter of law.

c. Other Factors

22. Another factor analyzed by the Clark court in finding a violation of the equal access provision is whether there was a "steady stream" of reports that recipients were having difficulty obtaining care. Clark, 758 F. Supp. at 578. The testimony from providers and parents of class members alike was that recipients have great difficulty accessing needed health care services in Oklahoma. As plaintiffs established, the lack of physician participation in Medicaid forces class members either to wait for unreasonable periods of time to receive needed care or to travel long

distances to find Medicaid participating providers, putting these children at risk of harm or even death.

23. The testimony at trial also demonstrated that providers are widely opting out of the Medicaid program or restricting their Medicaid caseloads.

24. Finally, defendants admitted at trial that reimbursement rates are inadequate and that the equal access provision is being violated.

2. Quality of Care

25. Aside from requiring that rates be set at a level high enough to ensure equal access, §1396a(a)(30)(A) also contains a quality of care component. Specifically, defendants are required to assure that payments to providers are consistent with quality. 42 U.S.C. § 1396a(a)(30)(A). The State may provide Medicaid services through a primary care case management system. The phrase "primary care case management services" means case-management related services (including locating, coordinating, and monitoring of health care services) provided by a primary care case manager under a primary care case management contract. 42 U.S.C. §1396d(t)(1). Such services may be provided by a physician, nurse practitioner, certified nurse midwife, or physician assistant. Id. at §1396d(t)(2). However, for many children with complex needs, it is medically inappropriate for them not to have access to primary care provided by a pediatrician.

26. Unless such children's primary care provider is a pediatrician, the care they need will be delayed or denied. Currently, class members who require the care of a pediatrician are often forced to see nurse practitioners, physician's assistants and other lesser qualified providers for primary care. The unavailability of pediatricians for children with complex needs, together with the statistical evidence of inadequate participation in this case, demonstrates that defendants have failed

to assure that payments to providers are consistent with quality of care and, thus, they have violated § 1396a(a)(30)(A).

C. "REASONABLE PROMPTNESS"

27. Under 42 U.S.C. § 1396a(a)(8), a State plan for medical assistance must "provide that all individuals wishing to make application for medical assistance under the plan shall have opportunity to do so, and that such assistance shall be furnished with reasonable promptness to all eligible individuals; . . ." This provision of the statute is referred to in the case law as the "reasonable promptness" provision. Determination of eligibility is reasonably prompt if the time taken by the agency does not exceed "ninety days for applicants who apply for Medicaid on the basis of disability" or "forty-five days for all other applicants." 42 C.F.R. § 435.911(a). The responsible state agency "must," among other things, "furnish Medicaid promptly to recipients without any delay caused by the agency's administrative procedures," and "continue to furnish Medicaid regularly to all eligible individuals until they are found to be ineligible." Id. at § 435.930(a)-(b).

28. Prior to Gonzaga University v. Doe, 536 U.S. 273 (2002), several cases held that section § 1396a(a)(8) created federal rights enforceable under § 1983. See Westside Mothers v. Haveman, 289 F.3d 852, 864 (6th Cir. 2002); Doe v. Chiles, 136 F.3d 709, 719 (11th Cir.1998). Subsequent to Gonzaga, however, courts have split over whether the reasonable promptness provision creates a private right of action. Some continue to hold that the "reasonable promptness" provision creates a private right of action. E.g., Sabree v. Richman, 367 F.3d 180, 192 (3rd Cir. 2004); Bryson v. Shumway, 308 F.3d 79, 88 (1st Cir. 2002). Other courts have held that the provision does not create a private right of action. E.g., Sanders v. Kansas Dept. of Social and

Rehabilitation Servs., 317 F. Supp. 2d 1233 (D. Kan. 2004); M.A.C. v. Betit, 284 F. Supp. 2d 1298 (D. Utah 2003).

29. The Court is persuaded by the rationale set forth in Sabree and Bryson that §1396a(a)(8) does create a private right of action. In particular, the Court is convinced that the provision contains the "rights-creating" language described in Gonzaga, and the provision is "phrased in terms of the persons benefited," Gonzaga, 536 U.S. at 284. Section 1396a(a)(8) includes the term "shall" -- a term which the Gonzaga court emphasized is evident in "the sort of explicit right- or duty-creating language" necessary "to impute to Congress an intent to create a private right of action." Id. at 284 n. 3. It also references "all eligible individuals" as those to whom medical assistance must be provided.

30. The Court is aware of dicta in Lewis v. New Mexico Dept. of Health, 261 F.3d 970, 976-77 (10th Cir. 2001), indicating that this particularly statutory provision is ambiguous in certain respects.[21] As set forth above, the Gonzaga court held that a plaintiff may bring suit under §1983

---

[21] The Lewis court wrote:

> Although the defendants do not raise the argument, we note the more difficult question for resolution on the merits is whether § 1396a(a)(8) creates a federal right directly benefitting the plaintiffs in this case. In order to create a federal right, the statute must reflect Congress's clear intent to benefit directly the particular plaintiffs in this case. See Blessing v. Freestone, 520 U.S. 329, 344-45, 117 S.Ct. 1353, 137 L.Ed.2d 569 (1997). This question turns on whether the plaintiffs may be included as "eligible individuals" under § 1396a(a)(8). Whether "eligible" means eligible for Medicaid or eligible for both Medicaid and waiver services is not entirely clear. But because construing this language involves a more complicated analysis of the Medicaid statutes, the inquiry is more appropriately reserved for resolution on the merits of the case. In light of the statute's ambiguity, the plaintiffs have at least alleged a non-frivolous claim.

261 F.3d at 977.

(continued...)

as an intended beneficiary of a statute only if the statute itself *unambiguously* demonstrates congressional intent to confer an individual or personal right on that plaintiff. 536 U.S. at 283 (emphasis added). However, the ambiguity found by the Lewis court was as to whether the plaintiffs there were "eligible," and the district court there subsequently found that those plaintiffs were in fact eligible. Lewis v. New Mexico Dept. of Health, 275 F. Supp. 2d 1319, 1332-33 (D.N.M. 2003). There is no ambiguity as to whether the plaintiffs here are eligible. See 42 U.S.C. § 1396a(a)(10)(A)(i)(III). The Court concludes that plaintiffs have an enforceable right of action under 42 U.S.C. §1396a(a)(8).

31. Several courts have held defendants liable for failure to comply with the "reasonable promptness" mandate. E.g., Doe v. Chiles, 136 F.3d 709, 711 (11th Cir. 1998) (affirming a district court finding that state officials were failing to furnish Medicaid assistance with "reasonable promptness" to eligible developmentally disabled individuals); Lewis v. New Mexico Dept. of Health, 275 F. Supp. 2d 1319, 1345 (D.N.M. 2003) (where the defendants admitted that individuals who had been allocated to the state's community-based waiver program "would not receive services until the following year"); Sobky v. Smoley, 855 F. Supp. 1123, 1149 (E.D. Cal. 1994) (where "insufficient funding . . . caused providers of methadone maintenance to place eligible individuals on waiting lists for treatment"); Linton v. Carney, 779 F. Supp. 925, 936 (M.D. Tenn. 1990) (where the state's policy caused Medicaid patients "to experience extended delays and waiting lists in attempting to gain access to long term nursing home care").

---

[21] (...continued)

32. Plaintiffs have offered substantial evidence that the delays in treatment for children with specific conditions are medically inappropriate. Importantly, plaintiffs have shown that system-wide delays in treatment exist and have presented convincing evidence that those delays are not reasonable. In violation of 42 U.S.C. § 1396a(a)(8), defendants are not ensuring that medical assistance is furnished with reasonable promptness to all eligible individuals.

33. The Court is aware of Bruggeman v. Blagojevich, 324 F.3d 906, 910 (7th Cir. 2003), in which the court held that Illinois officials' failure to adopt a plan for expanding the number of intermediate care facilities for the developmentally disabled in another part of the state did not violate 42 U.S.C. §1396a(a)(8). In so holding, the court remarked:

> the statutory reference to "assistance" appears to have reference to *financial* assistance rather than to actual medical services, though the distinction was missed in Bryson v. Shumway, 308 F.3d 79, 81, 88- 89 (1st Cir.2002), and Doe v. Chiles, 136 F.3d 709, 714, 717 (11th Cir.1998). Medicaid is a payment scheme, not a scheme for state-provided medical assistance, as through state-owned hospitals. The regulations that implement the provision indicate that what is required is a prompt determination of eligibility and prompt provision of funds to eligible individuals to enable them to obtain the covered medical services that they need, see 42 C.F.R. §§ 435.911(a), .930(a)-(b); a requirement of prompt treatment would amount to a direct regulation of medical services.

Id. at 910. The Court finds that this distinction, while accurate, does not preclude a finding in this case that defendants have violated §1396a(a)(8). Without financial assistance (provider reimbursement) sufficient to attract an adequate number of providers, reasonably prompt assistance is effectively denied.

D. EPSDT SERVICES

34. The EPSDT provisions are located in several different parts of the Medicaid Act. Under 42 U.S.C. § 1396a(a)(10)(A)(III), the State plan must provide for making "medical assistance" available to qualified children as defined in § 1396d(n). Id. A qualified child is one

"who has not attained the age of 19, who was born after September 30, 1983 (or such earlier date as the State may designate), and who meets the income and resources requirements of the State plan under part A of subchapter IV of this chapter." Id. at § 1396d(n). The term "medical assistance" is defined in § 1396d(a)(4)(B) to include, in part, payment for "early and periodic screening, diagnostic, and treatment [EPSDT] services (as defined in subsection (r)) for individuals who are eligible under the plan and are under the age of 21; . . ."

35. EPSDT services which must be provided to all eligible individuals under the age of 21 are defined as screening services, which must include a comprehensive health and developmental history, a comprehensive unclothed physical exam, appropriate immunizations, laboratory tests, and health education; vision services, dental services, hearing services, and "[s]uch other necessary health care, diagnostic services, treatment, and other measures as described in subsection (a) of this section to correct or ameliorate defects and physical and mental illnesses and conditions discovered by the screening services, whether or not such services are covered under the State plan."
42 U.S.C. § 1396d(r).

36. EPSDT screening services are to be provided according to a periodicity schedule "at intervals which meet reasonable standards of medical and dental practice as determined by the State after consultation with recognized medical and dental organizations involved in child health care." 42 U.S.C. § 1396d(r)(1)(A)(i); State Medicaid Manual, Pl. Ex. 2, at § 5140. Likewise, EPSDT vision, dental, and hearing services are to be provided at intervals which meet reasonable standards of [medical and/or dental] services, as determined by the State after consultations with recognized [medical and/or dental] organizations involved in child health care, . . ." 42 U.S.C. § 1396d(r)(2) - (4).

37. Finally, a state Medicaid plan must provide for

> (A) informing all persons in the State who are under the age of 21 and who have been determined to be eligible for medical assistance including services described in section 1396d(a)(4)(B) of this title, of the availability of early and periodic screening, diagnostic, and treatment services as described in section 1396d(r) of this title and the need for age-appropriate immunizations against vaccine-preventable diseases,
> (B) providing or arranging for the provision of such screening services in all cases where they are requested,
> (C) arranging for (directly or through referral to appropriate agencies, organizations, or individuals) corrective treatment the need for which is disclosed by such child health screening services, and
> (D) reporting to the Secretary (in a uniform form and manner established by the Secretary, by age group and by basis of eligibility for medical assistance, and by not later than April 1 after the end of each fiscal year, beginning with fiscal year 1990) the following information relating to early and periodic screening, diagnostic, and treatment services provided under the plan during each fiscal year: . . .
>> (i) the number of children provided child health screening services,
>> (ii) the number of children referred for corrective treatment (the need for which is disclosed by such child health screening services),
>> (iii) the number of children receiving dental services, and
>> (iv) the State's results in attaining the participation goals set for the State under section 1396d(r) of this title.

42 U.S.C. §1396a(a)(43).

1. Private Right of Action

38. The Court has previously concluded that 42 U.S.C. §§ 1396a(a)(10)(A), 1396d(a)(4)(B), and 1396d(r) create enforceable federal rights. OKAAP v. Fogarty, 205 F. Supp. 2d 1265, 1272 (N.D. Okla. 2002). Relying upon the three-part test set forth in Blessing v. Freestone,

520 U.S. 329, 340 (1997),[22] numerous other courts have done likewise. E.g., Pediatric Specialty Care, Inc. v. Arkansas Dep't of Human Services, 293 F.3d 472, 478-79 (8th Cir. 2002); Westside Mothers v. Haveman, 289 F.3d 852, 862-63 (6th Cir. 2002); Doe v. Chiles, 136 F.3d 709, 719 (11th Cir. 1998); Miller v. Whitburn, 10 F.3d 1315, 1319 (7th Cir. 1993); Arkansas Medical Soc'y v. Reynolds, 6 F.3d 519, 523-29 (8th Cir. 1993); Mitchell v. Johnston, 701 F.2d 337, 346-48 (5th Cir. 1983); Stanton v. Bond, 504 F.2d 1246, 1250-51 (7th Cir. 1974).

39. As discussed above, the United States Supreme Court subsequently held that, in order for a statute to be individually enforceable under § 1983, the statutory language at issue must unambiguously confer a right. Gonzaga University v. Doe, 536 U.S. 273 (2002). After Gonzaga, at least four courts have found that the EPSDT provisions of the Medicaid Act are enforceable by private right of action under 42 U.S.C. § 1983. See S.D. v. Hood, 391 F.3d 581, 606 (5th Cir. 2004); Memisovki ex rel. Memisovski v. Maram, No. 92 C 1982, 2004 WL 1878332, at *9 (N.D. Ill. August 23, 2004); Kenny A. ex rel. Winn v. Perdue, 218 F.R.D. 277, 293-94 (N.D. Ga. 2003); Collins v. Hamilton, 231 F. Supp. 2d 840, 846-47 (S.D. Ind. 2002); see also Clark v. Richman, 339 F. Supp. 2d 631, 640 (M.D. Pa. 2004). The Court concludes that the EPSDT provisions of the Medicaid Act unambiguously confer rights upon the class members in this case.

40. "The purpose of the EPSDT program is to ensure that poor children receive comprehensive health care at an early age, so that they will develop fewer health problems as they

---

[22] Three factors are significant when determining whether a particular statutory provision gives rise to a federal right: "First, Congress must have intended that the provision in question benefit the plaintiff. . . . Second, the plaintiff must demonstrate that the right assertedly protected by the statute is not so 'vague and amorphous' that its enforcement would strain judicial competence. . . . Third, the statute must unambiguously impose a binding obligation on the States." Blessing, 520 U.S. at 340-41 (citations omitted).

get older." Salazar v. District of Columbia, 954 F. Supp. 278, 303 (D.D.C. 1996). In short, EPSDT is "designed to provide health education, preventative care, and effective follow-up care for conditions identified during check-ups." Id. at 303; see Antrican v. Buell, 158 F.Supp.2d 663, 672-73 (E.D.N.C. 2001) (quoting Salazar); see also S.D. v. Hood, 391 F.3d 581, 586 (5th Cir. 2004).

2. Periodicity Schedule

41. Defendants have not drafted the State's EPSDT periodicity schedule in "consultation with recognized medical and dental organizations involved in child health care." 42 U.S.C. § 1396d(r)(1)(A)(i). This constitutes a violation of federal law. However, the State is not required to adopt the AAP schedule entirely.

3. Outreach

42. Outreach is a key component of the EPSDT mandate. The implementing regulations specify, inter alia, that the State "must provide for a combination of written and oral methods designed to inform effectively all EPSDT eligible individuals (or their families) about the EPSDT program," and "[e]ffectively inform those individuals who are blind or deaf, or who cannot read or understand the English language." 42 C.F.R. § 441.56(a). As the court stated in John B. v. Menke, 176 F. Supp. 2d 786 (M.D. Tenn. 2001), "without proper outreach, EPSDT is worthless." Id. at 803; see Stanton v. Bond, 504 F.2d 1246, 1251 (7th Cir.1974).

43. State officials must be aggressive in assuring compliance with the EPSDT mandate. See Mitchell v. Johnston, 701 F.2d 337, 347-48 (5th Cir. 1983); Bond v. Stanton, 655 F.2d 766, 768, 771 (7th Cir. 1981); Stanton v. Bond, 504 F.2d 1246, 1250-51 (7th Cir. 1974). Defendants have been aggressive in seeking to inform EPSDT eligible children about the EPSDT program, even though there is evidence that some SoonerCare PCPs have not been aggressive. The State runs the

risk of PCPs refusing to see Medicare patients altogether if the State penalizes PCPs for failure to ensure that EPSDT eligible children take advantage of the program. The State's capitated program provides a financial disincentive for PCPs to conduct aggressive outreach, but this does not detract from the extensive outreach efforts by the OHCA on its own.

44. Defendants argue that the State need not comply specifically with each and every aspect of federal agency guidelines as long as it has an aggressive outreach program calculated to notify potential recipients of availability of the EPSDT program. See Wisconsin Welfare Rights Organization v. Newgent, 433 F. Supp. 204, 212-14 (E.D. Wis. 1977). In Newgent, the court remarked that "compliance with the statute and regulations does not require that a fixed percentage of eligible children be screened; compliance is measured by availability of services to eligibles who request them." Id. at 212 (quoting Woodruff v. Lavine, 417 F. Supp. 824, 827 (S.D.N.Y. 1976), in which the plaintiffs alleged that only 10% to 14% of the eligible population had enrolled in the program). The Newgent court further stated:

> The fact is that the program is voluntary; intended beneficiaries cannot be compelled to participate. A carrot may be offered but a stick may not be used. Despite the best efforts of administrators to popularize such a program, it will still meet with resistance or indifference by members of the socio-economic group for whose benefit it is intended.

Id. (citing Woodruff, 417 F. Supp. at 827).

45. Although there are consistently low EPSDT participation numbers in Oklahoma, the Court concludes that defendants have been aggressive in informing, notifying, seeking out and screening EPSDT-eligible children. As the court stated in Woodruff:

> Performance is not to be tested by the ideal of perfection, but rather by the standard of substantial compliance with the statute and regulations. The test of compliance is not the proportion of the eligible population that participates in the program, but

> whether the State [. . .has] taken and [is] taking "aggressive steps to screen, diagnose and treat children with health problems."

417 F. Supp. at 837. The Court concludes that the State, through OHCA, is in compliance with the aggressive outreach mandate.

4. Monitoring Obligations

46. The State Medicaid Manual imposes monitoring obligations upon defendants. Under the heading "Program Monitoring, Planning and Evaluation," the State Medicaid Manual directs OHCA to:

> Assure that a participating child is periodically screened and treated in conformity with the [state periodicity] schedule and State set timeliness standards. To comply with this requirement, design and employ policies and methods to assure that children receive rescreening and treatment when due.
>
> * * *
>
> Design and employ methods to assure that children receive (1) those screening services initially or periodically requested or due under the periodicity schedule and (2) treatment for all conditions identified as a result of examination or diagnosis.

State Medicaid Manual, Pl. Ex. 2, at BB.0065 (§ 5310).

47. State officials have been held liable for failure to monitor whether recipients are receiving comprehensive EPSDT services. <u>See</u> <u>Bond</u>, 655 F.2d at 770; <u>John B. v. Menke</u>, 176 F. Supp. 2d 786, 802-03 (M.D. Tenn. 2001); <u>Salazar</u>, 954 F. Supp. at 329-30. A state's failure to meet participation goals can be part of the court's consideration in determining whether a state has failed to ensure that EPSDT-eligible children receive complete EPSDT screening services. <u>Salazar</u>, 954 F. Supp. at 329-30. However, the federal participation goal of 80% contained in the State Medicaid Manual is hortatory and not a Medicaid Act requirement. Defendants are required by statute (42 U.S.C. §1396a(a)(43)(D)(iv)) to report their progress in achieving the participation goal, which

Oklahoma does. Oklahoma has not achieved the federal participation goal, but neither have most other states. Failure to achieve a performance goal does not amount to a violation of federal law.

48. Defendants do monitor whether children are receiving EPSDT services, but they do not do it promptly, and do not always report deficiencies, especially those indicating that PCPs are not performing complete examinations or obtaining corrective follow-up treatment.

49. The State Medicaid Manual requires design and employment of policies to assure rescreening and treatment. The State has such policies and is in compliance with the State Medicaid Manual.

5. Dental Services

50. Aside from the dental treatment requirements of EPSDT, the phrase "maintenance of dental health," as used in the statute, shows the preventive dental care purpose of the EPSDT program. Mitchell v. Johnston, 701 F.2d 337, 347 (5th Cir. 1983). While the numbers for children receiving dental care are not where they need to be, defendants have taken steps to elevate those numbers by raising the reimbursement rates for dental care to 90% of the Medicare rates. The Court concludes that, although Oklahoma's dental program for Medicaid-eligible children is not a model, defendants are not in violation of federal law.

6. Transportation and Scheduling Assistance

51. Under 42 U.S.C. § 1396a(a)(43)(B) and (C), Oklahoma is required to provide or arrange for the provision of screening services and to arrange for provision of "corrective treatment the need for which is disclosed" by an EPSDT screening. The implementing regulations more specifically require defendants to "ensure necessary transportation for recipients to and from providers." 42 C.F.R. § 431.53; see id., § 441.62. Federal regulations further require states to effectively inform all eligible individuals that "necessary transportation and scheduling assistance . . . is available to the EPSDT eligible upon request." 42 C.F.R. § 441.56(a)(iv). Defendants provide thousands of rides every year to Medicaid-eligible children. Although defendants have not informed all eligible individuals about the financial assistance that is available in addition to rides, they are not in violation of federal law as it relates to transportation and scheduling assistance.

7. Xolair

52. Defendants must assure that all EPSDT-eligible recipients under age twenty-one receive such medically necessary health care treatment "to correct or ameliorate defects and physical and mental illnesses and conditions discovered by the screening services, whether or not such services are covered under the State Plan." 42 U.S.C. §1396d(r)(5). Several federal appellate courts have relied upon this provision, in part, to hold that a state agency must provide certain disputed medical supplies or services recommended or prescribed by a physician. See S.D. v. Hood, 391 F.3d 581, 593 (5th Cir. 2004) (prescribed disposable incontinence underwear); Collins v. Hamilton, 349 F.3d 371, 374 (7th Cir. 2003) (placement in long-term psychiatric residential treatment facilities); Pediatric Specialty Care, Inc. v. Arkansas Dep't of Human Servs., 293 F.3d 472, 480-81 (8th Cir. 2002) ("early intervention day treatment" under §1396d(a)(13)); Pittman by Pope v. Secretary of

Fla. Dep't of Health and Rehab. Servs., 998 F.2d 887, 891-92 (11th Cir. 1993) (liver-bowel transplant); Pereira by Pereira v. Kozlowski, 996 F.2d 723, 725-26 (4th Cir. 1993)(heart transplant); but see Ellis by Ellis v. Patterson, 859 F.2d 52, 55 (8th Cir.1988) (Medicaid-participating states have complete discretion to decide which, if any, transplants to fund). None of these cases, however, deals with a situation involving the use of an unapproved new drug to treat children.

53. The Medicaid Act allows the State to exclude coverage of an outpatient drug if it is not approved by the United States Food and Drug Administration ("FDA") for use as prescribed. In relevant part, the statute provides:

> (d) Limitations on coverage of drugs
> (1) Permissible restrictions
>
> (A) A State may subject to prior authorization any covered outpatient drug.
>
> * * *
>
> (B) A State may exclude or otherwise restrict coverage of a covered outpatient drug if--
> (i) the prescribed use is not for a medically accepted indication (as defined in subsection (k)(6) of this section);

42 U.S.C. § 1396r-8.

54. The term "covered outpatient drug" is defined, in relevant part, to mean a prescription drug which is approved for safety and effectiveness under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 355 or 357] or which is approved under section 505(j) of such Act [21 U.S.C. §355(j)]; . . ." Id. at § 1396r-8(k)(2)(A)(i). "The term 'medically accepted indication' means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 301 et seq.], or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i) of this section." Id. at §1396r-8(k)(6)

55. Subsection (g)(1)(B)(i) is found in the subsection addressing drug use review and the requirements for a drug use review program. It provides, in relevant part:

> (B) The program shall assess data on drug use against predetermined standards, consistent with the following:
>
> (i) compendia which shall consist of the following:
> (I) American Hospital Formulary Service Drug Information;
> (II) United States Pharmacopeia-Drug Information; and
> (III) the DRUGDEX Information System; and
>
> * * *
>
> (ii) the peer-reviewed medical literature.

Id. at §1396r-8(g)(1). The prescribed use of Xolair for children under the age of 12 with moderate to severe asthma is not for a medically accepted indication.

56. The drug review program is "to assure that prescriptions (i) are appropriate, (ii) are medically necessary, and (iii) are not likely to result in adverse medical results." Id. at §1396r-8(g)(1)(A). A medical necessity rule established by the OHCA requires that a service be (1) medical in nature and consistent with accepted health-care practice standards and guidelines for prevention, diagnosis, or treatment of symptoms of illness, disease, or disability; (2) supported by documentation demonstrating medical evidence sufficient to justify the service; (3) based on reasonable and predictable health outcomes; (4) necessary to alleviate a medical condition; (5) delivered in the most cost-effective manner and appropriate setting; and (6) appropriate for the client's age and health status. Def. Ex. 69, Bates 740 - 741, ¶ f.

57. The language of 42 U.S.C. §1396a(a)(17) "confers broad discretion on the States to adopt standards for determining the extent of medical assistance, requiring only that such standards be 'reasonable' and 'consistent with the objectives' of the Act." Beal v. Doe, 432 U.S. 438, 444

(1977). Oklahoma's standards for determining the extent of medical assistance in this situation, i.e., nonpayment for Xolair treatment, are reasonable and consistent with the objectives of the Act.

58. Under 21 C.F.R. § 310.3(h)(5), the newness of a drug may arise from "[t]he newness of a dosage, or method or duration of administration or application, or other condition of use prescribed, recommended, or suggested in the labeling of such drug, even though such drug when used in other dosage, or other method or duration of administration or application, or different condition, is not a new drug."

59. Under the Federal Food, Drug and Cosmetic Act,

> (p) The term "new drug" means--
>
> (1) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, . . .
>
> (2) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

21 U.S.C. § 321(p).

60. Section 505(a) of the Act, 21 U.S.C. § 355(a), provides that "(n)o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application . . . is effective with respect to such drug." In other words, all new drugs require approval unless they are "generally recognized as safe and effective" (what is commonly termed "GRASE") for their labeled uses. See, e.g., United States v. Sage Pharmaceuticals, Inc., 210 F.3d 475 478 n.7 (5th Cir. 2000) (citing Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609,

613-15 (1973)). Use of Xolair for children under 12 years of age would fall within the definition of "new drug" and it has not been approved as GRASE by the FDA.

61. The Western District of Oklahoma refused to grant relief to the parents of a child with Down's Syndrome who sought to enjoin the government from interfering with their desired use of a certain drug. Duncan v. United States, 590 F. Supp. 39, 43-44 (W.D. Okla. 1984). In so holding, the Duncan court relied upon Rutherford v. United States, 616 F.2d 455 (10th Cir. 1980), to find that users as well as manufacturers of new drugs were required to comply with statutory procedures for approval of the drug as a prerequisite for seeking to enjoin government officials from interfering with the introduction of a drug into interstate commerce. Duncan, 590 F. Supp. at 42-43. Plaintiffs here have not filed a new drug application.

62. In Rutherford, terminally ill cancer patients brought suit to enjoin the United States from interfering with interstate shipment of the sale of laetrile on the ground that it had not been approved for distribution under the Federal Food, Drug, and Cosmetic Act. The Rutherford court observed that

> the decision by the patient whether to have a treatment or not is a protected right, but his selection of a particular treatment, or at least a medication, is within the area of governmental interest in protecting public health. The premarketing requirement of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355, is an exercise of Congressional authority to limit the patient's choice of medication.

Id. at 457. The Tenth Circuit subsequently found that substantial evidence supported the decision of the FDA that laetrile was not generally recognized as effective for the reduction of pain. Rutherford v. United States, 806 F.2d 1455, 1459 (10th Cir. 1986).

63. The lack of FDA approval does not necessarily mean that a state is automatically entitled to deny coverage of drug that has been deemed medically necessary by a recipient's treating

physician. In Weaver v. Reagen, 886 F.2d 194 (8th Cir. 1989), an appellate court determined that the state could not deny Medicaid coverage of the drug AZT to AIDS patients who were eligible for Medicaid and whose physicians had certified that AZT was medically necessary treatment. The Weaver court reasoned:

> FDA approved indications were not intended to limit or interfere with the practice of medicine nor to preclude physicians from using their best judgment in the interest of the patient. Instead, the FDA new drug approval process is intended to ensure that drugs meet certain statutory standards for safety and effectiveness, manufacturing and controls, and labeling, 21 C.F.R. § 314.105(c) (1988), and to ensure that manufacturers market their drugs only for those indications for which the drug sponsor has demonstrated "substantial evidence" of effectiveness. Id. at § 314.126.
>
> * * *
>
> [T]he fact that FDA has not approved labeling of a drug for a particular use does not necessarily bear on those uses of the drug that are established within the medical and scientific community as medically appropriate. It would be improper for the [State] to interfere with a physician's judgment of medical necessity by limiting coverage of AZT based on criteria that admittedly do not reflect current medical knowledge or practice.

Weaver, 886 F.2d at 198. Plaintiffs have not shown that, at the time OCHA made its determination not to fund the use of Xolair for the children in question, there was substantial evidence of Xolair's safety and effectiveness when physicians prescribed Xolair for use by children under the age of 12, or that such safety and effectiveness reflected current medical knowledge or practice.

64. Oklahoma's definition of medically necessary services can reasonably exclude experimental treatment. See Rush v. Parham, 625 F.2d 1150, 1154-55 (5th Cir.1980). In considering the "experimental" nature of treatment for purposes of Medicaid coverage, the Fifth Circuit defined "experimental" as a treatment not "generally accepted by the professional medical community as an effective and proven treatment for the condition" or "rarely used, novel or relatively unknown." Id. at 1156 n.11 (quoting Enclosure # 2 to Intermediary Letters Nos. 77-4 & 77-5, (1976 Transfer Binder) Medicare & Medicaid Guide (CCH) P 28, 152 (1976)). Under this

definition, the prescription of Xolair beyond its labeled indication is experimental. The record does not establish that physicians commonly prescribe Xolair for children who have moderate to severe asthma and who are under 12 years of age. The Court concludes that defendants' decision to deny payment for Xolair for the children in question was based on a valid prohibition against reimbursement for experimental treatment.

65. As set forth above in the Findings of Fact, the FDA has approved Xolair as safe and effective for the treatment of moderate to severe persistent asthma, but it has not approved the use of Xolair for children under 12 years of age. Plaintiffs' evidence consists of peer reviewed literature and the statements of two doctors. OCHA's evidence consists of a study indicating the risk of malignancy, the FDA's failure to approve the drug for children under 12, the lack of approval by the NAEPP, and private insurance companies' refusal to pay for use of the drug. Defendants' reliance on the FDA's approval statement in limiting coverage of Xolair to children over the age of 12 was a reasonable exercise of its discretion to place limitations on covered services based on medical necessity and utilization controls.

E. AUTO-ASSIGNMENT / DEFAULT ENROLLMENT

66. Under 42 U.S.C. § 1396u-2(a)(4)(D), the State must assign a Medicaid recipient to a provider if the State provides Medicaid services through a managed care organization and the recipient fails to choose a managed care organization. However, states like Oklahoma that deliver Medicaid services through a PCCM managed care program must establish a "default enrollment process," which "takes into consideration . . . maintaining existing provider-individual relationships **or** relationships with providers that have traditionally served beneficiaries." Id. (emphasis added).

67. As noted by defendants' expert, Yvonne Powell, the federal government has issued specific instructions to state Medicaid agencies regarding the steps which must be taken to comply with the default enrollment mandate:

> To take prior relationships into account, the state first needs to check its fee-for-service payment records. If there are no recent claims, the state should ask the beneficiary for names of providers they would like to continue seeing. If there is no recent claim history, there is no response from the beneficiary, or the provider is not a "participating provider," then the state has met the requirement to "take into consideration."

Powell Report, Def. Ex. 16 at Ex. I, at 7 (citing State Medicaid Director Letter, January 21, 1998).

68. Defendants make no effort to check recent fee-for-service claims in the default enrollment process for children who have private insurance, but remain eligible for Medicaid. In this manner, the OHCA auto-assignment system does not honor the existing or prior physician-patent relationships of eligible children with private insurance. Defendants have been on notice for years of problems with the auto-assignment system, and are considering extension of the eligibility period.

69. However, the Court finds that, as to certain Medicaid children, the system takes into consideration existing provider-individual relationships, and as to others, takes into consideration relationships with providers that have traditionally served beneficiaries. Thus, the system does not constitute a violation of federal law; however, the contemplated increase the period of eligibility to twelve months would serve to alleviate some continuity of care issues.

F. CROSS-AGENCY AGREEMENTS

70. Under 42 U.S.C. § 1396a(a)(11)(A), state Medicaid agencies must enter into "cooperative arrangements" with other "State agencies responsible for administering or supervising the administration of health services . . . looking toward maximizing the utilization of such services in the provision of medical assistance . . . ." Under the implementing regulations, state Medicaid agencies are specifically instructed to "make use of other public mental health, mental health and education programs and related programs." 42 C.F.R. § 441.61(c); see State Medicaid Manual, Pl. Ex. 2, at BB.0058 (§ 5230) ("Successful relationships are based upon detailed planning, clearly identified roles and responsibilities, program monitoring, periodic evaluation and revision, and constant communication.")

71. DHS is responsible for enrollment and eligibility determinations for all children on Medicaid. Given the number of children eligible but not enrolled in this program and the short average periods of enrollment, OHCA could more effectively monitor its cross-agency agreement with DHS. The process of identifying Medicaid-eligible newborns is unduly complicated by defendants' reliance upon DHS caseworkers to pick up a form from the hospital and then enter the information into OHCA's system. Tr. Vol. XVII, at 2298:4 - 2299:4. Further, defendants have failed to consider the option of placing DHS enrollment caseworkers in the schools, preferring to rely on advertisements and OHCA's website to help facilitate enrollment. Tr. Vol. XX, at 2599:7-20. Yet, OHCA's outreach director concedes that the Internet is not necessarily widely available to Oklahoma's poor. Id. at 2599:21-24.

72. The Court finds no violation of 42 U.S.C. § 1396a(a)(11)(A).

III. SUMMARY AND DIRECTIVE

Based on the above, the Court holds that:

(1) in violation of 42 U.S.C. §1396a(a)(30(A), defendants are not assuring that payments are sufficient to enlist enough providers so that care and services are available under to Medicaid-eligible children to the extent that such care and services are available to the general population in the geographic areas served by the OHCA (i.e., defendants are not assuring "equal access");[23]

(2) defendants are not furnishing medical assistance with reasonable promptness to all eligible individuals, in violation of 42 U.S.C. §1396a(a)(8);

(3) defendants are in substantial compliance with all EPSDT provisions of the Medicaid Act other than the requirement set forth in 42 U.S.C. §1396d(r)(1)(A)(i) that they establish a periodicity schedule for EPSDT screening services "after consultation with recognized medical and dental organizations involved in child health care";

(4) defendants' auto-assignment/default enrollment system does not constitute a violation of 42 U.S.C. §1396u-2(a)(4)(D);

(5) defendants' cross-agency relationship with DHS does not constitute a violation of 42 U.S.C. § 1396a(a)(11)(A); and

(6) defendants, in compliance with federal law, may refuse to pay for experimental treatment desired by certain class members when their decisions are based upon reasonable concern for safety. In this regard, the Motion for Supplemental Relief and Request for Preliminary Injunction (Dkt. #

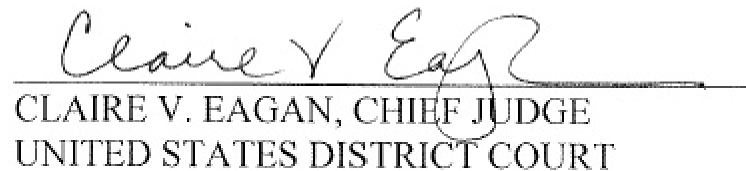
---

[23] However, providers have no private right of action to enforce this provision, and OKAAP is dismissed as a plaintiff in this case.

241) is denied as to Xolair coverage for D.R. and L.R.; it is moot as to L.H. and the other three Rhone children.

The parties shall immediately meet and confer with United States Magistrate Judge Paul J. Cleary in order to reach an agreed proposed injunctive order to be submitted to this Court within sixty (60) days, consistent with these Findings of Fact and Conclusions of Law. If the parties cannot agree to such an order, plaintiffs and defendants shall submit separate proposed injunctive orders.

IT IS SO ORDERED this 22nd day of March, 2005.



CLAIRE V. EAGAN, CHIEF JUDGE
UNITED STATES DISTRICT COURT